Access to Quality Cancer Care: Evaluating and Ensuring Equitable Services, Quality of Life, and Survival

Report Submitted by:

Jeanne Mandelblatt, M.D., M.P.H., Associate Professor of Medicine, Lombardi Cancer Center

K. Robin Yabroff, M.B.A., Research Scientist, MEDTAP International, Bethesda, MD

Jon Kerner, Ph.D., Associate Professor of Medicine, Lombardi Cancer Center

Note: The figures referred to in this paper are not available in this PDF file.

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1.1 POLICY RECOMMENDATIONS

The diffusion of such process and outcomes measures into practice, the practicality, reliability, and validity of these measures, and the impact these indicators have on practice patterns, access to care, patient's needs (Stovall, 1996) and the health of populations have not yet been evaluated. Such research will be key to assessing the success of enhanced access and quality of care paradigms.

2.0 INTRODUCTION

Access to care is a multidimensional concept. Access has been defined as "the timely use of affordable personal health services to achieve the best possible health outcomes"(Millman, 1993, #874). Access has been further defined in terms of levels, where primary access represents gaining entry into the health care system, secondary access refers to navigating through structural barriers once in the system (e.g., difficulty or delay in getting appointments, receiving continuity care, and difficulty getting a provider on the telephone), and tertiary access captures the interface between individuals and the system, including the ability of providers to understand and address patients' needs and socio-cultural contexts (Bierman et al, 1998, #1335; Lurie, 1997, #659; Lavizzo-Mourey and Mackenzie, 1996, #986). Perceived access - an individual's perception that they have been able to obtain all the medical care that they thought they needed - is another dimension of access to care (Beck and Schur, 1998, #772). Finally, a key component of access to care is the linking of the process of obtaining health care to the quality and outcomes of that care; this is often referred to as "realized access" (Anderson, 1995, #402).

The importance of access in ensuring health is reflected in the fact that the Year 2010 goals for the nation include assuring access to (primary) care for 95% of the population (Healthy People 2010, Bierman, 1998, personal communication). While access to medical care makes an important contribution to health, the impact of non-medical factors, such as housing and standard of living, may be as, or more, important in determining health status (Anderson et al, 1995, #402). However, for certain diseases, such as cancer, however, access to quality care can have a substantial impact on outcome, making cancer an important case study of access to care.

In this paper we first present a conceptual framework for evaluating barriers to access to quality cancer services over the full spectrum of care, from secondary prevention to end-of-life care. In the second section of the

paper we use this conceptual model to summarize barriers which are common across all phases of cancer care. In subsequent sections, we review each phase of care and use our conceptual framework to highlight barriers that are particularly germaine within each portion of care, critically assess the effectiveness of interventions designed to overcome phase-specific barriers, and make research recommendations. Finally, the paper concluded with a summary of key findings and presents research, education, and policy recommendations for ensuring equitable access to quality care and improved cancer outcomes for all Americans.

2.1 CONCEPTUAL FRAMEWORK FOR ACCESS TO CANCER CARE

Health behaviors, such as obtaining access to cancer and other medical services, are complex and multifaceted. The process of gaining access to care represents dynamic interactions of diverse individuals in their social context interfacing with health care providers, who, in turn, are operating in a variety of changing, and often constrained medical care structures and environments. Figure 1 graphically depicts our conceptual framework for describing the inter-relationships between these processes and structures of care in obtaining access to cancer care. Underlying the development of our model is the premise that a narrow approach to improving access, such as focusing on insurance factors alone, will not be sufficient to solve the current access inequities in the US health care system. The primary goals of this conceptual model were two-fold: to guide the review of diverse barriers to cancer care, and to provide a framework for evaluation of the effectiveness of interventions targeting specific barriers, or groups of barriers, particularly among populations at risk for poor cancer outcomes, including the elderly, low social class groups, and minorities (hereinafter referred to as "vulnerable" or under-served populations"). Another goal of our access model was to provide a context for framing future research and policy discussions.

Finally, a key component of our framework was the inclusion of measures of "realized access", or the outcomes of access (or lack thereof) to care (Anderson, 1995, #402). Although interest in measuring the quality and outcomes, of care is not new (Lohr and Brook, 1984,#1341; Williams and Brook, 1978, #1342; Relman, 1988, #1343; Donabedian, 1980, #1344; in HMO), a new era of quality performance began in 1989 with the first Health Plan Employer Data and Information Set (HEDIS), developed by the National Committee on Quality Assurance (NCQA)(Iglehart, 1996, # 450; Kelvin and Houston, 1996, #1351; West et al, 1997, #505; Kessler et al, 1997, #503; Blumenthal, 1996, #447 & #635; Brook et al, 1996, #448; Chassin, 1996, #449; Kahn et al, 1990, #1345; Draper et al, 1990, #1346; Keeler et al, 1990, #1347; Rubenstein et al, 1990, #1348 Epstein, 1990, #1349). At present, the only HEDIS measure of access to cancer care is a process indicator - the mammography screening rate; stage at diagnosis, an intermediate outcome, has been recently included in a "test" set of measures for development and validation (NCQA www, 1998, #1350; Weissman et al, 1994, #875; Docteur et al, 1996, #872). Several professional groups, such as the National Cancer Center Network are also developing practice guidelines. These recommendations concentrate largely on the processes of care; intermediate outcomes measures (e.g., patient satisfaction) are still in the preliminary stages of development (Jane Weeks, personal verbal communication, 1998). At present, none of the aforementioned efforts systematically incorporates outcome measures, such as survival or quality of life, into routine data collection efforts. Further development and validation of practical, easy to implement outcomes measures is a key priority for cancer care.

We chose to adapt Anderson's (1968, #1357; 1995, #402), Aday and Andersen and (1980, #1360) behavioral model of access to medical care since it most closely fulfilled our requirements. In the original model Anderson posited that the medical care people received was a function of the social, demographic, and financial characteristics of their family unit. Later iterations of the model focused on the individual as the unit of analysis, and categorized socio-demographic factors into those which predisposed, impeded or enabled, and/or affected perceived need in explaining health care service utilization. For predisposing, enabling, and need factors to be useful in promoting access, they should also have a degree of mutability (Anderson and Newman, 1973, #1359; Anderson, 1995, #402). Further refinements of their model included the addition of medical care organizational factors, and a quality of care component measuring health outcomes, or "realized access"(Anderson, 1995, #402).

The Anderson and Aday model of health services use has been applied to a wide variety populations (e.g., the elderly, African-Americans) (Wolinsky, 1991, #751; 1994, #1352) and health care services, including mammography (Miller and Champion, 1996, #1353). Other good models, including the Health Belief Model (Becker, 1975, #1297), the Transtheoretical Model (Prochaska & Di Clemente,1983, #1354), the PRECEDE Model (Green et al., 1980, #969), and the Theory of Reasoned Action (Fishbein and Ajzen, 1980, #970) were considered, and the strengths of these models contributed to the conceptualization of our framework. (e.g., health beliefs and behavioral intentions are included as individual-level barriers). Others have examined the longitudinal process of access from the patient's perspective, from primary (gaining entry into the system), to secondary (navigating

through structural barriers), and finally tertiary access (the ability of providers to understand and address needs) (Lurie, 1997, #659; Bierman et al, 1998, #1355). These three levels of access are incorporated into our model.

In our adaption, which portrays a cross-sectional representation of access, we have tailored the model to reflect the process of, and barriers to, cancer care. In our conceptualization, individuals or populations are seen in the context of their socio-cultural and regional environment. Since primary care providers are usually the source of first contact for cancer patients, and are responsible for screening activities, both primary and cancer care providers are included in the model. In turn, each of these types of providers operate within the context of a rapidly evolving, and often constrained, medical care system. We have added patient-provider and provider-provider communication as key components of our model, to capture interactions that can facilitate or impede access to care. Finally, as noted above, we highlight "realized access" outcomes in our model.

In contrast to Anderson's original work (1968, #1357), we have chosen to list "potential barriers" without distinction to their mutability or group (e.g., predisposing, enabling, or need) for two reasons. First, while not amenable to change, certain factors, such as age, can be useful for targeting of interventions. Second, instead of concentrating on potential mutability, this review concentrates on interventions which have been proven to be effective in changing access to care, as measured by one or more of the outcome measures outlined in the figure. We also highlight innovative interventions which have not been fully tested, but demonstrate promise in overcoming barriers, and suggest further areas for intervention development.

In the next section we summarize the literature describing barriers to cancer care in each of the domains portrayed in the model. This presentation is not meant to be exhaustive. Rather, we highlight key barriers to quality cancer care that are common to all phases of cancer care, form secondary prevention to end-of-life care. A review of chemoprevention, smoking cessation, and other new prevention strategies (e.g, genetic testing for cancer susceptibility and vaccines for virally-induced cancers, such as cervical cancer) is beyond the scope of this paper.

3.0 CROSS-CUTTING PATIENT, PROVIDER, AND MEDICAL CARE SYSTEM BARRIERS TO CANCER CARE

3.1 Patient/Population Barriers to Cancer Care

Barriers to cancer care have been documented in almost all settings and populations; however, certain groups, such as the elderly, un- or under-insured, lower social classes, racial/ethnic minorities, and new immigrants face unique barriers. Some of the results of diminished access, such as high mortality rates, may, in part, be due to higher rates of risk behaviors and incidence of certain cancers among these vulnerable populations (e.g., lung cancer among smokers and certain occupational groups, who are disproportionately minority) (Baquet et al, 1991, #865; Kogevinas, 1997, #1317). However, a recent analysis of a longitudinal study of a national random sample of US adults found that mortality excesses persisted among lower social class and elderly groups, even after controlling for such health behaviors (Lantz et al, 1998, #1021). This sentinel study underscores the need to better understand the pathways whereby predictors of reduced access to care (and its attendant sequelae) exert their influence. Such research is a prerequisite to designing effective interventions to improve access to care and improve health outcomes, particularly for vulnerable populations. This section uses our conceptual model of access to care to summarize barriers which are common across all phases of cancer care.

3.1.1 Age and Comordidity

The men and women aged 65 and over (hereinafter referred to as "elderly") are the fastest growing segment of the US population; by the year 2,010 one in five persons are projected to be in this age group. Within the elderly group, those aged 80 or more are the single fastest growing group. The elderly population accounts for a disproportionate share of cancers - at present more than 50% of new cases occurring among the 13% of the population that is 65 or older; the median age of all cancer cases is 70 (Erschler, 1997, #1363; Yancik, 1983, #840); with the "greying" of America, the elderly will account for an increasing absolute number of cancer cases in upcoming decades. Moreover, cancer survivors are increasingly elderly. For instance, for breast cancer, there are nearly 12 times as many cancer survivors among women in their seventies than among younger women (Lash and Silliman, 1998, #1364). Unfortunately, despite some progress in decreasing cancer mortality rates, rates of decline have eihter not occurred, or have occurred at slower rates for the eldlelry, compared to non-elderly groups (Bailar and Gornik, 1997, #1160; Kosary, 1997, #1100). Despite these impressive biologic and demographic imperatives, there is a still a paucity of research on barriers to cancer screening, treatment, and post-treatment care among elderly groups.

The effects of age on access to cancer care is multifaceted. First, the elderly often under-estimate their risk of cancer (Vernon et al, 1993, #770). Second, along with increasing risk of cancer with age, the elderly have an average of three or more chronic medical conditions. The life expectancy of most elderly women (and men) appears, however, to be sufficient to realize benefits from cancer screening (Mandelblatt et al, 1992, #791), although research on the impact of comorbidity on cancer screening use and survival outcomes has been limited and inconsistent (Satariano, 1993, #1391). In one study, elderly women with a greater number of chronic illnesses (≥ 3) were more likely to participate in breast and cervical cancer screening than those with fewer illnesses (<3) (Mandelblatt et al, 1993, #706; Kiefe etc, 1998, #1365). It is possible that women with more illnesses attended clinics more often, and were exposed to greater opportunities to be screened. This idea is supported by the finding that older women attending clinics four or more times per year are more likely to receive mammography than women attending less often (Hedegaard et al, 1996; #509). Alternatively, sicker women may have had a greater sense of susceptibility to illness, including cancer, that motivated them to be screened. Others have found chronic disease to both increase (Chao et al, 1987, #786; Bostick et al, 1994, #788; Grady et al, 1992, #789) and decrease (Klassen, 1991, #787; Burack and Liang, 1989, #572; Shoen et al, 1994, #797; Kiefe et al, 1998 #1365) mammogram and Pap smear use.

Third, age biases in care may exist. Virtually all studies that have examined relationships between age and cancer screening (with the possible exception of colorectal cancer screening) have noted that increasing age is a barrier to regular use (Hayward et al, 1988, #862&405; Weisman et al, 1989; Mandelblatt et al, 1992, #702; McCool, 1994, #851; Weinberger et al, 1991, #771; Coll et al, 1989, #679; Mamon et al, 1990, #409). However, when physicians recommend screening to their elderly patients, women will comply (Fox et al, 1994, #692). For instance, even when comorbidity is accounted for, being elderly is also associated with receipt of less intensive diagnostic work-up (Nicolucci et al, 1993, #1366), lower rates of definitive primary (Greenfield et al, 1987, #694; Silliman et al, 1997, #1367; Samet et al, 1986, #714; Mor et al, 1985, #837; Wetle, 1987, #838; Goodwin et al, 1996, #445; Farrow et al, 1992, #975; Lazovich et al, 1991, #974; Guadagnoli et al, 1997, #1210) and adjuvant cancer treatment (Ayanian and Guadagnoli, 1996, #971; Allen et al, 1986, #1197, Chu et al, 1987, #688; Silliman et al, 1989, #715), including bone marrow transplant (Mitchell et al, 1997, #477). After considering age and stage, older African-American women are particularly vulnerable to sub-optimal breast cancer treatment (McWhorter and Mayer, 1987, #1323; Diehr et al., 1989, #395; Samet et al., 1986, #714; Allen et al., 1986, #1197; Chu et al., 1987, #688; Axtell and Myers, 1978, #843). Cognitive impairments, which are more frequent in elderly than non- elderly groups, have also been noted to affect cancer treatment. For instance, in a longitudinal population-based study, Gooodwin and colleagues noted that impaired cancer patients were less likely to receive definitive treatment than non-impaired patients; even after considering treatment received, age, and stage, cognitively impaired patients were three times more likely to die of their cancer than non-impaired patients - this effect was especially true for colorectal and prostate cancer survival (Goodwin, 1996, #445).

Finally, the elderly are disproportionately represented in the lower social classes, and have rates of poverty, under-insurance, and high out of pocket costs (Yee and Capitman, 1996, #536; Petchers and Milligan, 1988, #422). These socioeconomic factors put the elderly at “double jeopardy”of experiencing barriers to cancer services; minority elderly women are at even further risk of under-service (NIA final report). Taken together, these findings suggest that ageism, together with classism and racism, act as barriers to appropriate cancer care.

3.1.2 Gender

In general, women tend to use health care services more often than men (Wolinsky et al, 1990;1991, #752 & #751), although when reproductive care is excluded, this gender gap in use diminishes (Mustard, June 1998, #1356). However, limited data suggest that gender may affect chronic disease care in important ways. For instance, in cardiovascular disease management, gender has been noted to be an important barrier to treatment, with women receiving significantly fewer diagnostic and therapeutic procedures than men, despite similar, or greater levels of disease (Ayanian and Epstein, 1991, #754; Steingart et al, 1991, #756). For cancer care, several researchers have suggested that women receive fewer early cancer detection tests than men in the same practices (Schapira, 1993, #603). In a study of the predictors of having late stage colorectal cancer at diagnosis, men were less likely to have late stage than women, controlling for age, race, area income, and source of health care (Mandelblatt, 1996, #1304). Such findings suggest that physicians may diagnose and treat women differently than men as the result of gender “stereotypes” (Wingard, 1984, #746; Bernstein and Kane, 1981, #755). Women generally prefer to see female providers (Lurie et al, 1997, #987), and patient gender has also been postulated to affect physician communication (Hooper et al, 1982, #827; Iverson, 1993, # 538) (see also below, Physician Gender and Patient-Physician

Communication sections). If confirmed, such experiences could constitute an important barrier to cancer care for women.

There are little data on the barriers to cancer care experienced by men. The generic barrier to men obtaining screening services is the low general use of routine medical care in the absence of symptoms (McCusker et al, 1980, #766; Womeodu and Bailey, 1996, #541). In AARP led focus groups on cancer screening, men reported that they: were proud of the length of time they had avoided going to doctors, did not want to appear vulnerable, wanted to be independent, and tended to rely on others (such as wives) to gather health information (Rubenstein, 1994, #808). However, when African-American men are cognizant of their increased risk, and perceive screening to be effective, they appear willing to undergo annual screening (Myers et al, 1994, #430A; Underwood, 1991, #1188). In making decisions about prostate cancer surgery, longevity is the most salient consideration (Singer, 1991, #1395), while for others concerns about quality of life and sexual functioning are more important (Singer, 1995, #1395). However, in contrast to the situation for women, who appear to want to be active participants in treatment decision making, men appear to prefer that physicians make their treatment decisions (Davison et al, 1995, #1187). Clearly, more research is needed on barriers, and interventions to improve access, to cancer services among males.

3.1.3 Insurance

Each year about 1.2 million US citizens join the 43.4 million Americans who are uninsured; more are under-insured for most medical care (Kaluzny, 1997; #542). Being uninsured and under-insured both have similar consequences: financial hardship for patients, uncompensated care by providers (Bashshur et al, 1993, #421), and substandard medical care (Burstin et al, 1992, #410). Minorities are disproportionately represented among the uninsured or under-insured, with 35% of Hispanics and 25% of Blacks reporting being uninsured (Iverson, 1993, #538).

Insurance status has been noted to have a consistently strong effects on the receipt of both early cancer detection and treatment services. For example, Ayanian and colleagues studied nearly 5,000 women with breast cancer and found that women who were uninsured or on Medicaid were significantly less likely to present at local stages of disease. Moreover, among women with regional and distant disease, these same groups of women had approximately a 50% increase in the odds of dying from their disease as did privately insured women, suggesting that un- and under-insured women received less optimal local or systemic treatment (Ayanian, 1993, #570). Patients without private insurance have also been noted to receive surgery for non-small cell lung cancer less often than those privately insured (Greenberg et al, 1988, #631); and rates of bone marrow transplant for treatment of leukemia or lymphoma that are 50% and 34% to 45% lower among self-pay and Medicaid patients than rates among privately insured patients (Mitchell et al, 1997, #625). Physicians may also fail to recommend costly chemotherapy for their un- or under-insured patients, believing that such groups are less likely to comply with the treatment regimen (Berger et al, 1988, #984).

Although strategies to remove economic barriers, such as providing expanded or universal insurance, will improve access to cancer care, recent research demonstrates that this is a necessary, but not sufficient condition to improve cancer outcomes (Adler et al, 1993, #533; Kiefe et al, 1994, #472). In several countries, even after economic barriers are removed, through the provision of universal health care, inequities in health care use persist (Roos and Roos, 1982, #1377; Siemiatycki at al, 1980, #1305). For instance, studies of cancer screening and outcomes in Canada (Katz and Hofer, 1994, #1306) and Finland (Salonen, 1982, #849) demonstrated that despite universal access to care, lower social class individuals persist in having lower screening and survival rates (Hart, 1998, #1307) than higher social class individuals.

In the US, in the past decade Medicare has extended benefits to include Pap, breast, and colorectal cancer screening; most recently, prostate cancer screening using digital rectal and PSA testing was added as a covered service. In 1997 Medicare added coverage of the costs of anti-emetic drugs used as part of cancer chemotherapy, Group C cancer drugs (investigational drugs monitored by the National Cancer Institute), and off-label use of certain drugs for cancer therapy. Finally, current Health Care Financing Administration regulations allow for the coverage of promising new therapies and clinical trials on a case by case basis ("coverage under conditions") (Bagley and McVearry, 1998; #736). However, Medicare alone has not been sufficient to remove certain financial barriers to care. Among inner city poor, older women on Medicare, providing free vouchers for testing was insufficient to remove financial barriers to screening (Kiefe et al, 1994, #472). In another study, Blustein noted that among Medicare beneficiaries, poor women and women with no supplemental insurance were less likely to have a claim for mammography than higher income women with supplemental coverage, suggesting that copays and deductibles still

represented a substantial barrier to care for disadvantaged elderly women (Blustein, 1995, #400). In 1998, Medicare eliminated co-pays and deductibles for mammography, and extended benefits to include annual screening (NCQR, 1998, #1350; Bagley and McVearry, 1998, #736); it will be important to confirm that the additional benefits diminish financial barriers.

Data from studies of other chronic illnesses also support and extend the hypothesis that Medicare insurance alone is not sufficient to remove barrier to care. Among Medicare patients hospitalized for cardiopulmonary and other conditions, Blacks (and those from poor neighborhoods) received poorer quality care and have more adverse outcomes than Whites or the non-poor. However, interestingly, race and poverty effects were offset by the site of care, where disadvantaged groups cared for in urban teaching hospitals had similar outcomes as Whites and the non-poor (Kahn et al, 1994, #1308). Together, these findings underscore the complex interactions between individual and health care system-level factors underlying observed levels of access.

3.1.4 Social Class

The influence of social class on access to cancer, and other health care services, goes beyond insurance inequalities (Curbow, 1986, #1309; Dutton, 1978). A full understanding of the consequences of social class on access to cancer care will require re-assessing definitions of socio-economic status, identifying and measuring those aspects of class that are most salient for cancer-related health behaviors, developing a sensitivity to the ways in which measurement varies across diverse populations, and delineation of the inter-relationships of race and class (Berkman and MacIntyre, 1997, #1311). For an in-depth discussion of the influence of social class on cancer the interested reader is referred to a recent IARC monograph (Kogevinas et al, 1997, #1317). The narrative that follows defines social class and summarizes key research describing the impact of social class on access to cancer care.

Current measures of socioeconomic status, such as income, education, occupation, and assets do not adequately capture the variations in social structure that affect health, and health care use. For instance, even at similar educational levels, Whites generally earn more income than Blacks; current adult occupation and income may not reflect the effects of earlier deprivation or living within the "culture of poverty"(Lewis, 1966, #881); and access to housing and food affect health outcomes (Johnson et al, 1995, #265; Krieger, 1993, #1312). Thus, we use the construct of "social class" to encompass a broad range of socioeconomic factors, and to capture societal experiences such as prestige and community standing and political power (Pearce, 1997, #1313; Susser, 1996, #1314; Liberatos et al, 1988, #1315). Within this broad definition, it is also important to recognize the heterogeneity of individuals and groups within lower and higher social class populations. For instance, while immigrants and US-born Blacks are each disproportionately represented in lower social classes, the needs, concerns, and experiences of cancer patients from each both groups are likely to be very different (Kerner and Breen, 1998, #1362; O'Malley et al, 1997, #821).

Regardless of the measures used and settings examined, studies of the impact of social class on breast and cervical cancer screening have consistently shown that lower class women are less likely to report any screening and/or regular screening than higher class women (Rutledge, 1988,#419; Potosky, 1998, #647; Mickey, 1997, #985). When screening is targeted to low social class women, and socio-cultural and economic barriers are decreased, or removed, social class differences in screening use decrease (Segnan, 1997, #1316). For example, after nearly two decades of concentrated efforts, socioeconomically disadvantaged African-American women have equivalent, or even better, cervical cancer screening rates than Whites (Makuc, 1989#1361); and African-American poor women now have similar rates of mammography use as poor Whites, although poor women's rates of screening are still substantially below those of non-poor women (Hiatt, 1996, #379). At present, there are very few studies on role of social class on colorectal cancer screening (Vernon, 1997, #1037).

For many cancers, where early diagnosis and/or treatment improve survival, the ultimate measure of "realized access" to cancer care is the mortality rate. For such cancer types (e.g., breast, cervix, and colorectal cancer), across genders, types of SES measure, and countries, patients in lower social classes consistently have lower cancer-specific survival than those in higher social classes (reviewed in Kogevinas and Porta, 1997, #1317; Gordon et al, 1992, #922); a similar pattern is observed for multiple myeloma (Savage et al, 1984, #1318), and lung and prostate cancers (Greenwald et al, 1996, #444).

In many cases, the observed survival disadvantage may be largely attributable to use of screening and stage at diagnosis, where lower class individuals are more likely to have their disease diagnosed at advanced stages, when survival is less likely, that their more advantaged counterparts (Mandelblatt, 1996, #1304; 1991, 1327; Dayal et al, 1987, #1319; Kosary, 1995, #1100;Vernon et al, 1990, #544; Anderson and May, 1995, #574). Patient delay in reporting symptoms does not appear to have a major effect on survival (Savage et al, 1984, #1318; Auvinen, 1992,

#1320; Coates et al, 1992, #670), although others have suggested that delay leads to poorer survival, largely mediated thorough stage differences at diagnosis (reviewed in Facione, 1993, #619).

However, even within stage, social class differences in survival persist (Freeman and Wasfie, 1989, #438), suggesting that adequacy of staging evaluation (Lash and Silliman, 1998, personal communication) access to timely treatment and other factors, such as social supports, and host factors also contribute to the observed class disparities in survival (Berg, 1977, #1321; Auvinen and Karjalainen, 1997, #1322; McWhorther and Mayer, 1987, #1323). For instance, in one Finnish study, Auvinen noted that social class differences in colorectal cancer survival disappeared after controlling for treatment received, suggesting that patients of lower class received less adequate treatment than those in higher classes (Auvinen, 1992, #1320). Finally, adequacy and completeness of treatment can also be affected by patient-provider communication, which is likely, in turn, to vary by social class (see below)(Epstein et al, 1985, #1324).

Regardless of treatment received, when cancer progresses, social class also influences access to palliative and supportive care. For example, patients testifying at the ACS hearings on Cancer and the Disadvantaged described difficulties obtaining costly at-home services, having few family or friends to help them, and having difficulty affording pain medications and nutritional supplements (Underwood, 1995, #1325). Together, these types of barriers lead to sub-optimal palliative care, and an increased burden of pain and suffering.

For all studies on access to cancer care, there are several methodological caveats that should be considered when evaluating prior research and planing future investigations and interventions, including the measurement of social class, units of analyses, and disentangling the combined effects of social class and race.

Approaches to measuring social class have been quite diverse, and vary in definition and scope, accuracy of assessment, handling of missing data, sources of data (e.g., administrative, census, or individual), sensitivity to detecting true differences between groups, and applicability for women, minorities, and the elderly.

There are several inter-related units of measurement used in social class research - individual, household, family, and area or neighborhood units (Krieger, 1993, #1312). The choice of the unit of measurement is often dictated by what is available. Most often, large cancer databases, such as SEER, lack individual social class measures. In these circumstances, characteristics of the individual's neighborhood of residence have been used as a proxy for personal circumstances (e.g., median census tract level of education, income, unemployment) (Breen and Figueroa, 1996, #1326; Mandelblatt et al, 1991, #1327; 1996, #1304). Area-level measures can also be viewed as contextual measures of class (Krieger, 1997, #1328; Mandelblatt, 1991, #1327). Few studies have examined individual and area-level indicators simultaneously (Krieger, 1993, #1312; 1997, #1328), and none that we are aware of have accounted for the correlations between levels (Diez-Roux, 1998, #530).

Disentangling the effects of social class and race on health, or cancer outcomes is complicated (Freeman, 1981, #879; American Cancer Society, 1985, #1394). On an individual level, among the non-elderly, while racial/ethnic minorities are disproportionally represented among the poor or near poor (44%), the majority of low-income individuals in the US are White (56%) (Kaiser Commission, 1995, #988); however, only 12% of White Americans are poor, in contrast to one-third of Blacks (Freeman, 1991, #1329; 1993; US Census, 1992, #775). Further, as noted above, even within similar occupational or educational groups, minorities earn less than non-minorities, and have different experiences with the health care system (Krieger, 1993, #1312)(see below, Discrimination). Finally, minority groups are also more likely to live in neighborhoods characterized by extreme poverty and low levels of education than Whites.

Imprecision in measuring social class also contributes to the difficulty defining the separate effects of race and class. For instance, in many studies of cancer processes or outcomes, such as rates of breast-conserving surgery (Michalski and Nattinger, 1997; 1170) or other treatments, stage at diagnosis (Mandelblatt, 1996, #1304), and breast (Dayal et al, 1982, #799; Bassett and Krieger, 1986, #800) or prostate cancer survival (Dayal et al, 1985, #), race effects have been noted to be mediated largely by social class. Such findings prompted the American Cancer Society's Subcommittee on Cancer in the Economically Disadvantaged to conclude that racial disparities in cancer mortality were largely due to socioeconomic factors (Freeman, 1991, #1329). However, the complex underlying psychological, social, biological, and behavioral processes and pathways whereby class exerts it influence remains poorly understood (Adler, 1993, #533; Mandelblatt, 1996, #1304).

Despite these limitations, the strength and consistency of the association between class, access to care, and cancer outcomes argue for the validity of the construct (Berkman and MacIntyre, 1997, #1311). This is a key access research and policy priority, and one which is prerequisite to diminishing the disproportionately higher burden of avoidable cancer morbidity and mortality in lower social class groups.

3.1.5 Race/Ethnicity

Individual characteristics such as race and ethnicity are not inherently barriers to cancer care (Henry, 1995, #988). Race is a composite term encompassing historical, biological, socio-cultural, and environmental factors, including exposure to racism (Freeman, 1991, #1329; 1993, #737). For instance, a key historical fact - that black Americans have only been legally free for three decades, after years of slavery and sanctioned segregation - affects the cultural, educational, and, ultimately, health, opportunities of this racial group (Freeman, 1991, #1329; 1993, #737).

Thus, minority status may compromise access at an individual level through cultural attitudes and perceptions of the care system, poverty, or because providers lack the training to meet the needs of specific population groups. For instance, some Latino (Perez- Stable, 1992, #618 JAMA; Lantz, et al, 1994, #764), poor, and African-American populations (Underwood, 1994, #1331) have been noted to hold certain fatalistic attitudes towards cancer or to focus on day-to-day survival to the exclusion of seeking needed early detection or treatment care (Freeman, 1991, #1329; Womedou and Bailey, 1996, #541; Lacey et al, 1993, #780; Gregg et al, 1994, #614; Powe, 1995, #1186; 1996, #1184).

Such perspectives are likely to contribute to the observations that, while the national percentage of women having at least one mammogram has increased, the rates of use, including regular use, by elderly, African-American, and Hispanic women remain significantly lower than rates among younger and non-minority (Breen and Brown, 1994, #686; Costanza, 1994, #689; Oakar, 1992, #711; Rimer et al, 1989, #470; Bickell et al., 1993, #685; Fox and Stein, 1991, #623; Fox et al., 1994, #692; Fletcher 1993, #604). Moreover, once African-American and other minority women are screened, if they have an abnormal result, as many as 30% to 50% do not receive timely, or any, diagnostic resolution (Mandelblatt et al., 1993, #1332; Wells and Horm, 1992, #716; Adami et al., 1986, #682; Gregorio et al., 1983, #695).

As noted above in the section on social class barriers to care, under-use of screening by African-Americans and other women of color is often confounded by the fact that these racial groups are also more likely to be socio-economically disadvantaged (Hedegaard et al, 1996, #509). Poor women are less likely to have regular screening than non-poor women (Stein et al., 1991, #397; Anderson and May, 1995, #574; Woolhandler and Himmelstein, 1988, #1333; Roberts et al., 1990, #1334), and are less likely than Whites to have a regular source of care (Chaulk et al., 1995, #1335; Burns et al, 1996). Since one of the strongest predictors of mammography use is having a primary care provider and receiving a recommendation for screening (e.g. Fox and Stein, 1991, #623; Fox et al., 1994, #692; Howard, 1987, #699; Mann et al., 1987, #1336; Herman et al., 1995, #1043; Vernon et al., 1990, #544; Gram et al.,1992, #693; Lerman et al., 1990, #701; Bastani et al., 1991, #684), this is another factor which explains the patterns of under-utilization observed for racial/ethnic minority women.

Across several cancer sites, including breast, cervical, colorectal, bladder, and prostate, when African-American and other minority patients are diagnosed with cancer, even after considering social class, they are more likely to be diagnosed at advanced stages of disease than whites (Mandelblatt et al, 1996, #1304; 1991, #1327; Wells et al, 1992, #716; Farley and Flannery, 1989, #802; Mitchell and McCormack, 1997, #1049); for cervical cancer, this racial gap has increased over time despite greater use of Pap smears among African American, compared to White women (Mitchell and McCormack, 1997, #1049).

African-American and other minority patients also have been observed to receive sub- optimal cancer treatment (McWhorter and Mayer, 1987, #1323; Diehr et al., 1989, #395; Samet et al., 1986, #714; Allen et al., 1986, #1197; Chu et al., 1987, #688; Greenfield et al., 1987; Silliman et al., 1989, #715; Lee at al, 1997, #558; Harlan et al, 1995, #468; Mayer and McWhorther, 1989, #393; Nattinger et al, 1992, #978), and to have lower survival rates, controlling for treatment, stage, tumor characteristics, and/or molecular markers of prognosis (Simon and Severson, 1996, #437; Eley et al, 1994, #546; Bain et al, 1986, #809; Gregorio et al, 1983, #695; Elledge et al, 1994, #811; Weiss et al, 1995, #436; Hsu et al, 1997, #440; Kimmick et al, 1991, #442; Samelson et al, 1994, #443; Hankey and Myers, 1987, #801; Elixhauser and Ball, 1993, #446).

There are several explanations for such apparent poor “realized access” to cancer early detection and treatment services among racial/ethnic minorities. First, in the case of breast cancer, African-American women are more likely to be uninsured and have greater co-morbidity than White women; these factors, in turn, predict lower rates of breast conserving surgery, and when breast conservation does occur, lower rates of radiotherapy (e.g., Eley et al., 1994, #546), and chemotherapy (Schleifer et al, 1991, #1192) than those reported for White women. Another potential explanation for sub-optimal care in this population is that Blacks have, historically, been found to be two to four times more likely to have their surgery performed by residents than faculty, even when privately insured (Egbert and Rothman, 1977, #1378); it is unclear if this race differential in access to faculty care affected health

outcomes. Third, racially-mediated differences in tumor biology and aggressiveness have been suggested to explain some of the observed racial differences in survival (Elledge et al, 1994, #811; Ownby et al, 1985, 738; Crowe et al, 1986, #866; Eley et al, 1994, #546). For instance, among men with equal access to care at Walter Reed Hospital, (Moul et al, 1996, #459) found that Blacks had higher prostate cancer recurrence rates than whites with similar treatment, age, stage, and tumor grade, and suggested that blacks had more aggressive disease (Moul, 1996, #459). Another recent study in an equal access system (Kaiser Permenante), death rates from prostate cancer were higher in for blacks than whites, controlling for age and stage, suggesting that tumor virulence is a key factor explaining racially differences in survival (Robbins et al, 1998, #1163). Fourth, in some of the aforementioned studies, some of the racial differences in access outcomes may also be the result of residual confounding by social class. Ansell and colleagues found, for example, that significant black/white differences in breast cancer survival were eliminated after controlling for SES (Ansell et al, 1993, #401); others have noted a similar trend (Bassett and Krieger, 1986, #800; Dayal et al, 1982, #799; Gordon et al, 1992, # 922), underscoring the need to understand the complex inter-relationships between race and social class.

Fifth, subtle biases of physicians has also been suggested as explanations of under-treatment of racial/ethnic minority groups (Ayanian and Guadagnoli, 1996, #971). This idea is supported by findings that providers interact with multi-ethnic populations in divergent manners. For example, across several different health care settings, ranging from private practice to HMOs, several groups have noted that physicians are more likely to order cancer screening for their White than their non-White patients (Gemson, 1988, #1392; Fox and Stein, 1991, #623; Fox et al., 1994, #692; Trock et al, 1993, #1379); among non-Whites, Hispanics are at the most risk of not having their regular provider order screening (Fox and Stein, 1991, #623). In another study of stage of breast cancer at diagnosis as a proxy of access to screening, Mandelblatt et al, noted that race was an independent predictor of stage, with Blacks and Hispanics more likely to have their cancer diagnosed at late stages than Whites, controlling for setting of care, income, and education (Mandelblatt, 1991, #1327). This finding prompted the authors to conclude that minorities may have different experience with the health care system, which is predominately White, than non-minorities (see racial discrimination below). When African-American patients do see providers with a similar racial background, they report receiving higher levels of preventive care and better satisfaction with care than when seeing White providers (Komarmony, 1996, #531). Finally, the social context of minority individuals also affects health care access. For instance, minorities are more likely to live in poor neighborhoods with fewer health care resources. These influences are discussed below in the section on individual context.

Additional barriers to adequate screening and treatment among racial/ethnic groups include lack of knowledge about treatment options, distrust of the health care system and the effectiveness of medical care, anxiety, embarrassment about being examined by a gender discordant physician, and fears and misconceptions about cancer (McWhorter et al.,1987, #1323; Diehr et al., 1989, #395; Samet et al., 1986, #714; Allen et al., 1986, #1197; Chu et al., 1987, #688; Greenfield et al., 1987, #694; Lantz et al, 1994, #764; Perez-Stable et al, 1994, #615; Fox and Stein, 1991, #623; Pearlman et al, 1996, #435; Long, 1993, #813; Lurie et al, 1997, #987; Stein et al, 1991, #397). Beliefs that religious faith is an alternative to medical care can act as a barrier to needed care (Womeodu and Bailey, 1996, #541).

Finally, cultural beliefs have been suggested as mediator for poor race-related cancer outcomes. In a seminal article, Lannin and colleagues examined the predictors of late stage at diagnosis for women with breast cancer and a matched population control group. Being African-American was significantly associated with having late stage at diagnosis, although this effect diminished after controlling for socioeconomic status. Most striking was the finding that after considering cultural beliefs (such as folk beliefs, religious beliefs, relationships with men, fatalism, beliefs about treatment, and knowledge), the race effect was no longer significant (Lannin, 1998; #1036). This study is the first that we are aware of to measure and segregate the intertwined effects of race, social class, and cultural beliefs, and to demonstrate that beliefs held by certain vulnerable groups are actually the key determinant of outcome. If confirmed in further research, this finding suggests an important mutable pathway for interventions to improve access to screening and diagnosis.

Hispanics: Over the past several decades, Hispanics have become the fastest growing segment of the US immigrant population; in urban centers such as Los Angeles and New York City Hispanics are approaching 50% of the population (US Census, 1992, #775; Ramirez et al, 1995, #1162). Hispanics are more likely to be poor and uninsured than Blacks or Whites. For instance, in 1990 Hispanics comprised about 9% of the population but more than 20% of the uninsured (Johnson, 1995, #265). Hispanic women are less likely to report use of Pap smears or mammograms than Whites or African-Americans (Fox and Stein, 1991, #623; Harlan et al, 1991, #571); rates of use also vary substantially across different Hispanic groups, with some of the lowest utilization among Mexican-

Americans (Trevino et al, 1991, #814; Buller et al, 1998, #511; Bastani et al, 1995, #498) and migrant workers (Skaer et al, 1996, #512). Although these findings are partially explained by educational level, income and insurance, ethnic differences remain an independent influence on screening behaviors (Harlan et al, 1991, #571; Solis et al, 1990, #768). For instance, in one study of stage of cervical cancer at diagnosis, a proxy indicator of screening use, after controlling for sociodemographics and source of care, Hispanic women were less likely to have in-situ or early invasive than advanced disease at diagnosis than Whites and Blacks (Mandelblatt et al, 1997, #709). After controlling for stage and other sociodemographic variables, Hispanics have also been observed to have lower colorectal (Goodwin et al, 1996, # 445) survival rates than non-Hispanics.

It has been suggested that acculturation and English language use, and not ethnicity per se, use are the key determinants of screening use and survival outcomes among Hispanic groups (Suarez et al, 1993, #1380; Kaplan et al, 1996, #1157; O'Malley et al, 1997, #821) (see also below, "Language, Acculturation, Literacy"). Knowledge and beliefs held by some Hispanics, such as low levels of knowledge about cancer symptoms or a belief that cancer can not be cured, may also contribute to the observed low rates of screening in this population (Perez-Stable et al, 1992, #618).

Native Americans and Asian-Americans: There are little data available on racial/ethnic barriers to care for other minority groups, such as Native Americans and Asian-Americans. Native Americans represent a diverse group, with many segregated on reservations and receiving care from the Indian Health Service, and others concentrated in urban centers. Poverty rates are two to three times as high among Native Americans as non-Native Americans (US Census, 1992, #775; Coughlin, 1998, #510); and there are limitations in cancer data collection efforts for these groups (Partin et al, 1997, #1156). Native Americans view health and illness in a holistic religious and cultural framework that often differs from traditional medical concepts (Johnson, 1994; Coughlin, 1998, #510). For instance, for many Native Americans, health is viewed as the balance between an individual and nature, with illness the result of physical and spiritual imbalances. Most Native Americans are also focused on the present; screening for future potential events is not part of their cultural context (Coughlin, 1998, #510). This may explain the observation that Native America (and Asian) women have been noted to be significantly less likely to receive mammography than Blacks, Whites or Hispanics, controlling for health care utilization, age and income (Hedegaard et al, 1996, #509).

For Asian-Americans, suspicion of Western medicine, taboos about women being examined by males, the large number of primary languages and a dearth of interpreters, low education, not having a regular physician, short duration of residence in the US, and low knowledge about cancer are additional barriers to seeking care for screening and cancer signs and symptoms (McPhee et al, 1997, #680; Kraut, 1990, #1381; Tossomeen et al, 1996, #532; Penn, 1995, #812). With the rapid influx of Asian populations and assimilation to US dietary habits, breast and other cancer rates, which have been historically low for this group, may begin to increase over the next several decades, making research with this population an important priority (Yi et al, 1996, #476).

Overall, there are many common and unique barriers to cancer care among ethnically and racially diverse groups; even common barriers may be perceived differently by individuals from dissimilar cultural backgrounds (Pearlman et al, 1996; #435). Thus, beyond addressing language, interventions to improve access for different ethnic sub-groups will need to be grounded in culturally-specific values and beliefs.

3.1.6 Trust

Many minority and poor groups have expressed mistrust of doctors and the health care system such attitudes have been noted to influence participation in clinical trials (Capps and El Sadr, 1992, #1382), compliance with screening recommendations (Fox and Stein, 1991, #623), delays in seeking care or follow-up on abnormal screening results and compliance with treatment recommendations. Distrust of doctors, combined with low education, may also result in misunderstanding of recommendations and poorer compliance with diagnostic follow-up or treatment recommendations (Kaiser Commission, 1994, #988; Underwood et al, 1995, #1325). Distrust barriers can be diminished through the development of a continuity relationship with primary and cancer care providers (Wilkes et al, 1994, #876)(see below).

3.1.7 Discrimination

After accounting for social class, health status, and insurance status, several minority groups, particularly Blacks, still remain less likely than Whites to obtain health care, and to receive less care once they enter the system (Blendon, 1989, #407; Kaiser Commission, 1994, #988;Jepson et al, 1991, #439). One explanation for this observation is that Blacks and other minorities experience unique barriers, such as discrimination when seeking care. This hypothesis is partially supported by observations that Native Americans expect to be treated in a discriminatory fashion, and prefer to be cared for by providers from their own cultural background (DeGeynt, 1973,

#1383; Kramer, 1992). Also, Krieger recently observed a significant association between perceived discrimination and hypertension among African-Americans (Krieger, 1990, #1390).

These suggestive results point to the need for further research to address the unique experiences of minorities that give rise to negative perceptions and attitudes regarding health care delivery (Blendon et al, 1989, #407). Underlying this concern is the question of whether these attitudes are associated with lower social class status or constitute a pattern common to most minorities regardless of their class. For instance, findings that blacks face repeated incidents of racial discrimination (Feagin, 1991) suggest that black attitudes toward health care may be shaped by such experiences and that an understanding of these attitudes may be essential to addressing reluctance or failure of black women and men to pursue needed cancer care. Support for this assertion can be found in the results of a national survey that revealed significant race differences in use of health care even after controlling for the effects of income, health status, age, and sex (Blendon et al, 1989, #407).

There are no published studies of access to cancer care that we are aware of that address the role of perceived discrimination in predicting cancer health-related behaviors and outcomes. Several federally-funded studies are in the process of measuring the ability of this domain to predict use of low-cost screening mammography, follow-up of abnormal mammograms (Kerner, NCI Grant # RO1 CA 65881), and patterns of breast cancer treatment (Hadley and Mandelblatt, AHCPR Grant # RO1 HS 4341007). The findings of these studies will be important in re-defining racially-related barriers to cancer care and designing appropriate interventions to address discrimination in access to health care.

Thus, attitudes and experiences that transcend lines of social class among blacks emerge as potentially significant in explaining reduced access to care and differences in perceptions of the quality of care received. For example, Blendon et al.,1989, #407) found that blacks of varied SES were more likely than whites to express dissatisfaction with their previous health care provider. This will be an important area for future access research.

While eliminating social class and racial inequality remains an elusive goal for society in general, interventions to improve access can be made more effective if they target the social and psychological sequelae of these endemic societal problems and acknowledge the heterogeneity of vulnerable populations.

3.1.8 Language/Acculturation/Literacy

Fluency in the English language, acculturation, and literacy levels represent another set of barriers to cancer care. For instance, among Hispanics, having a low level of acculturation and/ or poor language skills has consistency been associated with lower levels of use of services, and when care is obtained, with less compliance with recommended procedures, including cancer screening tests (Fox and Stein, 1991, #623; Wells et al, 1989; Marks et al, 1987, #765; Richardson et al, 1987, #822; O'Malley et al, 1997, #821; Kaplan et al, 1996, #1157).

Much of the existing cancer risk reduction and treatment information is transmitted in written formats. However, one-quarter of US adults are functionally or marginally illiterate (Kirsch et a, 1993, #963); rates are highest in elderly, low social class, and inner city groups, some of the same populations that are at high risk for poor cancer outcomes (Davis et al, 1996, #514). To the extent that materials target too high a reading level, patient literacy will constitute a barrier to care and compliance with instructions. Low literacy is a barrier to obtaining education about screening, diagnostic, and treatment services (Michielutte et al, 1990, #966); low reading levels are associate with low levels of use of mammography (Davis et al, 1996, #514). Compliance with medication regimens may also be compromised by a poor ability to read instructions (Weiss et al, 1991, #964).

Acknowledging this potential barrier, recent educational material prepared by the National Cancer Institute targets an 8th grade reading level (National Cancer Inst 1992, #965); and this level may still be too high. Recently, to overcome literacy-related barriers, interventions to increase knowledge about cancer screening have targeted alternative modes of communication, including videotapes about colorectal cancer screening (Meade et al, 1994, #434; Miller et al, 1997, #1105). To maximize accessibility, in addition to reading level, media messages should also consider the targeted population's cultural context and diversity, use short, non-technical terms, and incorporate graphics (NCI Cancer Communications Office, 1992, #965). Insuring linguistic equivalence, such as achieved by translation and back-translation, may not be sufficient to capture cross-cultural conceptual variations in attitudes, beliefs, or other access variables (Johnson, 1994).

Taken in combination, the barriers experienced by Hispanic (and other minority) groups, particularly those recently immigrating to the US, have been liken to those seen in underdeveloped countries (Ramirez et al, 1995, #11622).

3.1.9 Knowledge, Attitudes, and Beliefs

Despite differences in operational definitions of concepts, across all cultural, gender, class, and race groups, knowledge deficits, negative attitudes, and erroneous beliefs about cancer can act as potential barriers to realizing

access to early cancer detection or treatment (Vernon et al, 1990, #544; Fajardo et al., 1992, #691; Rutledge et al., 1988, #419; Nielson, 1990, #710; Gram and Slenker, 1992, #693; Griffiths and Williams, 1992, #696; Lauver 1994, #700; Douglass, 1995, #690; Jepson et al, 1991, #439; Morgan et al, 1995, #384. For instance, in a study of cancer in an older, low social class group of female cancer patients, Loehrer and colleagues noted that many women believed that smoking did not cause cancer, that bumps or bruises could cause cancer, and that faith healing and vitamins were viable cancer treatments (Loehrer et al., 21991, #882). Similarly, beliefs that "nothing is wrong" if there are no symptoms can be barriers to screening (Rimer et al, 1992, #1385; 1989, #470; Caplan et al, 1992, #473), and when abnormal results are noted, to compliance with follow-up recommendation (Rojas et al, 1996, #1389). Even when symptoms are present, many individuals state that they prefer not to know if they have cancer (Antonucci et al, 1989, #856). Embarrassment (Richardson et al, 1987, #822; Morisky et al, 1989, #858; Mandelblatt et al, 1993; Thompson et al, 1997), fear (Thompson et al, 1997, #535; Coyne et al, 1992, #848), and anxiety (Paskett et al, 1990, #785; Lerman et al, 1991, #869) have also been cited as barriers to obtaining screening, diagnostic, or treatment services.

However, the influence of such knowledge and attitudes on actual cancer-related behaviors have been inconsistent. For instance, in an urban Hispanic population, Morgan and colleagues noted that while cancer screening knowledge was low, knowledge did not related to use of Pap smears and mammograms (Morgan, 1995, #384). With few exceptions (Underwood and Sanders, 1990), studies using different theoretical frameworks, such as the Health Belief Model (Rosenstock, 1974, #967; Janz and Becker, 1984, #968), PRECEDE (Green, 1980, #969), the Transtheoretical Model of Stages of Change (Prochaska, 1991, #1390), or the model of Behavioral Intentions and Reasoned Actions (Fishbein and Ajzen, 1980, #970), have also been noted to be limited in their explanatory power, especially for minority and elderly populations (Burack and Liang, 1987, #572; Mandelblatt et al, 1993, #706; Fulton et al, 1991, #807).

3.2 INDIVIDUAL CONTEXT

In addition to personal attributes and life experiences, the social, economic, cultural context of family, neighborhood, and geographic locale also influence how individuals perceive symptoms and seek (or do not seek) health care, and the resources available when they do pursue care.

3.2.1 Social Supports, Family and Culture

Individual circumstances may be mediated by social, family or cultural context. For instance, despite diminished access to cancer care, an individual from a lower social class group may live in a cultural context, such as Seventh Day Adventisits, that promotes healthy behaviors, which, in turn, decrease the risk of cancer occurrence, and poor cancer outcomes (Freeman, 1991, #1329).

Social support networks can impact on the cancer care process at a variety of points. For example, an elderly cancer patient may be dependent on others for transportation to daily radiotherapy care (Iwamoto, 1996, #527), or a married woman with few supports may not seek care due to inability to obtain dependent care (Womeodu and Bailey, 1996, #541). Lack of social support can also be a barrier to certain post-hospital and long-term care services for cancer patients. Thus, without family at home (or monetary resources to pay for home services), a cancer patient may be forced to rely on a nursing home for care (Wallace, 1994, #537).

However, prior research on living arrangements, often used as a proxy for social support, or other measures of support have noted contradictory influences on cancer care. There is mixed evidence about the effects of social support on screening behaviors (Moritz and Satariano, 1993, #567; Vernon et al, 1990, #544). For instance, among a cross-section of older low-income Mexican-America women, social networks (defined as numbers of, and amount of contact with friends, and church membership and attendance) predicted greater use of Pap smears and mammograms. Similarly, in another cross-sectional study, Kang and Bloom noted that older Black women with larger social networks were more likely to receive mammograms and fecal occult blood testing than women with fewer social resources (Kang et al., 1993, #817), although social supports did not predict Pap smear use (Kang et al, 1994, #815). Zapka and colleagues also noted that talking with, or receiving encouragement from, friends about mammography were significant independent predictors of use (1989, #469). These types of findings have served as the framework for interventions, such as the "Save our Sisters" and "a Su Salud" projects, which are designed to enhance screening use through peer and family channels. However, some groups have failed to confirm the value of social support as a vehicle to improving access to screening.

When women develop cancer, Moritz and Satariano found that women living with a spouse or others had significantly higher adjusted odds of having regional or advanced breast cancer than local disease than women living alone (Moritz et al., 1993, #567). However, in a population-based study of stage for several cancers, Samet and

colleagues failed to demonstrate an effect of social support on stage at diagnosis for elderly patients (Samet et al., 1990, #676). Others have noted that unmarried adults were less likely to receive complete treatment, and more likely to die of their disease than married individuals (Goodwin et al, 1987, #675; Neale et al, 1986, #677). In two small prospective studies of breast cancer patients, social context, as measured by numbers of supportive friends and a positive work environment or level of social activities, predicted survival independent of tumor stage (Waxler-Morrison, 1991, #819; Hislop et al, 1987, #820); this effect has been noted for women more often than men (Reynolds and Kaplan, 1990, #921).

There are several reasons for these discrepant findings on the influence of social support on cancer care outcomes, including differences in study design and measures of social support, reliability and validity of measures used, sample size and power to detect effects, lack of control for clinical and other sociodemographic variables, social desirability response biases, and changes in support systems resulting from a cancer diagnosis. Prior to considering interventions to enhance social support, it will be important to address these issues and further elucidate the role of social supports in obtaining access to cancer care.

3.2.2 Neighborhood

In addition to personal resources, living in a socioeconomically deprived area, with high unemployment and crime, can lead to a life-view focused on day-to-day survival and an erosion of social cohesion, community participation, and trust (ie, "social capital") (Kawachi et al, 1997, #667). Such perspectives can represent a barrier to seeking cancer screening services, follow-up of any abnormal test results, or when symptoms develop, to a delay in obtaining needed care (Womeodu and Bailey, 1996, #541). Such areas of extreme deprivation tend to concentrate in inner cites (and very sparsely populated rural areas). Area-level indicators of low social class and deprivation have been consistently noted to be associated with poor cancer outcomes. For example, in one study of determinants of colorectal cancer stage at diagnosis in NYC, Mandelblatt et al, found that the effects of race and public hospital care on stage were attributable to area indicators of poverty, where individuals living in neighborhoods with high poverty or unemployment rates were more likely to have their cancer diagnosed at late stage than the non-poor (Mandelblatt at al, 1991, #1327;1996, #1304). Similarly, Breen and Figueroa examined several SEER areas and noted that the odds of having invasive vs in-situ cervical cancer were 60% higher for women living in socioeconomically disadvantaged neighborhoods than women residing in higher SES areas; and this variable explained the greatest amount of stage variation (Breen et al., 1996, #1326). Unfortunately, none of these studies had information available on individual SES, which may also influence outcomes. Do lower social class men and women living in higher social class neighborhoods have higher or lower screening rates as those living in lower class areas? We are unaware of any studies that address this question. This will be an important area for further research.

Neighborhood resources, such as number of mammography facilities per female population, have also been noted to influence breast cancer stage at diagnosis. Philips and colleagues examined lifetime adherence to regular mammography, and found that, controlling for age, race, education, and income, women living in areas with a lower rates of HMO market share, primary care shortages, and fewer mammography facilities using reminder systems, and higher screening charges were significantly less likely to have been adherent than women living in better resources areas (Phillips et al., 1998, #610).

Based on these types of research findings, British researchers have suggested an alternative conceptualization of measuring area social class - area deprivation - to better understanding such influences on access to care and health outcomes. Indicators of area proportion of the population living below the poverty level, numbers of female heads of household, rates of unemployment, rates of high school graduation, proportion of homeowners, and violent crime rates.

3.2.3 Geographic Locale

In addition to widely recognized regional variations in patterns of cancer care (see below), within areas, distance to cancer centers and other treatment facilities affects the type of care received for breast cancer (Mitchell and Hadley, 1997, #625). Men and women in rural areas may also be less likely to receive cancer screening or state-of-the art treatment as a result of inadequate resources, large distances to sites of care, or transportation problems (Kreher et al, 1995, #644; Harris and Linnengier, 1993, #761; Sawyer et al, 1990, #678).

3.3 PRIMARY AND CANCER CARE PROVIDERS

Health care providers play a pivotal role in ensuring access to cancer care for their patient populations; each medical encounter represents an potential opportunity, or missed opportunity, for education, screening, and case-finding. As noted above, provider recommendations are a key predictor of receipt of cancer early detection and

other services (Schapira et al, 1993, #603). However, physician's report several barriers to providing such services, including biases and beliefs about screening and treatment, deficient knowledge, lack of time and forgetfulness (McPhee et al, 1986, #1393; Battista et al, 1996, #1400), concern with acute illness, negative attitudes toward screening or lack of confidence (e.g., in CBE proficiency) (Battista et al, 1990, #1396; Rubin et al, 1990, #474; Lane and Burg, 1990, #1397), confusion about conflicting professional recommendations on standards of care (Gemson et al, 1986, #1398; McPhee et al, 1986, #1393; Dietrich et al, 1990, #1401), concerns about patient acceptance (Burack and Liang, 1987, #1399; McPhee et al 1986, #1393; Woo et al, 1985, #408), lack of reimbursement or cost concerns (Cummings et al, 1983, #1402; American Cancer Society, 1985; Woo et al, 1985, #408; Bassett et al, 1986, #800; Battista et al, 1989, #1400; Burack and Liang, 1986, #1399; Lane and Burg, 1990, #1397), and logistical or organizational barriers (McPhee et al, 1986, #1393; Battista et al, 1986, #1400; Lurie, et al, 1988; Battista et al, 1990, #1396). In this section, we briefly review these physician-based barriers. Since primary and oncology providers generally face similar barriers to providing cancer care relevant to in their respective practices, and their is a paucity of research on barriers specific to oncology practitioners, we summarize barriers for both groups, highlighting any data specific to oncologists.

3.3.1 Sociodemographic Characteristics

Provider gender (Battista, 1983; Battista et al, 1990, #1396; Schwartz et al, 1991, #471; Lurie at al, 1997, #987), age (Mann et al, 1987, #1336; Schwartz et al, 1991, #471), specialty (Bassett et al, 1985, #1403; Mann et al, 1987, #1336; Albanes et al, 1987, #1404; Weisman et al, 1989, #855; Bergner et al, 1990, #1405; Weinberger et al, 1991, #771) and years since graduation (Bergner et al, 1990, #1405) have all been noted to constitute barriers to optimal cancer screening and treatment services; however, studies on the effect of physician sociodemographic characteristics on cancer screening and treatment behaviors have been somewhat contradictory. For instance, while most studies have noted that female physicians are more likely to recommended and order breast (Zapka et al, 1992, #1406; Lurie et al, 1997, #987), cervix (Lurie et al, 1997, #987), and colorectal cancer screening for their female patients than their male counterparts, others have found no gender effect.

Black physicians care for 25% more Black patients and Hispanic physicians 21% more Hispanic patients than their White counterparts; minority physicians are also significantly more likely to treat uninsured and Medicaid patients than non-minority physicians, controlling for community characteristics (Komaromy et al, 1996, #531; Moy and Bartman, 1995, #850). Congruence of patient-provider race has also been suggested to increase cancer screening behaviors of multiethnic groups. Thus, increasing the supply and distribution of minority providers has the potential to decrease race/ethnicity-based barriers to care; this is one of the goals included in the Healthy People 2010 report (1998).

Physician training can also influence access to cancer services. For instance, to the extent that primary care post-graduate training programs emphasize prevention and early detection, as well as treatment of acute illness, providers may be more likely to deliver such services in their future practices. Among primary care physicians, there is substantial variability in use of cancer screening. Obstetrician-gynecologists order more cancer screening for their female patients than family practitioners; internists have generally been reported to have lower rates of screening than other primary care providers; and sub-specialists who provide primary care have been noted to screen at either lower or similar levels to primary care specialists (Zapka et al, 1992, #573; Bassett et al, 1985, #1403; Mann et al, 1987, #1336; Albanes et al, 1987, #1404; Weisman et al, 1989, #855; Bergner et al, 1990, #1405; Weinberger et al, 1991, #771; Schwartz et al, 1991, #471). Recommendations about treatment also vary by primary specialty. For instance, in a recent national survey, McFall and colleagues noted that surgeons preferred breast conservation more often than primary care physicians; primary care specialists were also less likely to view systemic chemotherapy as standard practice (McFall, 1994, #982). Since primary care physicians often first diagnose screen-detected cancers, and provide trusted treatment choice information to their patients, failures to present consensus recommendations (NIH Consesus, 1991, #972; 1980, #983) could be a barrier to informed patient decision making.

Post-surgical or medical oncology specialty training also appears to affect cancer treatment patterns. For example, in a 1987 survey, medical oncologists recommend breast conservation in hypothetical patients more often than surgical oncologists and general surgeons (Deber and Thompson, 1987, #981). Among Italian physicians, the GIVIO group also noted that oncologists were more likely to prefer breast conservation than surgeons (The Givio Investigators, 1988, #1207), this contrast was especially true for older patients (Liberati et al, 1987, #833). In another example, in preliminary data from the breast cancer PORT (patient outcomes research team), surgeons with post-graduate specialty training in surgical oncology were more likely to recommend breast conserving surgery to their elderly patients with local stage disease than surgeons with general board certification alone (Mandelblatt et al, unpublished data, 1998).

3.3.2 Knowledge, Attitudes, Beliefs and Personal Health Practices

Lack of knowledge has historically been noted as a barrier to physician-initiated cancer screening (Schwartz et al, 1991, #471. For instance, adequacy of clinician-performed breast examination (CBE) has been noted to be sub-optimal in some groups and settings, with sensitivities for detecting cancer as low as 40 to 50% (Shapiro et al, 1988, #853; Fletcher et al, 198X; Baines, 1992, #854); providers who perform more CBEs are more efficient in detecting masses (Miller at al, 1991, #861). There are also limited data suggesting that proficiency in performing sigmoidoscopy has been sub-optimal and may have constituted a barrier to colorectal cancer screening. With more recent attention to physician education interventions (see below, Phase 1), this importance of these barriers should become less salient.

As noted in the section on Age and Comorbidity, physicians appear to under-use cancer screening and treatment services among their elderly patients. Using hypothetical clinical scenarios, Liberati et al noted that physicians were less likely to choose systemic chemotherapy for an older woman than for a clinically similar younger woman (Liberati et al., 1987, #833). Reasons for under use of cancer services include conflicting professional recommendations about the age of cessation of cancer screening (NCI, 1992, #965; USPSTF, 1996, #1410), the historical exclusion of the elderly from clinical trials and other research protocols (Goodwin et al, 1988, #424; Cohen and Bartolucci, 1985; Yancik, 1983, #840); such exclusions persist despite evidence that therapy is well tolerated in this age group (Begg and Carbone, 1983, #841), assumptions about patient preferences, physicians under-estimation of life expectancy (Fox et al, 1997, #479), unmeasured effects of comorbidity (Satariano, 1992; 1993, #1407).

Physicians' preferences for surgical breast cancer treatments have been shown to be related to several important attitudes. For instance, Liberati and colleagues noted that physicians who believed that breast cancer patients should have a role in treatment decision making were more likely to prefer breast conservation (Liberati et al., 1991, #836); similar results were noted in an earlier study of Italian physicians (GIVIO, 1988, #1207; Liberati et al, 1987, #833).

In a study of nearly 3,000 members of the American College of Physicians, Schwartz and colleagues noted that physicians who practiced early detection themselves were more likely to recommend such care to their patients (Schwartz et al., 1991; #471).

3.3.3 Real and Perceived Time Constraints/Forgetfulness

Physicians consistently cite busy schedules and forgetfulness as their major barriers to providing screening (McPhee et al, 1991, #599). Logistic and system barriers contribute to these perceived time constraints. For instance, over the past decade, with the increase in managed care and Medicare and Medicaid regulation of medical practice, providers are spending a larger proportion of their time meeting administrative requirements. One unintended consequence of these system-level demands is that providers feel they have less time to spend with their patients (Weinberger et al, 1992, #859; Zapka et al, 1992, #1406). Decreases or caps on reimbursement levels can also lead physicians to increase their volume to maintain income. Low reimbursement rates for counseling and patient education (Weinberger et al, 1992), and capitated payments can further act as a barrier to providing cancer screening or aggressive treatment regimens. In this environment of eroding time for patient-physician communication, forgetfulness about ordering tests can occur more readily. Interventions to address these barriers are discussed below in Phase 1.

3.3.4 Socio-Cultural Competence

In addition to having an adequate scientific knowledge base, providers must be also knowledgeable about their patients' cultural and social needs. Some providers lack either the training or skill to provide care to diverse populations. Provider's failures to comprehend, respect, and accommodate the needs of their patients - in terms of day-to-day obstacles to health, gender, ethnicity, social class, education, or language - can result in barriers to successful cancer care (Kaiser Commission, 1994, #988; Trevino et al, 1991, #818; Lewin-Epstein, 1991, #630; Womeodu and Bailey, 1996, #541). For instance, one possible explanation for the failure of providers to discuss mammography as often with their Hispanic, compared to other patients, beyond the availability of translation services, is a lack of familiarity with the particular beliefs and cultural concerns of this diverse groups (Fox and Stein, 1991; # 623).

3.4 PATIENT-PROVIDER COMMUNICATION

Once barriers have been overcome to obtaining primary (e.g.), and secondary (e.g.), access, an important component of the quality of health care received includes the characteristics of the interactions between providers and patients (tertiary access)(Bierman, 1998; Blumenthal, 1996, #447). As noted by Blumenthal and others, access

to care and the quality of the patient-physician interaction depends on several elements in their relationship: communication, trust, and the ability of the provider to treat the patient with empathy and sensitivity (Blumenthal, 1996 #447; Donebedian, 1988). In the 1989 ACS hearings on cancer and the economically disadvantaged, several of these themes were voiced by cancer patients. Testimony included reports that care was fragmented and impersonal, and that communication with providers was difficult (Underwood et al, 1994, #1331). In a recent nationally representative sample of women, women with a source of care who perceived that they participated in the decision to be screened were 55% more likely to be adherent to regular lifetime mammography than women who felt the doctor decided (Phillips et al, 1998, #610). Similar observations have been noted in studies of breast cancer treatment, where women who feel that they participated in their treatment choice are more likely to be satisfied with their therapy.

Across all age, racial, ethnic, and social class patient groups, the most consistent barrier to one important component of cancer care - screening- is not having a regular source of care, or not receiving a provider recommendation for care (NCI Screening Consortium, 199X; Zapka et al, 1992, #573; Zapka et al, 1994, #1408; Bindman et al, 1996, #1008; O'Malley, 1997, #821; Grady et al, 1992, #789; Vernon, 1990, #544; White et al, 1993; Breen et al, 1996, #1409; Fox et al, 1994; 1991, #623). The correlarly, that men and women with a regular source of care are also more likely to receive cancer screening than those without a regular source, is also true (O'Malley et al, 1997, #821; Bindman et al, 1996, 1008); the level of enthusiasm of the doctor's recommendation is also important for lower social class women (Mickey et al, 1997, #985). However, for certain vulnerable groups, this is a necessary, but not sufficient condition to ensure access to care, since the quality of physician communication about cancer care appears to be affected by patient characteristics, such as race and ethnicity (Hooper et al, 1982, #827; Fox and Stein, 1991, #623; Roter et al, 1988, #825; Hall et al, 1988, #826), and social class (Pendleton and Bochner, 1980, #829). For example, while all ethnic groups having a source of care report physician recommendation to be important in their decisions about screening, physicians discuss mammography less often with their Hispanic than their non-Hispanic patients (Fox and Stein, 1991, #623), and Black patients are less likely to report advice about, or receive cancer screening than Whites seeing the same physician (Gemson et al, 1988, #1392). Blacks are also less likely to receive adequate breast cancer treatment than Whites using the same hospitals and physicians (Chu et al, 1987, #688; Diehr et al, 1989, #395). Similar results have been observed for the elderly, where older women are less likely to receive mammography (Fox et al, 1994, #692;Hedgaard, 1996, #509) or comprehensive breast cancer treatment(Greenfield, 1987, #694; Hillner, 1996, #1212;Newschaffer, 1996, #1181) than younger women in the same practice settings. Even in countries with universal health care systems, physicians who have a larger proportion of patients from lower social classes and inner city or rural area comply with recommended screening guidelines less than other physicians (Cohan et al, 1992, #782).

There also appear to be important gender effects on patient-physician communication, with communication styles and content of communications being noted to vary by gender for both providers and their patients. For instance, female patients have been noted to ask more questions (Waitzkin, 1985, #824), to receive more information (Hall and Roter, 1988, #826), and form more of a partnership relationship (Stewart, 1983, #830; Hooper et al, 1982, #827) than men. Female physicians have also been noted to be more emphatic (Roter et al, 1991, #828), to provide more information (Roter et al, 1991), and to spend more time with their patients (Cypress, 1980, #831; Roter at al, 1991, #828) than their male counterparts. These types of communication skills have been related to patient satisfaction (Roter et al, 1987, #832).

While most providers today feel that patients should be told cancer diagnostic and prognosis information and most patients prefer to be told, such communication is difficult. There are several explanations for this, including the facts that communication skills training is not a routine part of medical education, providers are often conveying "bad news", there are conflicting research findings on the ways to best deliver and frame such discussions, and that there are few data on patient preferences for communication (Butlow et al, 1996, #923). What data there are suggest that their are discrepancies between patient desires and provider practices. For instance, while the overwhelming majority of patients prefer to receive news about a cancer diagnosis from their primary care provider (Sardell and Treirweiler, 1993, #1189), this only occurs for 11% of patients (Lind et al, 1989, #927).

Patient provider communication is further hampered by the fact that providers consistently underestimate their patients distress in encounters related to conveying a cancer diagnosis or prognosis (Ford et al, 1994, #928). The content of communication about cancer can also act a barrier to care and psychological adjustment. For instance, uncertainty introduced by the use of ambiguous euphemistic terms can result in poor adjustment (Dunn et al, 1993, #924). The corollary, that receiving clear information from physicians and promoting patient-physician communication can reduce anxiety and improve coping also appears to be true (Molleman et al, 1984, #925; Lerman

et al, 1993, #926; Dermatis and Lesko, 1991, #929). Finally, patients perceptions of physician communication are strong predictors of satisfaction with cancer in-patient care (Blanchard et al, 1990, #912).

For the provider, patient-provide communication entails a constant confrontation of mortality and acknowledgment of inability to cure all patients. These factors can contribute to stress and burn-out, and ultimately constitute a barrier to patient-physician communication and delivery of quality care. Lastly, there are no data that we are ware of which address barriers to primary care-cancer provider communication.

Thus, after gaining access to care (primary and secondary access), interactions between patients and physicians, including communication and inter-personal relationships (Stewart et al, 1997, #658) (tertiary access) must be realized to ensure the desired outcomes of cancer care (Bierman et al, 1998, #871).

3.5 MEDICAL CANCER CARE ENVIRONMENT/CONTEXT

Attributes of the health care system within which patients and providers operate can also either facilitate or hinder obtaining needed care for cancer services along the continuum of care. Here we briefly review potential barriers; system attributes which specifically influence access to different phases of care are highlighted further in subsequent sections.

3.5.1 Organization/Structural Factors

Primary care is generally defined as care which is accessible, comprehensive, continuous, coordinated, and adequately communicated (Starfield, 1992, #639; Bindman et al, 1996, #1008; Institute of Medicine, 1984); these same components of care should also be included in any definition of comprehensive cancer care. Community health centers, primary care practices and clinics, hospital out-patient clinics, emergency departments, managed care practices, in-patient hospitals, and nursing homes and hospices are all settings in which primary and cancer care may be delivered. Across these settings, there are a variety of ways care can be organized and financed, such as fee-for-service (FFS), managed care, and/or federally-funded (Landon et al, 1998).

Over the past decade, hospital and other health care systems have experienced unprecedented financial constraints, with unparalleled rates of closings, relocations, mergers, and development of for-profit models (Kulzany, 1997, #542; Modern Health Cancer Care, 1994). For instance, community health centers, originally financed by federal, state, and local governments, initially improved access to care in both urban and rural settings; however, recent budget constraints have led to closings of many of these centers and erosion of this important source of care for under-served populations (Blumenthal et al, 1995, #897). Likewise, while public hospital systems have historically served as the "safety net" for medically under-served and disadvantaged groups (Gage et al, 1991, #884; Blendon et al, 1986, #885; Thorpe et al, 1987, #886), many of these hospitals have closed in the past decade due to large financial losses and cut-backs in funding. Many non-profit hospitals with large portions of uncompensated care have also been forced to close or reduce services (Rice, 1987, #839). Such hospital closures have occurred disproportionately in inner city and rural areas, seriously decreasing already limited access for the populations depending on those institutions (Rice, 1987, #839).

Loss of care resulting from such closures or restructuring of financial eligibility requirements have been noted to have a strong adverse effect on chronic disease health outcomes, ranging from hypertensive control to avoidable mortality (Lurie et al, 1984, #577;1986; Fihn and Wicher, 1988, #478; Bindman et al, 1990,#540); effects on cancer care are likely to parallel these trends. Moreover, even among those living in areas where care continues to be available, financial barriers are still reported by nearly one-half of insured persons (Kiefe et al, 1996, #883). The influence of these rapidly changing market forces and structures of care, together with increasingly expensive technological advances, on access to cancer care will be a critical research priority in the next century.

In the same time period, another dramatic change in the structure of the health care system has been the rapidly increasing proportions of the US populations enrolled in managed care organizations (Landon et al, 1998, #465). By 1997, more than one-quarter of Medicaid, 4.9 million Medicare Beneficiaries, and 65% of employer-insured individuals were receiving care in managed care settings (HCFA Managed Cancer Care Enrollment Report, 1994, #1411; Kulazny, 1997, #542) and up to 60% of non-staff HMO physicians hold some form of managed care contract (Kulazny, 1997; ref #542; Emmonds and Simon, 1996, #757) . In some states, such as California, all Medical recipients are enrolled in managed care. However, there are little data available on how the structure and financing of managed care organizations affects access to, and outcomes of, health care. In some settings and populations, women enrolled in managed care were more likely to receive mammography than those with Medicaid, Medicare, and the uninsured (Johnson and Murata, 1988, #499). While such research demonstrates that managed care settings have historically delivered more early cancer detection services than FFS practices, even accounting for self-selection factors (Weinick and Beauregard, 1997, #513; Zapka et al, 1992, #573; 1991, #432), it is not clear if

low social class, minority, and elderly persons enrolled in managed care will realize similar advantages (Kasier Commission, 1995, #988; Lurie, 1997, #659). This will be an important research priority in the next decade.

There are few data available on the use of cancer treatment services in managed care settings; and findings from existing research are inconsistent. Preliminary literature suggests that use of relatively inexpensive treatment, such as breast conserving surgery for breast cancer, occurs at higher rates in managed care than in FFS settings (Potosky et al, 1997, #455), while more expensive, but effective treatment options, such as bone marrow transplants for treatment of lymphoma or leukemia, may be used less often in HMOs (Mitchell et al, 1997, #477; Peters and Rogers, 1994, #642).

Selection of physicians into managed care may also influence access to services. By way of example, in a recent population based study of California physicians, Bindman and colleagues explored the affects of physician and physician's practice characteristics on inclusions and exclusion from managed care contracts. Interestingly, they found that while physicians' sociodemographic characteristics, such as age and race, did not affect inclusion, physicians who cared for a larger percent of uninsured and non-white patients were significantly less likely to have managed care contracts. The authors suggest that such selective contracting may be biased against doctors who provide greater amounts of care to under-served populations (Bindman et al, 1998, #993).

Finally, changes in employment and health can lead to high rates of enrollment and dis-enrollment from particular MCOs. Among the elderly, the group with the highest cancer rates, there are substantial biases in Medicare HMO enrollment and disenrollment, with sicker beneficiaries less likely to be enrolled, and once enrolled, to disenroll (Harrington et al, 1993, #991; Physician Payment review Commission, 1996, #992), even after considering the effects of gender, race, and ethnicity (Morgan et al, 1998, #990). Any discontinuity that arises from such patterns of care is likely to represent a barrier to both cancer screening and treatment services (Kalzany, 1997; #542).

Thus far, there have been only been a few studies of cancer (Francis et al, 1984, #1413; Greenwald, 1987; Vernon et al, 1992, #622) or cancer control outcomes in managed care (Kulzany et al, 1989, #1412; Greenwald, 1987; Riley, 1994, #637; Lee-Feldstein et al, 1994, #638; Potosky et al, 1997, #455; Mandelson and Thompson, 1998, #458; Robbins et al, 1998, #1163). Managed care organizations would appear to be ideally suited to provide effective cancer screening and treatment services, given the presence of access to care and linked administrative and clinical data systems. These organizational factors could facilitate identification of enrollees eligible for services, flag unmet needs, and track follow-up care (Mandelson and Thompson, 1998, #458). a recent study by Philips and colleagues on the predictors of mammography use supports this idea. The authors used linked individual and area data and demonstrated that women living in areas with a greater market share of HMOs were more likely to have had 7 or more mammograms in their lifetimes than women living in areas with lower HMO market share (Phillips, 1998, #610). However, data from other studies have suggested that managed care providers use health promotion activities primarily as a marketing tool, and not to improve the health of their covered populations (Schauffler and Chapman, 1998, #500; Jones, 1993, 989).

When the results of screening are abnormal, Greenwald noted that women in HMOs who made co-payments waited an average of 1.25 months longer between initial suspicion of cancer and obtaining a definitive diagnosis than those without co-payments (1987). In another instance, Francis and colleagues noted delays of diagnosis or treatment among colorectal cancer patients cared for in HMOs compared to FFS settings, although survival appeared similar in each setting (Francis et al, 1984, #1413). In terms of treatment, Lee-Feldstein and colleagues found that women treated in HMO hospitals for local stage breast cancer had poorer survival, controlling for age, tumor size, nodal status, and histologic type, than women treated in large community and teaching hospitals (Lee-Feldstein, 1994; #638). In contrast, Potosky et al failed to find such an effect; in fact, women cared for in HMOs had better survival than those cared to in other settings (Potosky, 1997, #455). Thus, the relationship between the organization and financing of care and cancer processes and outcomes is far from clear at this point; this will be an important area for future research.

Regardless of the organization of care, structural and process aspects of primary and specialty care can also act to facilitate or impede receipt of cancer services. For instance, among women with a regular source of care, Bindman and colleagues noted that several features of optimal primary care, including availability of that care, continuity, comprehensiveness, and communication, were each significantly related to the receipt of breast and cervical cancer screening, independent of insurance, sociodemographics, and chronic disease history (Bindman, 1996, #1008). On an area-level, as noted above, controlling for personal characteristics, women living in non-primary care shortage areas are more likely to receive regular mammography screening than those living in shortage areas (Philips et al, 1994). Primary care, as a marker of access to cancer specialists and treatment services, also

predicts cancer mortality. For instance, using a state-level area analysis of primary care physician supply, Shi found an inverse relationship between availability of primary care and cancer mortality (Shi, 1992, #877).

Other structural aspects of care, including hospital type and size, teaching status (Nattinger et al, 1992, #978; 1996, #1414), and availability of radiation therapy (Hand et al, 1991, #569; Lazovich et al, 1991, #974) influence access to care and the type of care received. For instance, women with local breast cancer cared for in teaching hospital settings are more likely to receive breast conservation than those seen in non-teaching settings (Nattinger, et al 1992, #978; Studnikci et al, 1993, #980; Lee-Feldstein et al, 1994, #638).

Within a given heath care structure, inadequate tracking mechanisms (e.g., to identify patients who miss appointments for screening, follow-up, or episodes of treatment) can also constitute a barrier to care. This may be especially true in under-resourced clinic and hospital settings. Thus, the structure of the health care system can have important influences on access to care.

3.5.2 Reimbursement and Financial Incentives

All insurance does not reimburse equally. For instance, in the fee-for-service sector, Medicare and Medicaid often pay providers less than private insurance policies for similar services (Physician Prospective Payment System, 1992, #992). Such differential reimbursement rates can act to discourage providers or institutions from accepting patients with certain insurance plans. Managed care capitation rates or financial incentives may also influence providers, where provisions of extensive services can result in a loss of income. The differential reimbursement for invasive procedures versus patient counseling may also act as a barrier to patient-physician communication about prognosis, treatment options, and quality of life. Finally, primary care gatekeepers (Eisenberg, 1985, #878), who often have financial incentives to minimize specialty referrals and hospitalizations (Blumenthal et al, 1995, #897), may act as a barrier to specialty cancer care.

3.5.3 "Report Cards"

Although interest in measuring quality is not new (Brook, 1995, #1415; Williams and Brook, 1978; Epstein, 1990, #1349; Donabedian, 1980), a new era of measuring the quality of health care began in 1989 with the first Health Plan Employer Data and Information Set (HEDIS), developed by the National Committee on Quality Assurance (NCQA)(Iglehart, 1996, #450; Kelvin and Houston, 1996, #1351; West et al, 1997, #505; Kessler et al, 1997, #1347; Blumenthal, 1996; Brook et al, 1996; Chassin, 1996; Kahn et al, 1990a; Draper et al, 1990; Keeler et al, 1990; Rubenstein et al, 1990, #1348; Epstein, 1998, #1016). Originally developed to evaluate employer-insured plans, HEDIS measures are now being applied to Medicare and Medicaid plans (Harris et al, 1998, #649). Mammography screening rates are the current HEDIS cancer health care quality indicator; other measures have recently been proposed, including measures of delay, stage distribution, type of treatments received, and care of survivors (Mandelblatt, Ganz, and Kahn, 1998, under review).

The diffusion of such process and outcomes measures into practice, the practicality, reliability, and validity of these measures, and the impact these indicators have on practice patterns, access to care, patient's needs (Stovall, 1996, #1158) and the health of populations have not yet been evaluated. Such research will be key to assessing the success of enhanced access and quality of care paradigms.

3.5.4 Geographic Region/Distribution of Resources

Health care resources and patterns of care vary by geographic region of the country. Urban areas have a greater density of health care than rural areas, and residents of urban centers have a higher likelihood of obtaining screening (Hayward et al, 1988, #862) and treatment services. The 70% of US counties designated as medically under served are disproportionately represented in inner cities and rural areas, the South, and regions populated by minority and poor groups (Kaiser Commission, 1994, #988), making it difficult to separate the effects of region and social class.

As noted in the preceding sections, area resources (such as primary care physician supply) affect mammography use (Philips et al, 1998, #610; Urban et al, 1994, #549) and stage of breast cancer at diagnosis (Mandelblatt et al, 1991, #1327). Geographic differences in access to surgical treatment have been noted for several cancers, including breast (Nattinger et al, 1992, #978; 1996, #451; Osteen and Karnell, 1994, #979; Farrow et al, 1992; Ballard-Barbash et al, 1996; PORT refs), and prostate cancer (Harlan et al, 1995, #468). Rates of use of systemic chemotherapy also show geographic variations (Osteen and Karnell, 1994), although these data are not always stratified by nodal status or other tumor characteristics (Ayanian and Guadagnoli, 1996, #971).

3. 6 CONCLUSION

There are pervasive patient, physician, and health care system barriers to accessing quality cancer care. The central barriers that act at the patient-level include low social class, minority status, and age. It appears that

social class may be a key final pathway that mediates the disproportionately poor cancer outcomes observed in these vulnerable population sub-groups. At the physician level, gaps in training about, and sensitivity to the cultural needs of diverse populations constitutes an unaddressed barrier to cancer care. Growth of managed care represents the major potential barrier and facilitator to better access to care; it remains to be seen which of these will result. Additional research is needed that cuts across these three units (patient, provider, and system) to comprehensively examine the pathways whereby these barriers act to produce observed outcomes. Such investigation will be key in eliminating the current inequalities in access to health care in the US.

4.0 PHASES OF CANCER CARE

The continuum of cancer care spans regular early detection testing, and when cancer develops, diagnosis and treatment, care of survivors, and, finally, to support for terminally ill patients and their families (Figure 2). Once cancer is detected, palliative care occurs across all remaining phases of care (Figure 2a); similarly, randomized controlled trials may be offered across the entire spectrum of cancer care. However, for ease of presentation, while these latter two aspects of care are mentioned in each relevant phase, they are discussed in more depth in separate sections. Since palliative care holds many of the same principles and concentrates on similar domains as end of life care, these topics are discussed in the same section.

All of these diverse aspects of care each have differing factors which affect access, varying degrees of professional practice consensus and evidence supporting the effectiveness of intervention to overcome barriers, and diverse methodological challenges inherent in defining the most valid measures of "realized access". Thus, for each phase of care, we highlight the most salient barriers and relevant outcomes of realized access. For instance, for the first phase of care, cancer screening, individuals' knowledge, attitudes, and beliefs, and sociodemographics, combined with features of primary care and communication between provider and patient are the key arenas where potential barriers can occur. Appropriate indicators of realized access for this phase of care include screening rates and stage at diagnosis.

While comprehensive in scope, this review is not meant to be exhaustive, rather, it is intended to provide an overview of the key issues within each phase of care. Thus, we concentrate our review on selected cancer sites and populations, where access has the greatest potential to improve outcomes. For example, early detection is particularly effective for breast, cervical and colorectal cancer, and treatment has a large impact on survival for hematologic, testicular, and breast cancers; at present, access to treatment for non-small cell lung, pancreatic, and gastric esophageal cancers has less differential survival effect. In the following sections we present and overview of each phase of care, highlight methodological issues inherent in studying access to the particular phase of care, review phase-specific barriers to care, critically review interventions developed to overcome these barriers, and suggest areas for future research.

4.1 PHASE 1 - EARLY DETECTION

The first phase of cancer care involves screening for, or early detection of cancer among asymptomatic populations. There are three cancer sites where early detection tests have been shown to be effective in reducing mortality- breast, cervix, and colorectal (USPSTF, 1996, #1410; Schapiro et al., 1982, #1417; Guzick, 1978, #1009; Selby et al., 1992, #1109; Mandel et al., 1993, #1103). While the efficacy of early detection of prostate cancer with prostate specific antigen (PSA) is under evaluation in the prostate, lung, colorectal and ovarian cancer screening trial (PLCO), there are presently no convincing data on the effectiveness of screening for prostate cancer. Based in the current evidence, screening is not recommended by the United States Preventive Services Task Force (USPSTF, 1996, #1410). Thus, although the prostate specific antigen (PSA) test has quickly diffused into practice, we have not included this site in our review for this phase of care. In addition, although chemoprevention and other primary prevention interventions (e.g., smoking cessation) have the potential to reduce cancer mortality, a discussion of barriers to primary prevention is beyond the scope of this review. Finally, while there has been a rapid increase in cancer biomarkers and tests of genetic susceptibility (e.g., BRCA1/2 for breast/ovarian cancer), there are insufficient data on their costs and expected benefits to recommend their use as wide-spread population screening tools.

At present, evidence-based guidelines recommend initiation of annual or biennial mammography for women at the age of 50, of triennial pap test (after two to three annual negative smears) for women beginning at the age where sexual activity begins, and annual FOBT and/or sigmoidoscopy every three to five years for all persons 50 years of age and older (USPSTF, 1996); other groups recommend annual clinical breast examinations starting at age 20 or 40. Unfortunately, rates of screening vary tremendously among eligible patient groups and across

different types of cancer screening tests. In 1992, fewer than 30% of eligible Americans had received a single FOBT within the recommended time frame; fewer than 15%, a proctosigmoidoscopy; fewer than 60% of women, a mammogram; and fewer than 80% of women, a pap smear. Further, stage of disease at diagnosis and cancer survival rates differ among population groups, reinforcing the observation that there are limitations in realizing access to cancer screening. This effect is particularly dramatic for vulnerable populations—the elderly, women, the under- or un-insured, and members of lower social classes or minority groups.

This section focuses on barriers to initial screening for breast, cervical, and colorectal cancer, summarizes interventions to overcome these barriers, including an in-depth case study of the effectiveness of interventions to increase breast cancer screening rates, and suggests areas for additional research. Ultimately, to realize the potential reductions in mortality attributable to screening, populations must present for regular, on-going life time testing. Since the barriers to such on-going screening may differ from those that act to impede uptake of an initial screen, we summarize research on these barriers separately.

4.2 BARRIERS TO INITIAL SCREENING OF ASYMPTOMATIC POPULATIONS

In this section, we discuss patient, physician, and system or medical environmental barriers to initiation of cancer screening and identify areas for additional research in the promotion of cancer screening. We then review interventions to promote screening in colorectal and cervical cancer, and present an in-depth review of interventions to increase mammography. Finally, we identify areas where policy interventions might increase initiation of cancer screening.

There are many potential patient, provider, and system based barriers to initiation of cancer screening as highlighted in Figure 3. The most appropriate indicator of realized access for this portion of care is a process-level measure - rates of screening among asymptomatic age-eligible populations of individuals with no prior screening. For initial screening, stage of diagnosis will not be an appropriate indicator, since this first screen will detect prevalent disease, the frequency of which will differ according to the risk characteristics of the patient population (Brown, et al., 1995, #487; Kerlikowske and Barclay, 1997, $1418). For instance, May et al, 1998, #529) recently reported on data from close to 300,000 mammographies as part of the National Breast and Cervical Cancer Early Detection Program. In the first round of screening in a population, where approximately half of the women had undergone previous mammography, breast cancer detection rates were 5.1 per 1000 mammograms. In subsequent rounds of screening, breast cancer detection rates declined to 2.0 per 1000 mammograms. The percentage of invasive tumors greater than 2 cm was 51% of identified breast cancers in the first round and declined to 33% in subsequent rounds of screening. It appears that the first round of screening detected prevalent breast cancers at more advanced stages, and that subsequent rounds of screening detected primarily incident disease at earlier stages. Additionally, rates of identified breast cancers per 1000 mammograms and proportion of invasive tumors increased with age, reflecting greater prevalence of breast cancer among older women. However, for on-going, regular screening, stage is an appropriate intermediate outcome measure. In this latter case, an organizational-level indicator could be expressed as the proportion of local stage disease among all age-eligible women with one or more prior mammograms who having been receiving care in the setting for two or more years.

4.2.1 Patient-Based Barriers to Initial Cancer Screening

As depicted on Figure 3, the main patient-based barriers to realized access to initial cancer screening include age, gender, insurance, race/ethnicity, and knowledge, attitudes and behavior; these barriers results in differences in screening rates across populations.

4.2.1.1 Age

In an analysis of cancer screening rates among participants of the 1992 National Health Interview Survey, Potosky et al, 1998, #647) described the association between age and rate of cancer screening in asymptomatic individuals (Table 4.1). In general, screening frequency was noted to decline with increasing age.

Table 4.1. Screening Use by Age Group for Asymptomatic Individuals Without Related Health Problems[1]

	Mammography[2]	Pap Smear[2]	FOBT[2]	Sigmoidoscopy
18-29	NA	82.3	NA	NA
30-39	NA	84.3	NA	NA

40-49	55.8	81.0	14.5	5.3
50-64	56.3	70.5	26.2	10.0
65-69	54.4	62.9	29.0	13.0
70-79	47.2	51.2	29.9	12.3
80+	28.1	36.1	20.8	13.2

[1] Data from 1992 National Health Interview Survey weighted to US Total Population
[2] Trend significant at p<.05 SOURCE: Potosky et al., 1998
Rates of mammography, FOBT in the previous two years and pap smears within the past three years
For instance, about 80% of women under the age of 50 reported a pap smear within the previous three years, compared to only 36.1% for women 80 and older; mammography rates also declined with age. Similar trends for lower mammography and pap smear rates for older individuals have been documented elsewhere (Hedegaard et al., 1996 (509). It should be noted, however, that there remains some controversy about he age of cessation of screening for both breast and cervical cancers; this may account for some of the age-related declines in screening. Rates of FOBT and proctosigmoidoscopy (PRSIG) were under 30% for all each groups, and there tended to be a U-shaped relationship between screening and age, with both younger and the oldest-old groups being less likely to be screened that those ages 65 to 79 years.

There are several issues specific to the elderly that may account for the observed declines in screening among this age group from those observed for those under 65. First, limitations in mobility and other functioning and comorbidity (with associated decreases in life expectancy) may affect preventive behaviors (see section 3.1.1). Second, in the context of preventive care, elderly individuals may be more concerned with quality than quantity of life than younger individuals. Related to this perspective, the elderly often feel that they are "too old" for screening, and that they are not susceptible to cancer (Mandelblatt et al, 1992, #1419). However, if physicians recommend screening, the elderly will comply (Fox et al, 1994, #692).

4.2.1.2 Gender

Two of the three recommended cancer screening tests included in our review are for women only. As a result, there is little information describing differences in screening behavior by gender and barriers to care associated with gender. One study recently reported that women were less likely than men to have ever had colorectal cancer screening--33% vs. 43% (CDC, Bowdy, 1998, #1069). However, data from the National Health Interview Survey for individuals 50 and above show mixed gender trends --FOBT screening within the past 3 years was similar for women and men (27% and 25%, respectively), while proctoscopy within the past 3 years was reported by only 7% of women, compared to 12% for men (Anderson and May, 1995, #574).

As noted in the overview (Section 3.1.2), any gender-mediated differences that exist may be related to gender-related differences in interactions with the medical care system. For instance, physicians have been described as recommending fewer sigmoidoscopic exams for female patients than for male patients (Schapira et al., 1993, #603).

4.2.1.3 Insurance

Health insurance plays an important role in cancer screening. In this section, we report the most recently available data on insurance and cancer screening, discuss some recent trends in insurance coverage for screening, and speculate on the impact of these trends.

Despite attention to expanding insurance coverage for cancer screening, data from the National Health Interview Survey indicate the even among those with insurance, rates remain below the Year 2,000 goals (Potosky et al, 1998, #647). Rates of screening also vary by the type of insurer, where those covered by private fee-for-service (FFS) and Medicaid FFS have lower rates of mammography, pap smear and FOBT than individuals in managed care. Uninsured persons have the lowest rates of screening of all groups (Table 4.2).

Table 4.2. Screening Use by Type of Health Insurance for Asymptomatic Individuals Without Related Health Problems Aged 40-64[1]

	Mammography	Pap Smear[2]	FOBT	PRSIG
Managed Care	67.4	85.2	25.7	8.2
Private FFS	60.1	81.8	21.4	8.3
Medicaid FFS	39.9	82.3	17.8	6.9
No Coverage	28.3	65.9	7.7	4.3

[1]Data from 1992 National Health Interview Survey weighted to US Total Population
[2]Includes women aged 18-64 SOURCE: Potosky et al., 1998

Similar trends of low screening rates among the uninsured (Hedegaard et al., 1996 (509); Katz and Hofer, 1994, #1306; Ayanian, 1993, #570), and those on Medicaid, compared to insured or other types of coverage, have been documented elsewhere (Rutledge et al., 1988, #419; Ayanian, 1993, #570).

The level of cost sharing associated with different types of tests also affects participation in screening. As part of the RAND health insurance experiment, rates of pap smear use were compared among women assigned to cost-sharing versus non-cost-sharing. Women receiving health insurance through a plan with no cost-sharing were more likely to obtain pap smears than women in the cost-sharing plan (Lurie et al, 1987, #1420).

Even among managed care plans that utilize cost-sharing, the structure of the managed care plan--Group model HMOs typically offer centralized services and maintain patient databases centrally while IPA model HMOs are typically more diffuse--may affect the receipt of cancer screening (Gordon et al., 1998). Data from the California Behavioral Risk Factor Surveillance Surveys (BRFS) were used to assess mammography, pap smear, FOBT, and PRSIG utilization in age-appropriate populations receiving health insurance outside of Medicare, Medicaid, or military-funded health plans. Adjusting for race/ethnicity, education, household income, personal history of cancer, and overall rating of health individuals, women receiving care through a Group model HMO were more likely to have received pap smear (OR=2.83; 95%CI:1.51,5.30), mammogram (OR=3.06; 95%CI:1.67,5.63), and FOBT (OR=2.66;95%CI:1.54,4.61) within the past two years than women receiving care through indemnity plans. This effect was statistically significant in each case. Women receiving care through IPA model HMOs were more likely to receive screening tests within the past two years for pap smear (OR=1.90;95%CI:1.01,3.55), mammography (OR=1.61;95%CI:0.86,3.03), FOBT (OR=1.62;95%CI:0.90,2.91) than women receiving care through indemnity plans, but this effect was generally not significant and not as strong as for Group model HMO. Although the odds of receiving PRSIG was higher for women receiving care through a Group model HMO (OR=1.26; 95%CI:0.64, 2.45)or an IPA model HMO (OR=1.07; 95%CI:0.51, 2.26) than an indemnity plan, neither of these associations were statistically significant. Results were similar for men receiving care through Group model HMOs--they were more likely to have received FOBT (OR=1.82;95%CI:1.03, 3.22) and PRSIG (OR=1.32; 95%CI:0.69, 2.53). However, men receiving care through IPA model HMOs, were less likely to receive either FOBT (OR=0.61; 95% CI:0.30, 1.23) or PRSIG (OR=0.99; 95%CI:0.47,2.08) than men receiving care through indemnity plans.

Medicare currently provides coverage for triennial Pap smears, annual mammograms (without co-pays), annual FOBT and triennial sigmoidoscopy; Medicare also recently expanded benefits to include PSA testing, despite the absence of data on the effectiveness of this examination (Bagley and McVearry, 1998, #736). Thus, for individuals aged 65 and older, insurance barriers should be reduced. However, even among Medicare beneficiaries, variations in screening use exists. For instance, screening rates have been reported to be lower among those with Medicare and Medicaid or Medicare alone than among those with Medicare and supplemental insurance (Table 4.3) (Potosky et al, 1998, #647; Blustein, 1995, #400). Of note, elderly persons cared for in managed care settings have the highest screening rates. This may, in part, be due to the required reporting of the National Center for Quality Assurance (NCQA) HEDIS measures among MCOs.

Table 4.3 Screening Use by Type of Health Insurance for Asymptomatic Individuals Without Related Health Problems Aged 65 and Older[1]

	Mammography	Pap Smear	FOBT	Sigmoidoscopy
Medicare and Managed Care	62.4	66.0	39.8	15.4
Medicare and Private FFS	47.9	54.6	29.8	13.5
Medicare and Medicaid	27.5	38.7	10.2	7.2

Medicare Only	27.8	32.5	14.9	8.8

[1]Data from 1992 National Health Interview Survey SOURCE: Potosky et al., 1998

Comparisons of asymptomatic cancer screening rates from the US and Ontario, Canada indicate that universal insurance coverage alone does not guarantee appropriate rates of screening. Although it might be expected that universal insurance would lead to higher rates of screening, rates of cervical screening were similar in the two countries, and rates of mammography were actually lower in Ontario than in the US (Katz and Hofer, 1994). Increased household income was associated with higher odds of receiving mammograms for Canadian women, leading the authors to speculate that social class plays a central role in access even in an environment with universal health insurance.

Together, for all age groups, these data suggest that insurance is an important necessary component of realizing access to screening, but is, in and of itself, not sufficient.

4.2.1.4 Social Class

As summarized previously in Section 3.1.4, social class differences in access to health care are pervasive; these differences exist for cancer screening services (Potosky et al., 1998; Rutledge et al., 1988, #419) (Table 4.4; 4.5). Across all types of cancer screening and for all ages, there is an association between lower educational level (a proxy for social class) and lower utilization. There is also an association between lower levels of household income and lower screening rates. Similar trends for lower screening rates for individuals with lower educational attainment and household income have been documented elsewhere (Rutledge et al., 1988, #419.

Table 4.4 Screening Use by Educational Attainment and Household Income for Asymptomatic Individuals Without Related Health Problems Aged 18-64[1]

	Mammography	**Pap Smear**	**FOBT**	**Sigmoidoscopy**
Education				
<12 years	38.4	65.9	14.8	5.4
High School Graduate	53.5	77.1	18.4	6.4
>12 years	66.9	87.5	24.2	9.7
Household Income				
<20,000	38.9	73.0	14.3	5.5
>=20,000	62.0	82.8	22.0	8.2

[1]Data from 1992 National Health Interview Survey weighted to US Total Population
SOURCE: Potosky et al., 1998

Table 4.5 Screening Use by Educational Attainment and Household Income for Asymptomatic Individuals Without Related Health Problems Aged 65+[1]

	Mammography	**CBE**	**Pap Smear**	**FOBT**	**PRSIG**
Education					
<12 years	33.6		43.6	20.6	8.6
High School Graduate	49.0		54.6	29.6	12.1
>12 years	59.8		60.4	37.2	20.6
Household Income					
<20,000	37.5		46.0	22.2	10.7
>=20,000	57.5		60.9	35.6	15.5

[1]Data from 1992 National Health Interview Survey weighted to US Total Population
SOURCE: Potosky et al., 1998

4.2.1.5 Race/Ethnicity

There are also some differences in screening use by race/ethnicity, with Hispanics generally having the lowest cancer screening rates (Tables 4.6 and 4.7).

Table 4.6 Screening Use by Race/Ethnicity for Asymptomatic Individuals Without Related Health Problems Aged 18-64[1]

	Mammography	Pap Smear	FOBT	Sigmoidoscopy
White, non-Hispanic	57.1	79.0	21.1	7.7
Black, non-Hispanic	56.5	85.6	19.6	9.7
Hispanic	51.3	78.1	12.9	6.0

[1]Data from 1992 National Health Interview Survey weighted to US Total Population
SOURCE: Potosky et al., 1998

Table 4.7 Screening Use by Race/Ethnicity for Asymptomatic Individuals Without Related Health Problems Aged 65 and Older[1]

	Mammography	Pap Smear	FOBT	Sigmoidoscopy
White, non-Hispanic	45.9	51.6	29.1	12.6
Black, non-Hispanic	42.4	50.4	21.1	12.4
Hispanic	42.9	54.7	15.8	10.6

[1]Data from 1992 National Health Interview Survey weighted to US Total Population
SOURCE: Potosky et al., 1998

However, describing screening within such broad racial/ethnic categories may mask underlying differences in behavior. For example, in a study of cancer screening in a group of multiethnic Blacks and Hispanics, rates of mammography and pap smears were quite different across Columbian, Dominican, Ecuadorian, Puerto Rican, Caribbean, Haitian, and US-born Black women (O'Malley et al., 1997, #821). Similarly, in the Pathways Project to promote cancer screening in ethnically diverse and underserved communities, while the percentage of women over the age of 50 reporting ever having had mammography were similar for Whites and Blacks (92.7 and 90%, respectively), Latina, Chinese, and Vietnamese women had substantially lower rates, and each group differed form the others (79.6%, 72.7%, and 46.4%, respectively) (Hiatt, 1996, #379).

Variations in screening rates within ethnic groups may be explained, in part, by differences in language use. This hypothesis is supported by the observation that significantly lower rates of mammography screening and clinical breast examination (CBE) are reported among non-English speaker than English speakers (Table 4.8) When language is evaluated within racially defined group, rates of screening for English-speaking Hispanic and Chinese women are more similar to those of White women.

Table 4.8 Use of Mammography in San Francisco Bay Area (BACCIS) for English Speaking and non-English Speaking Women

	Mammography in past 2 years		CBE in past year	
	N	Percentage (SE)	N	Percentage (SE)
English	1325	65 (1)	1323	68 (1)
No English	269	31 (3)	270	25 (3)
Hispanic	229	56 (3)	230	57 (3)
English	149	63 (4)	149	67 (4)
No English	80	43 (6)	81	37 (5)
Chinese	278	37 (3)	277	29 (3)
English	89	60 (5)	88	47 (5)
No English	189	26 (3)	189	20 (3)
White	500	66 (2)	499	68 (2)
Black	472	69 (2)	472	74 (2)

SOURCE: Hiatt and Pasick, 1996

Another related explanation for racial/ethnic group differences in screening use is that groups vary in levels of acculturation. For instance, in Hispanic populations, lower levels of acculturation (as measured by birth outside of the US) and use of Spanish language are associated with lower rates of cancer screening (Stein, 1991, #397; Hiatt and Pasick, 1996, #379).

Finally, another potential confounder in the observed relationships between screening and race/ethnicity is social class, underscoring the complexity of the relationship between race/ethnicity, social class and screening (Hedegaard et al, 1996, #509). As an example, in a community health center setting of low-income women, where over-two thirds of the patient population had annual income at or below the federal poverty level, African-American women were more likely to have been screened in the previous one-year period than Caucasian women adjusting for the effect of age group, level of subsidized care, average number of encounters per year, and primary clinic site (RR=1.16; 95% CI: 1.01, 1.32) (Hedegaard et al, 1996, #509). Thus, the role of patient race/ethnicity in realized access to cancer screening is complicated and likely to be associated with level of acculturation and social class.

4.2.1.6 Knowledge, Attitudes, and Beliefs

In addition to the barriers described above, patient knowledge, attitudes and beliefs about cancer and cancer screening may also play a role in realized access to screening. For instance, patients often report that they believe that cancer screening tests are unnecessary in the absence of symptoms, and that they mistrust physicians to act in their best interests (Grady, 1992, #789; Myers, 1991, #548).

Individuals who have never been screened also reported more concerns about inconvenience, discomfort, trouble, embarrassment and pain involved in screening than adherent individuals (Davis et al., 1996, #514; Stein et al., 1991, #397; Myers, 1991, #548). For example, in a study developed to assess attitudes to flexible sigmoidoscopy and colonoscopy, respondents who had never been screened reported that they would be willing to give up one month and three months of life, respectively to avoid colorectal cancer screening.

Concerns about modesty or dignity may prevent individuals to seek screening for cervical, breast, prostate, or colorectal cancer. Cultural restrictions on gynecological exams by male physicians for women from Moslem and some Latina cultures, and breast self-exams for women from Asian cultures, where touching one's own body parts may be taboo, may further exacerbate these types of barriers (Kagawa-Singer, 1997, #1256). Additionally, underlying beliefs that talking about something can cause it to happen or that one's fate is unalterable may be additional beliefs that constitute barriers to screening (Kagawa-Singer, 1997, #1256; Mo, 1992, #1338).

Finally, literacy can influence knowledge, which, in turn, affects screening behaviors. For instance, women with low levels of literacy report less accurate knowledge about screening mammography (Davis et al., 1996, #514). Women with low levels of literacy are more likely to report that they might be more likely to get a mammogram if a friend recommended one or if a relative recommended one than similar women with higher levels of literacy (Davis et al., 1996, #514). Thus, a person's context, or environment, had the ability to mediate knowledge, attitudes and behaviors as well.

4.2.1.7 Individual Contextual Factors

Many of the knowledge, attitudes and beliefs described above are associated with an individual's culture, informal learning, social networks, and social support. In a study of low income Mexican American women, Suarez et al (Suarez et al., 1994, #816) described the association between knowledge, attitudes, and beliefs about cancer screening, social networks, and cancer screening. After adjusting for the effects of age, marital status, health insurance, educational attainment, birthplace, and traditional attitude towards family, increasing levels of social network were associated with higher rates of pap smear and mammography utilization. Additional descriptive work in social networks and utilization of cancer screening, particularly among elderly, low social class, and minority groups, will be useful for the development of interventions to increase cancer screening.

Finally, geographic location is also associated with access to cancer screening. For example, rural women have been reported to have lower mammography screening rates than women living in non-rural areas (Katz and Hofer, 1994, #1306). This may be due, in part, to limited availability of screening facilities. Mandelblatt et al reported that, even among women living in an urban area, lower concentrations of mammogram facilities was associated with lower rates of breast cancer screening (Mandelblatt et al., 1995, #1421).

4.2.2 Physician-Based Barriers to Initial Cancer Screening

Physicians play a critical role in screening. One of the strongest predictors of whether a patient will undergo screening is the physician recommendation (Grady, 1992 , #789); Fox and Stein, 1991, #623). In the absence of a physician recommendation, patients may assume that cancer screening is unnecessary. Yet, physician ordering of cancer screening tests is generally lower than rates recommended in preventive health care guidelines (Schwartz, et al 1991, #471; Fox et al., 1988, #420). As noted in the overview, there are many explanations for this behavior, including gender, time and forgetfulness, beliefs about screening efficacy, concerns about patient compliance, and

discomfort with patients from different backgrounds and cultures. Since many of these domains were discussed previously, in this section we highlight selected barriers.

Studies of physician knowledge about cancer screening have reported that physicians are generally aware of guidelines (Schapira et al, 1993, #603), but may not perceive these tests to be beneficial in the absence of symptoms (Schapira et al., 1993, #603). In fact, it has been reported that some physicians do not believe that routine cancer screening is important in elderly patients (Weisman et al., 1989, #855), a group at the higher risk of cancer.

In the past, physicians have been noted to have specific concerns such as cost of screening, patient compliance or inconvenience, or, in the case mammography, be worried about patient exposure to radiation (Fox et al., 1988, #420); it is unclear of these are persistent barriers at present.

Physicians may also be less likely to recommend screening tests in situations where patients are dissimilar from themselves. For instance, (Grady et al.,1992, #789) reported that older, poorer and less educated women were less likely to receive physician encouragement for mammography screening. (Lurie et al.,1993, #1102) reported that male physicians are less likely to perform regular Papanicolaou tests and mammography screening than are female physicians. This difference may be largely associated with differences in beliefs in prevention effectiveness, discomfort in performing pap smears and clinical breast exams, and taking a sexual history from female patients. Further, fewer male than female physicians felt that they shared responsibility for patient receipt of pap smear (76% vs. 89%) or mammography (83% vs. 95%) (Lurie et al., 1997, #987). Even after matching on physician specialty, fewer male than female physicians felt that they shared responsibility for patient receipt of pap smear (76% vs. 89%) or mammography (83% vs. 95%) (Lurie et al., 1997).

Because of the critical role that physicians play in recommending cancer screening, additional research is critical to overcoming such barriers. Physician training in communication about cancer risk and screening, particularly in vulnerable populations, is one important area for additional research. In the case study of mammography screening presented at the end of this section, we identify several interventions which are effective in improving rates of mammography screening. Future physician-targeted research, particularly in populations with little exposure to screening or in settings where these populations are accessible (e.g., the emergency room) may lead to improved initiation of cancer screening.

4.2.3 Medical Care System Barriers to Initial Screening

Several components of the structural and process of care at the organizational level effect access to screening. One example is having “continuity of care” within a given source of care. (O’Malley et al.,1997, #821) described a screening rates in a multiethnic community. Women with a usual site of care were more likely to have ever received a mammogram or a Papanicolaou smear compared to women without a usual site of care.

The location of cancer screening has also received increased attention. Mobile mammography, although touted as an effective mechanism to introduce mammography into underserved populations, has not been thoroughly evaluated. This may also be an effective mechanism to increase screening rates for elderly in retirement communities or the non-elderly at the workplace. Additional research on the simultaneous provision of multiple screening exams at radiologic facilities, in mobile mammography units, at the workplace, or in retirement communities may lead to improved screening rates for all tumor sites.

Other system barriers to screening have been reviewed in Section 3.4.

4.3 INTERVENTIONS TO INCREASE CANCER SCREENING

Having summarized barriers to screening, we next turn to assessing the effectiveness of interventions in overcoming these barriers. These interventions are divided into three broad categories based on unit target for change: physician, patient, or system-targeted interventions. We further classify interventions as cognitive, behavioral, or sociologic (Fineberg, 1986, #1096) . Cognitive strategies provide new information, increase existing knowledge, and clarifying misperceptions. Behavioral interventions alter cues or stimuli associated with screening behavior; and sociologic interventions use social norms or peers to increase screening adherence.

Several comprehensive reviews of interventions to increase cancer screening have been recently published (Vernon, 1997, #1037; Paskett, 1998, #1042; Snell and Buck, 1996, #1039; Mandelblatt and Kanetsky, 1995, #708). As examples we discuss one patient-targeted behavioral intervention to increase FOBT and a patient-based cognitive intervention to increase adherence to cervical cancer screening. Finally, we present an in-depth case study assessing the effectiveness of patient-, physician- and system-targeted interventions to increase mammography screening.

Myers et al., 1991,#548) developed a patient-targeted intervention to increase fecal occult blood test (FOBT) adherence in a population of men and women ages 50-74 who were members of an Independent Practice

Association (IPA) health maintenance association. Over 2000 subjects were mailed an FOBT kit and randomly assigned to receive one of four increasingly intensive interventions—an advance letter and reminder letter after 15 days (usual care), usual care and a 30 day reminder call (group 1), group 1 follow-up and a coloRecord booklet (group 2), and all of the above plus an instruction call, where the caller reviewed steps with subject and tried to get the subject to commit to completion of FOBT (group 3). Adherence was considered as completion of the FOBT kit within 90 days. In the control group, 27.4% of subjects were adherent; in group 1, 37.1%; in group 2, 37.3%; and in group 3, 48.1%. Differences among these intervention groups were statistically significant. For subjects in group 3 that received an instructional telephone call prior to day 10, adherence was significantly higher than in all other groups. Thus, the behavioral interventions of a reminder letter and an instructional phone call appeared to increase FOBT adherence, while the educational intervention did not affect participation rates.

There have been numerous interventions developed to improve access to cervical cancer screening (Marcus et al., 1998, #1038). One interesting approach involves the use of multimedia educational interventions targeted to underserved populations (Meade et al., 1994, #434; Yancey et al., 1994, #150). For example, Yancey et al (1994, #150) developed a culturally sensitive video tape for African American and Latino women to encourage cervical screening. The content of the video was presented in both English and Spanish languages, and included education on cervical cancer. Effectiveness of the video was assessed at two clinics in a week on, week off design where the video played continuously while women waited for their appointments. Women with appointments or walk-ins during the week the video was playing were considered the intervention group and women seen at the clinics on alternative weeks were considered the control group. Compared to control, significantly more women who had appointments during the video week had mammography within 3-5 months.

4.3.1 In-Depth Case Study: Effectiveness of Interventions to Increase Mammography Use

We selected breast cancer screening with mammography for a comprehensive case study, since this cancer site has the greatest body of literature available for critical review. We performed a comprehensive literature search and included articles that met the following criteria: randomized or concurrent control design, clear definitions of outcomes, data available for abstraction for re-analysis, and lack of major threats to internal validity. Data were systematically abstracted from eligible articles, and data on the intervention effects were combined to yield summary effect sizes. Appendix A includes a more detailed outline of the search strategy and analytic methods.

As was described above, we divided eligible interventions into three groups - patient, physician, or both. We did not include system-based interventions per se, although they are included to the extent that they target physician behavior (like reminder systems). We then sub-divided interventions further by mechanism of action: cognitive, behavioral, or sociological. Where possible, we also described interventions in relation to the type of comparison group. The following sections summarize the results of the review.

4.3.1.1 Patient-targeted interventions

Cognitive interventions

Cognitive strategies provide new information, increasing existing knowledge as well as clarifying misperceptions. Patient-targeted cognitive strategies employed a variety of approaches including provision of generic information about screening (McPhee, 1989 #520; Champion, 1994 #564; Skinner, 1994, #516; Davis, 1998, #579), and provision of information based on specific theories of cognitive change such as the health belief model, social learning theory, and focus of responsibility (Rimer, 1992, #425; Rothman, 1993, #805; Bastani, 1994, #662; Champion, 1994, #564; Aiken, 1994, #664; Clover, 1992, #669). Interventions based in theories of cognitive change typically identify patient attitudes to screening and breast cancer and provide focussed educational material directed at increasing compliance with mammography. For example under the health belief model, a woman is likely to undergo screening mammography if she believes that she is susceptible to breast cancer (perceived susceptibility), that consequences of breast cancer are severe (perceived severity), that mammography has benefits in terms of reducing the impact of breast cancer (perceived benefits), and that barriers associated with receiving a mammography are low (perceived barriers) (Becker and Maiman, 1975). An intervention based on the health belief model would provide targeted educational material addressing perceived susceptibility and severity of breast cancer and the perceived benefits and barriers to receiving mammography.

Based on differences in the approach of these interventions, we sub-divided patient- targeted cognitive strategies into generic patient education and theory-based education.

Interventions that compared generic patient education strategies to usual care are described in Table 4.9. Although several interventions led to an increase in mammography screening (McPhee, 1989 #520; Nattinger, 1989;

Skinner, 1994; Champion, 1994 #564), overall this effect was small, 2.4%, and not significant (95% CI:-5.2,10.1). Thus, provision of generic cancer information does not appears to be effective in increasing mammography screening rates.

Table 4.9 Patient-Targeted Cognitive Interventions to Increase Mammography Screening: Generic Patient Education

Study	Intervention	Effect Size	95% CI
McPhee, 1989 #520	Patient education	3	(-6.4, 12.4)
Champion, 1994 #564[1]	Patient information	11%	(-3.7, 25.7)
Skinner, 1994[1]	Patient education	13%	NE
Davis, 1998 #579	NCI education brochure	-3	(-14, 8.1)
Q-Statistic 3.06	**Summary**	**2.4**	**(-5.2, 10.1)**

1 Randomized Controlled Trial
2 Concurrent Control Group

We divided **theory based cognitive interventions** into two groups based on the type of comparison group. Studies where comparison groups were inactive controls or usual were care are described in Table 4.10 and studies where comparison groups were active controls (e.g., generic patient education) are described in Table 4.11.

Table 4.10 Patient-Targeted Cognitive Interventions (Compared to Usual Care Controls) to Increase Mammography Screening: Theory-based Patient Education

Study	Intervention	Effect Size	95% CI
Rimer, 1992 #425	Health belief, social learning theory, opportunity and letters vs. nothing	33%	(24.9, 41.1)
Champion, 1994 #564[1]	Health belief model education vs. no information	10%	(-4.9, 24.8)
Champion, 1994 #564[1]	Health belief model and information vs. no information	25%	(11.8, 38)
Aiken, 1994 #664[2]	Health belief model vs nothing	20.4%	(10.0,30.8)
Aiken, 1994 #664[2]	Health belief model and compliance exercises vs. nothing	22.8%	(18.7, 26.9)
Q-statistic 8.1	**Summary**	**23.6**	**(16.4, 30.1)**

1 Randomized Controlled Trial
2 Concurrent Control Group

Compared to usual care, theory based cognitive interventions appear to be very effective in increasing the rate of mammography utilization--overall, 23.6% more women received mammography (95%CI: 16.4, 30.1). In the two studies where additive interventions were assessed, the effect of multiple interventions was greater than a single intervention (Champion, 1994 #564; Aiken, 1994 #664). Neither of these two studies were sampled for the multiple comparisons we present here, so insufficient power to detect differences may explain the insignificant result in the single study (Champion, 1994 #564).

We identified seven theory-based cognitive interventions which utilized active comparison groups (Bastani et al, 1994 #662; Clover et al, 1992 #669; Rothman et al, 1993). The comparison groups included generic information provided by videotape (Rothman, 1993) or letter (Bastani, 1994 #662) and a generic recommendation provided in a letter (Clover, 1995).

Table 4.11 Patient-Targeted Cognitive Interventions (Compared to Active Controls) to Increase Mammography Screening: Theory-based Patient Education

Study	**Intervention**	**Effect Size**	**95% CI**
Clover, 1992 #669[1]	Health belief model and compliance exercises vs. practitioner recommendation.	9	(-1.0, 19.0)
Rothman, 1993[2]	Videotape with internal focus of responsibility vs. informational videotape	10.7	(-15.7, 26.4)
Rothman, 1993[2]	Videotape with external focus of responsibility vs. informational videotape	1.9	(-19.1, 21.0)
Bastani, 1994 #662	Health belief vs. generic educational letter	-6	(-12.9, 0.9)
King, 1994	Telephone counseling	14	(7.9, 20.1)
Banks, 1995	Loss-framed vs. gain-framed factually equivalent videotapes	14.7	(-1.8,31.3)
Davis, 1997	Telephone counseling and scheduling vs. Appointment birthday card	13%	(3.2, 22.8)
Q-statistic 22.5	**Summary**	**8.5%**	**(0.4,16.5)**

1 Randomized Controlled Trial
2 Concurrent Control Group

All but a single intervention had a positive effect on mammography utilization (Rothman, 1993; Bastani, 1994 #662; Clover, 1992), and the overall effect was marginally significant. Compared to active comparison groups, 8.5% more women receiving a theory-based cognitive intervention received mammography (95% CI: 0.4, 16.5).

Patient-targeted cognitive interventions which utilize specific educational theories to provide information to patients are very effective when compared to usual care, and less effective when compared to active controls. Generic patient education strategies do not increase rates of mammography screening.

Behavioral Interventions

Behavioral interventions alter cues or stimuli. Patient-targeted behavioral interventions include telephone reminders (Mohler et al, 1995; Lantz, 1995), letters from clinical program directors or primary care clinicians (Irwig et al, 1990; Clementz et al, 1990; Landis et al, 1992; Kendall, 1992; King et al, 1994; Taplin et al, 1994; Mohler et al, 1995; Lantz, 1995 #433;), and financial incentives to the patient in the form of vouchers or coupons (Janz et al., 1997 (666); Kiefe et al., 1994 (472)). As above, these interventions were further divided for interventions which used usual care comparison groups (Irwig, 1990; Clementz, 1990; Ornstein, 1991; Landis, 1992; Dickey, 1992 #605;Mohler, 1995; Lanz, 1995 #433) and active comparison groups (Kendall, 1992 Taplin, 1994; King, 1994).

Table 4.12 Patient-Targeted Behavioral Interventions to Increase Mammography Screening Using Usual Care Comparison Groups

Study	Intervention	Effect Size	95% CI
Irwig, 1990	Physician reminder letter vs. no letter	14	(4, 24)
Irwig, 1990	Physician reminder letter with appointment time vs. no letter	33	(24.2, 41.8)
Clementz, 1990[1]	Sequential physician letters to patient and general prevention education vs. usual care	-10.0	(-23.0, 2.4)
Ornstein, 1991[1]	Patient reminder letter	-6	(-13.3, 0.5)
Landis, 1992	Physician reminder letter vs. no letter	10	(-2.7, 22.7)
Dickey, 1992	Patient health diary reminder vs. no reminder	7.5	NE
Mayer, 1994	Physician reminder vs. No reminder	28	(5.9,50.1)
Mohler, 1995[1]	Physician reminder letter vs. usual care	7	(-15.8, 22.8)
Mohler, 1995[1]	Physician phone call vs. usual care	18	(0.5, 35.5)
Mohler, 1995[1]	Medical assistant phone call vs. usual care	32	(13.2, 50.8)
Lantz, 1995 #433[1]	Physician reminder letter and telephone call vs. usual care	17.3	(11.7, 22.9)
Q-Statistic 86.8	**Summary**	**13.3**	**(2.7, 23.9)**

Behavioral interventions using usual care comparison groups led to increased rates of mammography utilization in most cases (Irwig, 1990; Landis, 1992; Dickey, 1992 #605; Mohler, 1995; Lantz, 1995 #433) (Table 4.12). The effects were significant with the exception of four interventions (Landis, 1992; Mohler, 1995). Two led to decreased rates of mammography screening (Clementz, 1991; Ornstein, 1991) compared to usual care.

Overall, 13% more women received mammography after receiving a behavioral intervention compared to usual care (95% CI: 2.7, 23.9). Many of the studies had small samples leading to wide confidence intervals. Additionally, the Q-statistic is fairly high (86.8) indicating heterogeneity among the studies.

We identified eleven behavioral interventions in six studies which used active controls ((Taplin et al, 1994; King, 1994; Kendall and Hailey, 1993; Mayer, 1994; Somkin, 1997; Davis, 1997). Patient targeted behavioral interventions using active control groups generally also led to increases in the rates of mammography screening (Taplin et al, 1994; King, 1994; Kendall and Hailey, 1993; Mayer, 1994; Somkin, 1997) (Table 4.13).

Table 4.13 Patient-Targeted Behavioral Interventions to Increase Mammography Screening using Active Control Groups

Study	Intervention	Effect Size	95% CI
Kendall and Hailey, 1993	Reasurring physician reminder letter vs. standard letter	20	(0.9, 39.1)
Kendall and Hailey, 1993	Anxiety provoking physician reminder letter vs. standard letter	6	(-12.9, 24.8)
King, 1994[1]	Physician reminder letter, breast cancer information, and free mammography referral vs. information and referral	14	(7.9, 20.1)
King, 1994[1]	Preventive office visit letter, breast cancer information, and free mammography referral vs. information and referral	2	(-6.6, 8.6)
Taplin, 1994[1]	Physician letter vs. Program letter	-1.2	(-8.8, 6.4)
Taplin, 1994[1]	Postcard and letter from program director, vs. letter from program director	11.7	(4.5, 18.9)
Taplin, 1994[1]	Postcard, letter from personal MD vs. program director	14.9	(7.4, 22.4)
Mayer, 1994	Reminder postcard and gift vs. reminder postcard	-4	(-17.6, 9.6)
Mayer, 1994	Telephone reminder and scheduling vs. Reminder postcard	4	(-10.0, 18.4)
Somkin, 1997	Patient letter and reminder in chart vs. Physician referral to receive mammography	10.5	(7.2, 13.8)
Davis, 1997	Phone call with reminder vs. birthday card reminder	-6.0	(-13.8,1.8)
Q-Statistic 38.1	**Summary**	**5.9**	**(1.4, 10.3)**

When the results of these studies were combined for quantitative analysis, the overall rate of mammography was 5.9% higher for women receiving behavioral interventions compared to active controls (95% CI: 1.4, 10.3).

We found only two patient-targeted studies that addressed financial incentives (Kiefe et al, 1994; Janz et al., 199). Both studies included multiple interventions and were effective in increasing the rate of mammography screening. One intervention consisted of a physician letter, patient reward for completion of mammogram, and peer counseling. In this study, the comparison group received only usual care (Janz, 1997). Women in the intervention group were more likely to receive mammograms (38% vs. 16%) than women in the control group (22; 95% CI: 14.1, 29.9). The other study intervention consisted of patient education, an educational pamphlet, and a voucher for a free mammogram. More women in the intervention group received mammogram than did women in the control group (34; 95% CI: 19,49).

Sociologic interventions

Examples of patient-targeted sociologic interventions might utilize community peers or media representations of appropriate behavior to influence screening behaviors. We identified four interventions which utilized sociologic

interventions to increase adherence to mammography screening (Janz, 1997; Calle, 1994; Houts, 1990; Davis, 1998 #579) (Table 4.15).

Table 4.14 Patient-Targeted Sociological Interventions to Increase Mammography Screening
Peer Counseling

Study	Intervention	Effect Size	95% CI
Houts, 1990	Individualized counseling based on ACS guidelines	9	(1.4, 16.6)
Calle, 1994[1]	Counseling by friend	15	(7.1, 22.9)
Janz, 1997[1]	MD letter, coupon and health belief peer counseling	22	(19, 49)
Davis, 1998 #579	Physician recommendation, NCI based peer educational videotape vs. Physician recommendation alone	3	(-7.9, 13.9)
Q-statistic 7.0	**Summary**	**14.3**	**(7.9, 20.6)**

1 Randomized Controlled Trial
2 Concurrent Control Group

Although caution must be used in interpreting combined estimates from only three studies, the effects were similar across the three studies and the Q-statistic indicates that the null hypothesis of homogeneity cannot be rejected. Each of these interventions increased the rate of mammography screening, and overall, sociologic interventions led to a 14.3% increase in screening mammography (95% CI: 7.9, 20.6).

Sociological interventions may be particularly effective in patient populations where physician mistrust is high and continuity of care is low. Further, a sample of women non-adherent to mammography screening reported that they might be willing to participated in cancer screening if a friend or relative suggested it (Davis, 1998 #579).

4.3.1.2 Physician-Targeted Interventions

In addition to the patient-targeted interventions described above, we also identified interventions targeted at changing physician practice. These studies typically randomized physicians or practice groups to receive cognitive, behavioral, or sociologic interventions. Patient samples were then taken within physician group to assess compliance with mammography screening in the intervention and control groups. The results of these studies are summarized below.

Cognitive interventions

Physician-targeted cognitive strategies include educational efforts (Dietrich et al, 1992 (681)), practice audits with feedback (McPhee, et al., 1989 #520; Tierney et al, 1986; Nattinger et al., 1989; Dietrich, 1992 #681) and combination strategies with interventions targeted at physicians and patients (Fletcher et al, 1993,#604; Rimer, 1992; Tierney, 1986 #608; McPhee, 1989 #520; Landis, 1992; Urban et al., 1995, #663; Somkin, 1997).

Unfortunately, due the manner in which raw data were presented in a single study, we could not construct confidence intervals to assess whether or not these strategies led to statistically significant increases in screening (Dietrich, 1982). These data were not included in quantitative analyses. Physician targeted cognitive interventions led to significant increases in the rate of mammography utilization--17% higher than for usual care (95% CI: 12.2,21.5)(Table 4.15).

Table 4.15 Physician-Targeted Cognitive Interventions to Increase Mammography Screening: Audit Systems or Physician Education

Study	Intervention	Effect Size	95% CI
McPhee, 1989 #520[1]	Audit with feedback vs. usual care	21	(14.7, 27.6)
Tierney, 1986[1]	Audit with monthly feedback and physician reminder vs. sual care	15	(10.3, 19.7)
Tierney, 1986[1]	Audit with monthly feedback vs. usual care	14	(9.4, 18.6)
Nattinger, 1989[2]	Audit with feedback vs. usual care	24	(10.7,36.7)
Dietrich, 1992	Physician education vs. Usual care	21	NE
Dietrich, 1992	Audit and office system vs. Usual care	18	NE
Dietrich, 1992	Audit and office system and physician education vs. Usual care	21	NE
Q-Statistic 3.0	**Summary**	**16.9**	**(12.2, 21.5)**

Behavioral interventions

Physician-targeted behavioral strategies mainly consisted of reminder systems, both computerized and non-computerized (McPhee et al, 1989 (520); Ornstein et al., 1991; McPhee et al., 1991 (599); McDonald et al., 1984; Tierney et al., 1986 (608); Chambers et al., 1989 (522); Becker et al., 1989 (606); Cheney et al., 1987; Yarnall et al, 1993; Cowan et al., 1992; Landis et al., 1992) (Talbe 4.17). A single study utilized changes in the office system to alter physician behavior (Dietrich et al, 1992 (681)). As with other interventions, we divided physician targeted behavioral interventions into those with usual care controls (Table 4.16) and active controls (Table 1.17)

Table 4.16 Physician-Targeted Behavioral Interventions to Increase Mammography Screening using Non-Active Comparison Groups
Physician Reminders

Study	Intervention	Effect Size	95% CI
Cohen, 1982 #609	Patient check-list vs. usual care	28	(21.7, 34.3)
McDonald, 1984[1]	Computerized Reminder vs. Usual care	6	NE
Tierney, 1986[1]	Computerized Reminder vs. Usual care	16	(11.2, 20.8)
Cheney, 1987[1]	Non-computerized reminder vs. Usual care	20	(10.0, 30.0)
McPhee, 1989 #520[1]	Computerized reminder vs. Usual care	16	(9.4, 22.6)
Chambers, 1989 #522	Computerized reminder vs. usual care	6	(1.3,10.7)
Becker, 1989 #606	Physician reminder vs. Usual care	20	(7.5,31.9)
Wolosin, 1990[2]	Flow sheet vs. Discussion of mammography	19	(12.1, 26.1)
McPhee, 1991[1]	Computerized reminder vs. Usual care	5	(-0.3, 10.3)
Ornstein, 1991[1]	Computerized reminder	4	(-3.4, 11.2)
Cowan, 1992[1]	Periodic health exam fact sheet	11.3	(-3.7, 26.3)
Landis, 1992	Physician prompts	2	(-11.8, 16.2)
Q-Statistic 54.2	**Summary**	**13.5**	**(8.5, 18.6)**

1 Randomized Controlled Trial

2 Concurrent Control Group
NE Not evaluable

All physician reminder interventions led to increases in mammography utilization (Cohen, 1982; McPhee et al, 1989 (520); Ornstein et al., 1991; McPhee et al., 1991 (599); McDonald et al., 1984; Tierney et al., 1986 (608); Chambers et al., 1989 (522); Becker et al., 1989 (606); Cheney et al., 1987; Yarnall et al, 1993; Cowan et al., 1992; Landis et al., 1992), but the effect was not always significant. The effectiveness of one study could not be assessed from the information presented in the paper (McDonald et al., 1984). Overall, when compared to usual care controls, physician targeted behavioral interventions led to a 14% increase in mammography screening (95% CI: 8.5, 18.6).

We identified four interventions within three studies that utilized active comparison groups to assess the effectiveness of physician reminders (Litzelman, 1993; Grady, 1997 #665; Burack, 1994 #660)(Table 4.17). All led to increases in the rate of mammography screening. Overall, behavioral interventions led to 7.2% increase in the rate of mammography screening compared to active controls (95%CI: 4.8,9.7).

Table 4.17 Physician-Targeted Behavioral Interventions to Increase Mammography Screening Using Active Comparison Groups
Physician Reminders

Study	Intervention	Effect Size	95% CI
Litzelman, 1993	Physician reminder requiring response vs. reminder alone	7	(0.0, 13.0)
Burack, 1994 #660	Computerized reminder, physician staff education, facilitated scheduling, elimination of out of pocket costs vs. physician staff education, facilitated scheduling, and elimination of out of pocket costs	12.0	(9.4, 14.6)
Grady, 1997 #665[2]	Cue enhancement and education vs. education alone	6.8	(6.5, 7.6)
Grady, 1997 #665[2]	Education, Cue enhancement, feedback and reward vs. education alone	4.8	(4.1, 5.5)
Q-Statistic 11.5	**Summary**	**7.2**	**(4.8, 9.7)**

1 Randomized Controlled Trial
2 Concurrent Control Group
NE Not evaluable

Sociologic interventions

As noted for interventions targeting women, sociologic interventions utilize established norms to alter behavior. Examples of physician-targeted sociologic interventions include academic detailing and peer supported adherence to guidelines. We only found a single physician-targeted study that utilized a sociologic intervention (McCarthy et al, 1997). McCarthy et al (1997) attempted to alter the process of care at three urban internal medicine clinics. Responsibility for identifying, offering and ordering mammography was shifted from the clinician to LPNs and medical assistants. Additionally continuous feedback was provided to physicians. 77% of the women in the intervention group and 65% of the women in the control group received mammograms within 60 days of their visit.

4.3.1.3 Combined Physician and Patient Strategies

We identified nine studies that utilized several types of interventions targeted to both physicians and patients to increase rates of mammography screening (McPhee, 1989; Becker, 1989; Ornstein, 1991; Fletcher, 1993 #604; Nattinger, 1989; Rimer, 1992 #425; Landis, 1992; Urban, 1995 #663; Somkin, 1997). As with patient-targeted and physician-targeted interventions, we categorized interventions as cognitive or behavioral based on their mechanism of action. We did not find any sociologic studies simultaneously targeted to patients and physicians.

Cognitive interventions

We identified four patient and physician combined cognitive interventions (Fletcher, 1993 #604; McPhee, 1989; Rimer, 1992 #425; Urban, 1995). With the exception of a single intervention (Urban, 1995 #663), these combined

strategies led to significant increases in the rates of mammography screening. Since the strategies employed by the interventions were very heterogeneous, we did not combine results in quantitative analysis.

Table 4.18 Patient and Physician-Targeted Combined Interventions
Cognitive Interventions to Increase Mammography Screening

Study	Intervention	Effect Size	95% CI
McPhee, 1989 #520	Audit with feedback and patient reminder vs.audit alone	25	(16.2, 33.8)
Rimer, 1992 #425	Health education materials, free referral, reminder letter, telephone call, office based training, tutorial, and tailored feed-back vs. usual care	11%	(2.2, 20)
Fletcher, 1993 #604	Physician education, physician reminders, multimedia and public education vs. nothing	10	(5.6,14.3)
Urban, 1995 #663	Community organization, direct mail education, patient reminder letters, physician mailing, office training, and patient reminder system training vs. usual care	-2.7	(-9.7, 4.3)

Behavioral interventions

We identified six physician and patient combined behavioral interventions (McPhee, 1989 #520; Nattinger, 1989; Becker, 1989; Ornstein, 1991; Landis, 1992; Somkin, 1997). All but a single intervention (Ornstein, 1991) led to increased utilization of mammography screening . Since the strategies employed by the interventions were very heterogeneous, we did not combine results in quantitative analysis.

Table 4.19 Patient and Physician-Targeted Combined Interventions
Behavioral Interventions to Increase Mammography Screening

Study	Intervention	Effect Size	95% CI
Nattinger, 1989	Visit-based strategy with patient education with completed radiology requisition	18	(7.4, 28.6)
Becker, 1989 #606	Physician and patient reminder vs. No reminder	21	(7.2, 33.8)
McPhee, 1989 #520	Physician and patient reminder vs. Physician reminder alone	16	(7.3, 24.7)
Ornstein, 1991	Physician reminder, patient or public reminder vs.	-0.3	(-7.5, 6.9)
Landis, 1992	Physician prompt and patient reminder	20%	(1.5, 38.5)
Somkin, 1997	Patient reminder, physician reminder in chart vs. Physician referral	14.9	(11.5, 18.3)

4.4 SUMMARY

In this meta-analysis of interventions to increase mammography screening, we found that theory-based patient educational interventions were effective in increasing rates of mammography in women when compared to usual care as well as generic education, but the size of the increase in utilization was greater when compared to usual care (23%) than generic educational strategies (8.5%). Generic educational strategies alone did not lead to significant increase rates of mammography screening. Behavioral interventions, such as having physicians remind patients about screening appointments, were consistently effective in increasing mammography utilization, however, as with theory-based education, the size of the increase was greater when compared to usual care (13%) than to an active comparison group (6%). Sociologic interventions using peer counselors or normed behaviors increased mammography screening rates by 14%.

Physician-targeted cognitive interventions using audit with feedback or education increased rates of mammography utilization by 17%, and behavioral interventions using reminder systems were effective in increasing mammography utilization. When compared to usual care, reminders increased rates of screening by 14%, and when compared to active controls, reminders increased rates of screening by 7%. Finally, interventions which

simultaneously targeted physicians and patients were generally effective in increasing rates of mammography screening, although their content was sufficiently variable to limit generalization. It should be noted that while we have presented these interventions as strategies to overcome barriers to initial uptake of mammography, some of the studies included women who had received one or more prior screenings. Unfortunately, none of the papers provided data stratified by prior screening history, so it is not possible to assess the intervention effectiveness separately for each group. Since the barriers to ever, compared to recent, on-going screening may be different (Phillips and Kerlikowski, 1998) and require different intervention approaches, this will be an important area for future investigation.

The meta-analyses we reported were based on published randomized controlled trials or prospective studies with concurrent conrols and were grouped according to similar mechanisms of action (i.e., behavioral, cognitive, or sociologic), target of intervention (i.e., patient, physician, or both), and type of control group (i.e., active control or usual care) where possible. Despite our attempts to group homogeneous studies, there were differences in the patient populations studied, the number of interventions used, baseline levels of mammography utilization, the content of usual care, and the duration of the study which may limit the interpretation of our results. Thus, we have provided the Q-statistic, which is a measure of homogeneity of the studies included in each summary (a larger number is associated with greater heterogeneity). Additionally, we attempted to highlight comparisons where a lack of homogeneity might affect the interpretation of a given group of results.

We found few studies that employed a rigorous controlled design and included sufficient sample to test for differences in effectiveness across population sub-groups (e.g., elderly vs non-elderly, minority vs non-minority, etc). It is possible that physician-initiated interventions will be more effective in increasing screening among elderly women, while sociological types of interventions, such as peer recruitment and counseling may work best for minority and immigrant groups. Multiple-level interventions may be necessary to improve screening rates among hard to reach groups - such as low social class, minority groups with low trust of the medical care system. For instance, use of opportunistic screening in alternative settings such as the emergency room may be cost-effective methods to increase access to screening (Mandelblatt et al, 1997). Another unique approach involves targeting those at highest risk of cancer, such as first degree relative of breast or colorectal cancer patients (Houts et al, 1990). Such strategies may also be important as genetic testing becomes more readily available. Other promising strategies include targeting effect interventions in communities with high rates of late stage disease, where screening can detect disease earlier (Andrews et al, 1994 #1426; Kerner et al, 1988 #758).

These will all be important areas for new research. Research is especially needed to develop interventions to colorectal cancer screening, since barriers to these tests are likely to be quite different from those experienced for, and targeted in, breast and cervical cancer interventions.

4.5 BARRIERS TO REGULAR, ON-GOING SCREENING

Following the initiation of asymptomatic cancer screening, individuals enter the second portion of phase 1 of cancer care, interval screening. As noted above, the effectiveness of screening for decreasing mortality from screen-detectable cancers assumes regular lifetime use from recommended age of initiation to suggested age of cessation. Unfortunately, for some sites (breast and cervix) there is still no consensus on the optimal ages for commencement and conclusion of screening. The lack of consensus is due to several factors, such as a paucity of data for the oldest age groups, conflicting data on the value of mammography in women ages 40 to 49, and concerns about cost-effectiveness.

Once screening begins, most professional groups generally agree about the periodicity of on-going screening: mammography screening every 1-2 years with annual clinical breast examination, pap testing every 3 years, and annual FOBT and/or sigmoidoscopy every 3-5 years. Despite extensive research efforts and major studies documenting the number of persons ever obtaining breast, cervical and colorectal screening, few have specifically addressed adherence to interval screening. What data exist suggest that rates of adherence to regular screening are significantly lower than for the initial screening procedure (De Waard, 1984, #1094; Burack, 1997, #431). In one survey of women over the age of 50, only 20% reported at least two recent annual mammograms (Zapka et al., 1991, #432). Adherence to interval pap smear screening frequencies are also below targeted levels or certain groups (e.g., Hispanic women). Data on adherence to interval screening for colorectal cancer are more limited given the lack of evidence-based screening guidelines prior to 1996. Thus, low rates of adherence to interval screening guidelines indicate limitations in realized access to care for all patients.

4.6 BARRIERS TO INTERVAL SCREENING

Patient, physician, and system barriers to realized access to interval screening are highlighted in Figure 4. Although physician-related barriers to adherence to interval screening guidelines may be similar to those associated with initial screening, patient-related barriers may be quite different. For instance, when compared to individuals that receive regular screening,

figure 4 - rescreening barriers

patient factors associated with a lack of screening adherence have been shown to differ among populations that had never heard of screening, heard of screening, but had never been screened, and those who had non-regular adherence (Mickey et al., 1995, #463; Philips and Kerlikowski, 1998, #610). For instance, in multi variate analysis factors that predicted adherence to lifetime breast cancer screening included younger age (<65), higher social class, and access to care measured on an area level (e.g., HMO market share, reminder systems, no primary care shortages). Among women never having a mammogram, being a non-HMO member was a distinct barrier; interestingly, the area-level access factors did not predict ever having an exam, suggesting that women's attitudes, or predisposing factors, or other issues, such as provider recommendation, may be more important in to obtaining a first screen (Phillips and Kerlikowski, 1998).

As indicated in Figure 4, the most appropriate outcome measures of adherence to screening guidelines include two potential process measures, the rate of regular screening among previously screened individuals (e.g., completion of at least two screening tests, at any point in time) and the rate of adherence to expected lifetime screening. Outcome measures include stage of disease at diagnosis and survival following diagnosis. For all measures, the demoninator should included age-eligible individuals with one or more prior screens who have been receiving care for at least one (for mammography) to three (for Paps) to five years (for sigmoidoscopy). In practice, implementation of the outcome measures may be complicated for several reasons, such as lack of data tracking systems, small samples, low rates of disease, mobility of patient populations, difficulties enumerating the appropriate numerator and denominator groups, and ability to control for other factors which predict survival following cancer diagnoses (e.g., clinical characteristics such as hormonal receptor status and differences in treatment). Interpretation of measures is also limited by lack of consistent definitions of interval adherence (e.g., annual vs biennial mammography) and significant variability in prior screening histories of different patient populations. Development, testing, and validation of measures that address these methodologic and pragmatic issues will be necessary before interventions to increase realized access to interval screening can be properly assessed.

In the following sections we review patient, physician, and system barriers to realized access to interval screening. We also review findings on stage of disease at diagnosis as both a proxy for regular screening, and as an intermediate outcome measure. We then identify areas for additional research and describe the few interventions that have been completed to date. Finally, we identify policy options to increase realized access to interval screening.

4.6.1 Patient Barriers to Regular Screening

Patient barriers to interval screening adherence include age, gender, health insurance, social class, race/ethnicity, and knowledge, attitudes and behaviors.

4.6.1.1 Age

In contrast to the situation for initial screening, where increasing age is consistently associated with decreased screening, reports of age effects in interval screening are more variable. For instance, in a study of about 700 low income women aged 50 and older, the rate of regular mammography screening tended to increase with age, and was 29.5% for women aged 50-64; 33.9%, aged 65-74; and 26.9%, 75 and older (Mickey, 1997, #985). Zapka et al also found similar increases in interval screening in the 65-75 year-old population, where this group was more likely to be adherent to repeat screening mammography than younger women (51-64) adjusting for the effect of education, insurance, history of breast problems or abnormal mammogram, family history, frequency of clinical breast exam, and type of physician (Zapka et a., 1991, #432).

Others, however, have reported that younger age is associated with higher rates of mammography rescreening (de Waard, et al, 1984, #1094; Fink et al., 1972, #1097). Reasons for discrepant observations may include low power to detect age effects, particularly in the oldest age groups, different age categorization, and varying definitions of regular screening.

As noted in section 3.1.1, increases in comorbidity with advancing age complicates the assessment of rescreening in the oldest age groups. However, Mandelblatt and colleagues used a decision analysis and demonstrated that screening continues to save lives for all ages of elderly women, even in the presence of chronic illness, such as hypertension and heart failure. In the oldest age group, women 85 years and older, with the most severe comorbidity (heart failure) patient preferences for the discomfort of mammography, evaluation of any false positive results, and living with advanced cancer were the most important determinants of the screening decision (Mandelblatt et al.,1992, #791).

Paralleling the data on re-screening rates, stage of disease at breast cancer diagnosis also shows a similar U-shaped relationship with age, where women under age 50 and over 64 are more likely to have late stage at diagnosis than women 50 to 64 years, controlling for SES, race, access to care, and setting of care (Mandelblatt et al, 1992, #791). While data for the elderly group were not further separated, it is possible, based on the screening data form other studies, that the increased late stage rates in this age group were attributable to higher rates among the oldest women (ie, those 75+).

As was the case with breast cancer, elderly women are generally less likely to receive regular Pap smear screening than younger women, with the result that increasing age is consistently associated with advanced stage or cervical cancer at diagnosis, or having invasive, compared to in-situ disease (Mandelblatt et al, 1995, #1421; Mandelblatt, 1991#1327). Thus, it appears that increasing age acts as a barrier to interval screening adherence for cervical cancer.

In contrast to the age effects associated with breast and cervical cancers, age has been consistently described as being inversely associated with stage of disease for colorectal cancer patients. For example, Mandelblatt et al assessed stage of disease by age group using data from New York City tumor registry and reported that the odds of being diagnosed with late stage disease decreased in a linear fashion by 3% for every 5-year increase in age (Mandelblatt et al., 1996). The authors suggested that the elderly may be more likely to have rectal examinations, either for screening or in the course of evaluations of symptoms. This age trend for colorectal cancer screening has also been reported elsewhere (Brown et al., 1990, #1427).

Thus, age related barriers to realized access to interval screening appears to differ by tumor type. Younger populations may face limitations in access to interval screening for breast and colorectal cancer, due in part, to conflicting recommendations for screening, while older populations may face limitations in access to interval screening for cervical cancer, and for the oldest age groups, breast cancer.

4.6.1.2 Gender

Based on indirect evidence, there appear to be some gender differences in access to regular screening. For instance, men are more frequently diagnosed with early stage colorectal cancer than women (Kosary et al., 1995, #1100; Mandelblatt et al., 1996, #1304). In one regional population-based data set, significantly more men than women with colorectal cancer were diagnosed with early stage disease (39.3% vs 37.9). This effect persisted after controlling for the effects of age, race/ethnicity, hospital type, neighborhood SES, and changes in neighborhood SES, although the absolute differences were small (Mandelblatt et al., 1996, #1304). As screening for colorectal cancer becomes more prevalent, it will be important to re-evaluate gender effects on access to regular screening.

4.6.1.3 Insurance

Insurance status effects use of regular screening, with uninsured women being the least likely to demonstrate realized access to regular screening. For example, in a study of regular mammography in low income women 50 and over, 33% of those with health insurance received regular mammography compared to only 18% of those without health insurance, and the uninsured were 2.5 times more likely to be diagnosed with late stage disease than insured women (Mickey et al., 1997, #985). Additionally, women who have ever put off seeing a doctor because of financial constraints are more likely to be diagnosed with late stage disease (Lannin, et al 1998, # 1036), suggesting lower access to regular screening.

Among the insured, regular mammography utilization has also been reported to be associated with the type of health insurance (Zapka et al., 1991, #432; Burack, 1997, #431) with more women receiving care through HMOs adhering to interval screening than women with other insurance (Burack, 1997, #431). Among individuals with insurance, there also appear to be differences in stage of disease at diagnosis associated with the type of insurance coverage. Riley et al.,1994, #637) combined data for individuals with Medicare and staging information from SEER tumor registries to assess differences in outcomes for traditional fee-for-service vs managed care settings. Individuals who received coverage under Medicare health maintenance organizations (HMOs) were more likely to be diagnosed with early stage breast, cervical, or colorectal cancer than individuals who received coverage through fee-for-service, traditional Medicare providers. For women who received care through an HMO, the odds of being diagnosed with distant vs. earlier stages of breast cancer was 0.73 (95% CI: 0.57,0.94) and the odds of being diagnosed with regional vs. earlier stages of cervical cancer was 0.34 (95%CI: 0.21,0.56). For men and women who received care through an HMO, the odds of being diagnosed with regional vs. earlier stages of colorectal and rectal cancer were 0.85 (95%CI: 0.75,0.96) and 0.86 (95%CI: 0.70,1.06), respectively. HMO patients were also more likely to be diagnosed with early stage melanoma than FFS patients. Receiving care through an HMO was not associated with differences in the stage of disease at diagnosis for prostate, buccal cavity and pharynx, bladder, corpus uteri and uterus, not otherwise specified, ovary, or kidney. Thus, insurance through HMOs, which typically

provides insurance coverage for, and promotes regular ongoing cancer screening services, is associated with earlier stage of disease at diagnosis among those developing cancer.

Although recent state and federal legislative changes require insurance coverage for interval screening for breast, cervical and colorectal cancer in selected populations (Bagley, 1998, #736), these differential rates of rescreening and/or stage of disease at diagnosis among different types of insurance plans indicate that some barriers to care will not be eliminated with the provision of insurance alone.

4.6.1.4 Social class

As in the case for obtaining an initial screening examination, social class also effects receipt of regular, life-time screening. For instance, for low-income women without a high school education, rates of regular mammography utilization have been reported as significantly lower than in women with more than a high school education; and rates increase with income even within lower-income groups (Mickey, 1997, #985). Family income also appears to play a large role in stage of disease at diagnosis, a proxy for regular screening. For breast cancer patients in a single geographic area, 91% of women with family income above $10,000 per family member; 82% of women with income between $5,000 and $10,000 per family member; and 72% of women with income under $5,000 per family member were diagnosed with early stage disease ($p<0.05$) (Lannin et al, 1998, #1036).

Social class effects have also been measured for individual context, or the community in which the individual resides. Women who live in low-income census tracts are more likely to have their breast and cervical cancers diagnosed late than those living in high-income census tracts (Mandelblatt et al, 1991, #1327; 1995, #1421; Mitchell and McCormack, 1997, #1049). Further, the percentage of women living in low-income areas diagnosed late in the disease course for cervical cancer has increased significantly since the 1980s (Mitchell and McCormack,1997).

Mandelblatt et al., 1996, #1304) linked tumor registry data to census area level data to assess factors associated with later stage of disease at diagnosis in colorectal cancer patients. The authors used an index of the percentage of families below the poverty level and the percentage of unemployment to classify the areas in which colorectal cancer patients resided. Adjusting for the effect of age, gender, race/ethnicity, and hospital type, individuals living in the lowest SES areas were 45% more likely to be diagnosed with late stage disease than individuals living in the highest SES areas. The effect of living in the lowest area SES was a significant predictor for later stage of disease at diagnosis for all age, race, gender, and source of care groups compared to similar individuals living in the highest area SES, indicating that low social class was the common pathway by which these other variables exerted their influence on stage of disease at diagnosis. Together, these data suggest barriers to interval screening for individuals living in lower social class neighborhoods.

4.6.1.5 Race/Ethnicity

Minority men and women tend to have lower rates of regular screening and higher rates of advanced cancer than non-minorities. For instance, in interviews in a low-income African American population, only ten percent of women were getting “regular” mammograms, defined as a mammogram in the past year and at least one previous mammogram (Mickey et al, 1995, #463). As a result, in part, of such trends fewer Black women are diagnosed with localized breast and cervical cancer than Whites (Table 4.20). In fact, (Mitchell and McCormack ,1997, #1049) reported that the percentage of white cervical cancer patients diagnosed late in disease has decreased significantly from 1976 to 1990, but during the same time period, the percentage of Black cervical cancer patients diagnosed with late stage disease has increased significantly. Hispanic women also have significantly greater rates of late stage disease than Whites (data not shown), and while there may be a trend for this rate to be decreasing, Hispanic women have not yet have realized mortality reductions from breast or cervical cancer screening (Mitchell et al., 1997, #1049). Thus, racial/ethically mediated barriers to regular screening for women are not decreasing and may, in fact, be increasing for some populations (Mitchell and McCormack,1997, #1049).

Table 4.20 Percentage of Cancer Cases Diagnosed with Localized Disease, 1986-1993

	White	Black
Breast Cancer	60	49
Cervical Cancer	54	40
Colorectal	38	32

SOURCE: SEER data, Kosary et al, 1996

Similar findings have been reported for the impact of race/ethnicity on colorectal cancer outcomes (Man'delblatt et al, 1996, #1304)(Table 4.21). For instance, in a study of colorectal cancer patients, 32.7% of Black patients, 34.4% of Hispanic patients, and 40.1% of White patients were diagnosed with early stage disease. The odds of late stage diagnosis for Black and Hispanic patients were 1.24 and 1.09 times that of White patients after adjusting for the effect of age, gender, hospital type, neighborhood SES and change in neighborhood SES, but only the difference between White and Black colorectal cancer patients was statistically significant (Mandelblatt et al., 1996, #1304).

4.6.1.6 Knowledge, Attitudes and Behaviors

Although there are little data available on the influence of knowledge, attitudes and beliefs, what information that exists suggests a strong role of these domains on re-screening behavior. Using stage at diagnosis as a proxy for regular screening, a recent study of women with breast cancer included detailed descriptions of knowledge, attitudes, and beliefs. These were categorized as folk beliefs, fundamentalist religious beliefs, perception of risk or fatalism, belief in treatment for cancer, breast cancer knowledge, and relationships with men. At least one statement in every category was associated with late stage of disease at diagnosis (Lannin et al., 1998, #1036). For example, women with breast cancer who agreed with the statement that air causes cancer to grow faster were more likely to be diagnosed with late stage disease. Women who believed that cancer susceptibility resulted from "high blood", "thin blood" or a "root" or spell were also more likely to be diagnosed with late stage disease. Beliefs that God would heal cancer without treatment for an individual that prays or that the devil could cause a person to get cancer were similarly associated with late stage of disease at diagnosis. Breast cancer patients who believed that women who have breast cancer surgery or women with problems are no longer attractive to men were also more likely to be diagnosed with late stage disease. Additionally, patients who felt that men would rather not know that the women in their lives had breast cancer were more likely to be diagnosed with late stage disease (Lannin et al., 1998, #1036).

All of these attitudinal/belief variables remained the strongest predictors of stage, after considering social class and race. Thus, culturally-based attitudes and beliefs held by lower class and minority women need to be addressed to achieve recommended adherence to interval screening and reductions in avoidable late diagnoses with attendant reduced survival.

4.6.2 Provider Barriers to Realized Access to Interval Screening

Primary care provider factors associated with limitations in realized access to interval screening are likely to be similar to those associated with initial screening—beliefs about usefulness of screening and concerns about patient compliance (Fox et al., 1988, #420; Schapira et al., 1993, #603; Weisman et al., 1989, #855). As with initial screening behavior, the physician's recommendation of screening is one of the strongest predictors of regular screening (Zapka et al., 1991, #432; Mickey, 1997, #985). In cases where physicians discussed mammography, made appointments for mammograms in their office, or mailed a reminder, women of all ages were more likely to receive regular mammography (Mickey, et al 1997, #985). Weisman et al.,1989, #855) reported that some physicians do not believe that routine cancer screening is important in elderly patients, a group at higher risk of most cancer; this it likely to constitute a barrier to regular screening for this at-risk population.

Characteristics of the health care encounter are also associated with differences between women who received regular mammography, those who had never had mammography, and those who had never heard of mammography. More women receiving regular mammography, compared to women who had never had the test, reported that they had had a breast exam performed by a physician or nurse, were taught breast self-exam in the doctor's office and were comfortable in their ability to do the same, and were familiar with screening guidelines (Mickey et al., 1997, #985).

Patients of female physicians have also been reported to have higher rates of breast and cervical cancer screening than those with male providers (Lurie et al, 1993, #1102; Lurie et al, 1997, #987). These differences have been attributed to the observations that female physicians are more likely than male physicians to believe in a 12-month mammography screening interval and feel comfortable in performing a pap smear, performing a clinical

breast exam, and taking a sexual history from a female. Further, more female physicians than male physicians feel that the responsibility for pap smear and mammography belongs with the physician or is shared by the physician and the patient (Lurie et al, 1997, #987). Such differences in attitudes and behaviors associated with differences in provider gender, which predict initial screening use, may also affect regular, on-going screening use. This will be an interesting area for future research.

4.6.3 System Barriers to Realized Access to Interval Screening

System barriers to realized access to interval screening include a lack of continuity of care, differences in hospital type, and location of screening facilities. Women with a prior screening history who reported that they had a regular physician and had visited at least once in the preceding year were more likely to get rescreened with mammography (Fink et al., 1972, #1097). Further, women with multiple visits to a regular health care facility are more likely receive regular mammography than women with less frequent visits (Mickey, 1997, #985). Other health care system factors have been reported to affect adherence to regular mammography screening. A recent study linked data from the 1992 NHIS, a national survey of mammography facilities, county-level HMO market share data, and county-level data on the supply of primary care providers. Residence in counties without a primary care provider shortage, with reminder systems, or with higher HMO market share were independently associated with an increased likelihood of having received an age-appropriate number of mammograms compared to having received a mammogram within the past two years (Phillips et al, 1998).

Similar findings have been reported in association with stage of disease at diagnosis. In a study of breast cancer patients in a single geographic area, women who reported that they did not have a regular doctor were 3.5 times more likely to be diagnosed with late stage breast cancer than those with regular providers (95% CI: 1.9,6.4). Further, those that reported that they had not seen their doctor at least once in the previous year were 3.6 times as likely to be diagnosed with late stage breast cancer as compared to women who had seen their doctor within the past year (95% CI: 2.0,6.3) (Lanin et al., 1998, #1036).

The type of hospital (public or private) has also been described as being associated with stage of disease at diagnosis. In studies assessing factors associated with stage of disease at diagnosis for patients with breast and cervical cancer in a single geographic area, patients treated in public hospitals were independently more likely to have their breast or cervical cancers diagnosed at advanced stages than women cared for in non-public settings (Mandelblatt et al, 1991, #1327); this difference was not significant for colorectal cancer patients (Mandelblatt et al., 1996, #1304). All comparisons were adjusted for area level socioeconomic factors (individual context). The authors hypothesized that under-resourced public hospitals may have more difficulty offering mammography, a high cost service, or conducting pap smears, than performing a simple, inexpensive office FOBT.

(Fink et al., 1972, #1097) found that amount of time required to travel to screening location was associated with rate of rescreening—women who had to travel further were more likely to not complete screening than those living in closer proximity to a facility offering mammography. Even in an urban area, where there are large concentrations of mammography facilities, living in an area with a larger mammography capacity was protective for being diagnosed with late stage breast cancer (Mandelblatt et al, 1995, #1421).

4.7 INTERVENTIONS TO OVERCOME BARRIERS TO REGULAR SCREENING

We found only three interventions specifically developed to address increasing utilization of interval screening. As with initial screening, these interventions are presented as either patient targeted or physician targeted and are classified as behavioral, cognitive, or sociological.

4.7.1 Patient-targeted Interventions

4.7.1.1 Behavioral Interventions

Schapira and colleagues evaluated the effectiveness of an intervention to increase adherence to interval mammography screening in a sample of women undergoing initial screening examination at single cancer center. The authors used a plastic card sized to fit a wallet with a woman's screening anniversary printed on it. Over 70% of women that received the plastic card returned for rescreening compared to 35.6% that received an appointment card, and 35.6% that received a verbal recommendation to return for annual mammography. The combination of a reminder and a plastic card did not increase rescreening (72.1%) over the level seen using the plastic card alone (72.7%) (Schapira, 1992, #668).

Mayer et al., 1994, #1046 performed a series of studies to increase repeat mammography adherence using a reminder postcard, postcard combined with a voucher for small gift, and a telephone reminder compared separately

to no reminder. Rates of completion ranged from 32% to 48% for the reminder postcards strategies (not significantly different from each other). However, when compared to no reminder, women who received a physician reminder had a significantly higher rescreening rate (47% vs. 19%). Thus, the provision of a reminder of any type may increase rescreening.

Thus, patient targeted behavioral interventions using reminders appears to be effective in increasing regular mammography utilization. Similar interventions using tangible reminders might be adaptable for FOBT and pap tests. Long-term adherence with interval screening under these strategies should be assessed as well.

4.7.1.2 Patient-Targeted Cognitive and Sociologic Interventions

We did not identify any patient-based interventions targeted to cognitive or sociological barriers. Since patient-targeted cognitive interventions using theory based patient education were effective in promoting initial mammography utilization, adaptation of these interventions to address issues with long term mammography, pap smear, and FOBT screening utilization might also be effective. Further, cognitive interventions might be developed explicitly in target populations to address folk beliefs and improve cancer knowledge.

Similarly, since patient-targeted sociological interventions were successful in enhanced initial use of mammography screening, such interventions could be modified for regular breast cancer screening use. These approaches may also be appropriate to encourage on-going colorectal and pap smear screening.

4.7.2 Physician-Targeted Interventions

We only identified one study specifically involving an intervention to increase physician repeat screening behaviors. In that study, (Burack et al., 1997, #431) reported on the sustained effectiveness of computerized physician reminders to promote regular adherence behavior for screening mammography at Health Department and HMO sites of care. The intervention was targeted to a low-income, mostly minority urban population who had received a mammography in the preceding year. Women were randomized to receive either a limited intervention consisting of physician and staff orientation and elimination of out-of-pocket costs, or a full intervention consisting of the limited intervention plus computerized medical record reminders that identified women eligible for repeat mammography. Rates of subsequent mammography utilization at the Health Department were 44% for the full vs. 28% for the limited intervention. At the HMO, rates of mammography utilization were 45% for the full intervention and 46% for the limited intervention, indicating that the full intervention was equally effective in both settings, while the limited intervention was more effective in the HMO than the health department setting. The authors speculated that these results may reflect underlying differences in patients or the content of care received at the HMO as compared to the health department.

Physician-targeted cognitive interventions such as education and practice audits, which are effective in increasing initial mammography screening utilization, have not specifically been applied to regular recommendation of screening tests. This, and the use of sociologic approaches, will be an important areas for future research.

4.7.3 System-Targeted Interventions

We did not identify any system targeted interventions to increase realized access to screening interval adherence. As mentioned by Marcus and Crane in a comprehensive review of cervical cancer screening (Marcus, 1998, #1038), true long term improvements in the rates of interval screening require an intensive population-based screening monitoring and reminder system, such as those used in Europe. In the absence of broad changes in US health care delivery, such intensive monitoring system might be best systematically implemented through state health departments.

Another possible approach would be to “package” on-going screening with other preventive services and routine medical care, such as receiving cancer screening at the same time as an annual Influenza vaccination in elderly populations.

Finally, extension of NCQA HEDIS measures to indicators for adherence to life-time screening might encourage health delivery systems to increase access to this phase of care.

4.8 SUMMARY

Despite widespread gains in initial cancer screening, there are little available data describing adherence to regular, on-going screening. Clear, consistent and appropriate outcome measures need to be developed, validated, and implemented for this phase of care. Although there appear to be several patient barriers to interval adherence to cancer screening, including patient age, gender, insurance coverage, social class, race, knowledge, attitudes, and beliefs, one of the strongest predictors of screening remains physician recommendation. Thus, interventions focused

on improving access to continuity primary care and enhancing physician recommendations are likely to have the greatest impact on cancer mortality rates. Interventions targeted to patients and populations must also consider culturally-based attitudes and beliefs.

Appendix A. Selection of interventions to increase mammography screening

We utilized the (OVID) search mechanism with MEDLINE in the years 1980-1998 to identify published English language articles on interventions to increase mammography utilization.

The search strategy was as follows: we used the terms mass screening or mammography or physical exam or breast (N=20,442) to identify the subset of studies focussed on mammography screening. We then developed a series of terms to identify settings in which interventions could take place: "primary health care", "gynecology", "family physicians", "internal medicine", "physicians", "physicians practice patterns", "physician-patient relations", "medical specialties", "preventive medicine", "internship and residency", "family practice", or "health promotion" (N=45,659).

The combination of these two searches yielded 640 studies. To be eligible for inclusion, studies had to be randomized controlled trials or concurrently controlled trials. Pre/post designs and uncontrolled trials were excluded. Published abstracts were also excluded as they were judged to have too brief a description of methods for assessment.

To assess study design, abstracts and associated MEDLINE terms (e.g., random allocation, longitudinal studies, intervention studies, prospective studies and follow-up studies) were reviewed for evidence of prospective follow-up with either randomized assignment to an intervention or control group.

Approximately thirty-five studies were selected from the literature review. Reference lists of these studies were also searched to identify other eligible studies. A total of forty-five studies were included in the meta-analysis.

Qualitative analysis

Because studies were designed explicitly to address specific barriers to mammography, we separated studies by the focus and type of intervention. Interventions were first divided into physician-targeted and patient-targeted. Both physician-targeted and patient-targeted interventions were grouped as cognitive, behavioral, or sociologic based on categorizations developed by Fineberg (Fineberg, 1986, #1096).

Studies that utilized multiple interventions were categorized by the strategy that varied the most between intervention and control group. These were reviewed separately from studies where only a single intervention was utilized. The effectiveness of these studies in increasing rates of mammography screening is briefly discussed. In cases where fewer than 3 studies were identified, individual study effects are reviewed.

Quantitative analysis

We evaluated the appropriateness of applying quantitative analyses to the grouped studies using a chi-square test of heterogeneity where 3 or more studies were identified. Summary statistics were calculated only in cases where the null hypothesis of homogeneity could be not be rejected. We used a random effects model to combine information within these studies and present individual effects sizes as well as a summarized risk ratio.

5.0 PHASE 2: EVALUATION OF ABNORMAL SCREENING RESULTS

Among individuals overcoming barriers to screening, a proportion will have an abnormal result. Abnormal results are defined as those requiring non-routine follow-up, including those with results that are probably normal, but require an additional test, and those with results suspicious or positive for cancer. If resolution does not occur at all, or in a timely manner (usually defined as within three to four months of the index test), the benefits of screening to down-stage disease and improve survival will not be realized, despite the expenditure for screening (Mandelblatt et al, 1997, #709).

Following additional assessment in Phase 2 of care, abnormal results can be determined to be non-cancerous, and the individual can return regular screening phase I, or be confirmed as malignant. Once a cancer diagnoses is established, the patient moves to diagnostic work-up and a staging evaluation.

In this section we describe barriers to this phase of cancer care, including access to follow-up of abnormal screening results, and once cancer is confirmed, to diagnostic and staging evaluation. Where interventions have been developed to address barriers, these are highlighted, and areas for additional research are suggested.

5.1 FOLLOW-UP OF ABNORMAL CANCER SCREENING TESTS

As the numbers of individuals receiving regular, lifetime screening increases, so will the numbers of people requiring evaluation. Since cancer is still a relative rare event, many of these individuals will be found to have falsely positive screens. For example, an estimated 600,000 breast biopsies are performed annually in the US (Osteen, 1991, #1434); as many as 80% of these yield benign results (Winchester et al., 1983, #1435;Artz et al.,

1991 #1436). Expressed in another way, the cumulative probability of a false positive mammogram has been estimated to be as high as 24% over a ten year period (Elmore al, et, 1998, #1095). Unfortunately, technology for reliably triaging abnormal results into lesions with high and low probabilities of malignancy are not yet available; such technologies have the potential to save considerable health care dollars. Thus, evaluation of abnormal results is necessary to ensure that, for those destined to have cancer, the benefits of early detection are realized.

When women do present for diagnostic resolution of abnormal screening results, there are little data on the most accurate and cost-effective diagnostic techniques (Layfield et al, 1993, #1428; Lindfors et al, 1994, #1429; Hillner et al, 1996, #1212; Lawrence et al, 1998, #1437).

Continued adherence to regular screening following an abnormal test result is also an important consideration for women who have a false positive result. Evaluation of an abnormal test has been associated with psychological distress, even after it has been confirmed as a false positive (Lerman et al, 1991). Issues associated with false positive screening tests and future compliance with abnormal follow-up as well as compliance with interval screening is an important area for additional research.

Unfortunately, at present many groups of individuals fail to receive timely, or any resolution of an abnormal screen, with rates of non-resolution varying considerably across settings and populations. For instance, between 20% and 99% of women who have abnormal mammograms are reported to receive appropriate diagnostic follow-up (Kerlikowske, 1996, #388; Mandelblatt et al, 199X; 1997, #709); and between 20% and 74% of women with abnormal pap smear tests receive appropriate follow-up (Michielutte, 1985, #1104; Lacey, 1993, #780; Marcus, 1992, #870; Mandelblatt et al, 1997, #709, 1993 #705). This variability in resolution of suspicious screening results indicates that barriers exist for this phase of care.

In the following sections, we identify issues underlying the measurement of realized access to follow-up of abnormal screening results, and describe patient, physician, and system barriers associated with access to follow up of abnormal results. We identify areas where additional research may lead to improved care for vulnerable populations. Next, we describe interventions to increase follow up of abnormal results and include a case study of interventions to improve compliance with abnormal pap smear results. Finally, we describe policy options to improve realized access to follow up of abnormal screening screen test results.

5.1.1 Outcome Measures of Realized Access to Screening Follow-up Care

Over the past two decades cancer control activity and research has focused primarily on interventions to increase participation in screening programs (Rojas, 19967, #1389). Little attention has been devoted to follow-up to abnormal screening tests. In those studies that have been done, there is a lack of consensus on the definition of an abnormal screening result as well as the most appropriate and clinically relevant time period within which follow-up should be resolved. As a result, outcome measures for the assessment of realized access to care have yet to be operationalized, validated, and translated from the research setting to the clinical setting.

Cancer screening test results are generally interpreted and categorized as normal, unevaluable, or requiring follow-up before the next recommended screen (American College of Radiology, 1995; NIH Consensus Conference, 1995, #1035). For example, the American College of Radiology (ACR) defines abnormal screening test results as those which are probably benign, but require follow-up, indeterminate, or suggestive of, cancer or positive for, cancer. However, the categorization of a suspicious test result still varies widely among physicians (Elmore, 1994, #1430) and professional organizations. Further, definitions of abnormal results used in research studies both include (Marcus, 1992, #870) and exclude unevaluable test results along with suspicious test results. The development of clear and consistent definitions of abnormal screening test results is a critical component to improving the assessment of follow-up care. The Bethesda system for interpreting cervical cytology results was developed with this goal in mind. In the Bethesda system, results are grouped into categories based on recommended clinical follow-up.

Recommendations for evaluation of an abnormal screening test may range from immediate biopsy to other secondary screening methods, or repeat screening within 3 to 6 months. Follow-up recommendations vary widely among physicians (Elmore et al., 1994, #1430) as do the time intervals used to assess follow-up after abnormal screening (Paskett et al, 1990, #806 &785; Paskett et al., 1995, #777). However, once these is a consensus on what constitutes an abnormal result, and how to evaluate it, developing an outcome measure for this phase of care also requires delineation of a biologically relevant time period (ie, based on tumor doubling rates or differences in within stage survival) for resolution after the index abnormal test. Selection of a time period is confounded by the fact that populations being evaluated are heterogeneous in risk of disease, screening history, and symptom status. For

instance, in a previously unscreened population with higher rates of prevalent disease, screening abnormalities are more likely to represent true positives where delay can result in resolution at an advanced stage more often than in populations receiving routine screening. Further, true positives in individuals undergoing screening because of cancer symptoms may be more likely to represent advanced disease than in asymptomatic individuals. Additionally, growth rates of screening detected cancers vary. For instance, cervical cancer develops over a 10-30 year period, whereas the development time from colonic polyp to invasive cancer may be as short as 3-5 years. In these situations, the clinically relevant period for assessment of realized access to follow up care may differ across populations and tumor sites. Finally, because the sensitivity of screening tests for breast, cervical, and colorectal cancer differ from each other and across patient populations (based on underlying prevalence of disease), using stage of disease at diagnosis or survival following diagnosis as the outcome measure for this phase of care will be affected by underlying sensitivity of the screening test. For example, in populations where the majority of screening tests are false positive tests, lack of follow-up will not be reflected in stage of disease at diagnosis or survival following diagnosis.

Given the complexity of these methodological issues which will need to be resolved prior to development of an outcome indicator of access to abnormal screening follow-up, we suggest the use of a process indicator at this time. A suggested measure is the proportion of cases (with abnormal results requiring non-routine follow-up) where the time form the index test to final disposition (cancer/no cancer) is less the, or equal to three to six months. (Mandelblatt et al., 1998, submitted; Kerlikowski et al.,1996, #388).

5.1.2 Barriers to Realized Access for Follow-Up of Abnormal Screening Tests

As described in Figure 5, many of the barriers associated with realized access to appropriate follow-up care are similar to those associated with screening. Additional features that may play a greater role in realized access include physician-patient and physician-physician communication and systems issues related to timing and scheduling of appointments. In the following sections we summarize these patient, physician, and system barriers to follow-up after an abnormal screening result. Table 5.1 summarizes our definition of abnormal screening results used for the purpose of this review.

Table 5.1 Definitions of Abnormal Screening Results

Tumor type	Test Type	Definition of Abnormal Test	Range of recommended follow-up procedures	Reference
Breast	Mammography	benign, but require follow-up, indeterminate, suspicious for cancer, or positive for cancer	immediate biopsy, additional views, ultrasound, repeat within 6 months	ACR, 199X
	Clinical Breast Exam (CBE)	Palpable lump	Biopsy, sonogram, re-examine after menses	
Cervical	Pap test	ASCUS Low grade and high grade squamous intra epithelial lesions ,	Repeat smear Colposcopy and endocervical curettage	NIH, 1996
Colorectal	Fecal Occult Blood Test	Any positive result	Colonscopy	
	Sigmoidoscopy	Polyps or cancer	Colonoscopy	

5.1.2.1 Patient barriers to realized access to care

We identified several patient based barriers to realized access to follow-up of abnormal screening results including age, insurance, social class, and race/ethnicity. This are briefly summarized below.

5.1.2.1.1 Age

The association between patient age and follow up with abnormal cancer screening tests is not consistent. Some studies have reported lower rates of follow-up associated of abnormal breast cancer screening with increasing

patient age (Kerlikowske, 1996, #388), while others have reported that younger individuals, especially those with fewer health problems are less likely to adhere to follow-up (Michielutte et al., 1985). Still others have found no association between age and follow up after abnormal screening results or number of days to resolution (Lillquist, 1996). These inconsistent findings may be due to differences in categorization of age, populations evaluated, and definitions of abnormal results and delayed follow-up.

5.1.2.1.2 Gender

Follow up after abnormal colorectal cancer screening is the only situation where gender-related barriers to realized access to follow up care can be assessed; however, we did not find any research in this area. As colorectal cancer screening rates increases in the general population, this will be an important area for future research.

5.1.2.1.3 Insurance

Associations between health insurance and follow-up after abnormal screening exam are equivocal. In a CDC sponsored breast cancer screening program, longer intervals from abnormal mammography to diagnosis have been associated with a lack of health insurance (Lillquist, 1996). However, lack of health insurance or the type of health insurance were not found to be associated with a lack of follow-up in a study conducted in an urban, inner-city public health clinic (Rojas et al., 1996, #1389); the small number of patients may have limited the power to detect differences associated with insurance.

Others have reported that the type of insurance may affect the time to diagnostic resolution for abnormal screens. For instnace, in a study of patients being treated for suspected breast cancer in different HMOs, women who made co-payments reached diagnostic resolution 1.25 months later than those who did not make co-payments (Greenwald, et al., 1987, #1431), although
iti is unclear if this delay was clincially importnat. Additional research addressing the association between insurance and follow-up of abnormal screening results is warranted.

5.1.2.1.4 Social Class

Women of lower social class have been described as having higher rates of inadequate or delayed follow up (Kerlikowske, 1996, #388). More specifically, lower rates of any follow up after abnormal pap smear and longer intervals to diagnosis among those who do follow-up after an abnormal screening result have been observed among women that are less well educated (Michielutte et al., 1985, #1104; Lillquist, 1996). Additionally, lower income has been noted to be associated with higher rates of inadequate 6-month follow-up after abnormal mammography result (McCarthy et al., 1996, #517).

In a small study conducted in an urban public hospital among women who had an abnormal screening resul , (Rojas et al.,1996, #1389) did not find an association between level of education and lack of follow-up. This may have been due, in part, to a small sample and low power to detect differences among groups.

5.1.2.1.5 Race/Ethnicity

In large studies of screening, rates of timely follow-up after an abnormal mammogram, defined as within 3 months of the index test, have been estimated to range from 83-95% among white women compared to 80-88% among non-whites (Kerlikowske, 1996, #388). Low rates of follow-up have also been reported in largely black populations receiving breast examination, mammography or pap smears in an emergency department (Mandelblatt et al., 1996, #709) or in no-cost screening programs (Rojas et al, 1996, #1389). Longer delays in seeking medical care following notification of suspicious screening results have also been reported for African- American, Asian, and Latina women than for White women (Chang et al., 1996, #555). For example, using data from a mobile mammography screening program in an urban population, Chang et al (1996) reported that non-White women notified of abnormal or suspicious mammogram had a significantly greater delay between the index screening test and the first diagnostic test than White women. This effect was found even after adjusting for patient age, family history of breast cancer, report of palpable mass, and income.

However, other studies have reported that racial differences in delays following abnormal mammogram results may be partially attributable to socioeconomic status, age, marital status and history of previous mammogram (McCarthy et al., 1996, #441).

Race and perception of discrimination may shape experiences with the health care system and delay following abnormal screening test results. Alternatively, features of the health care system available to individuals of lower social class or minority groups may not have sufficient resources to provide adequate tracking of individuals with outstanding follow-up. These issues are discussed in greater detail in the medical care environment section below.

5.1.2.1 .6 Knowledge, Attitudes and Beliefs, and Communication

(McCarthy et al.,1996, # 517) surveyed a group of women that received inadequate follow-up (both immediate and at 6 months) and women who did receive timely follow-up about their breast health behaviors, attitudes, and perceived barriers to care. Women who had fewer mammograms in the previous 5 years, who performed breast self exam infrequently, who perceived their current health as being poor, and worried very little about breast cancer were more likely to have inadequate 6-month follow-up after mammography, although none of these factors were associated with adequacy of immediate follow-up.

Others have reported that some women may be fatalistic in their approach to the test results (Rojas, 1996, #1389), may not want to know if something is wrong, may fear painful diagnostic procedures (Rojas, 1996, #1389), or may think they are too old for treatment (Mandelblatt, 1992, #1419). For instance, compared to women that received follow-up after an abnormal mammogram, non-compliers were more likely to report that the cost of lost wages and medical care or other barriers limited their ability to seek follow-up (Rojas, 1996, #1389).

Individuals with abnormal test results may also misinterpret the communication of their results, thinking that results are normal and do not require further attention. McCarthy et al.,1996) interviewed women with abnormal mammograms by telephone to find out why they did not adhere to follow-up. Slightly more than half of these women indicated that they thought their mammogram was normal (McCarthy et al., 1996, #441), despite documentation that at least some of them had been notified of the abnormal result. (Rojas et al., 1996, #1389) also reported that women who did not receive follow-up after an abnormal mammogram were less likely to state that they had been told to seek follow-up.

The manner in which the abnormal screening result and follow-up actions are communicated may also play a role in patient compliance with follow-up (Lerman et al., 1992; Miller et al., 1997,#1105). Some of the most effective patient-targeted follow-up interventions we reviewed were telephone counseling sessions designed to address psychological barriers to adherence, including perception of cancer risk and concern about the condition.

5.1.2.2 Physician-Barriers to Realized Access to Follow-up Care

Physician-physician communication is the first pathway for communication of an abnormal screening test result. A lack of communication between the primary care provider and cytopathologist, radiologist, gynecologist, or gastroenterologist may also play a role in low rates of follow-up after an abnormal screening result. Lack of communication between referring physicians and specialists in managed care has been documented (Roulidas, 1994, #1108), and may lead to confusion about primary responsibility for patient notification.

Once the abnormal test result is received, the primary care provider must communicate results to the patient. As noted above in the section on patient barriers, physician-patient communication plays a large role in delay or lack of follow-up of abnormal screening results. Some primary care physicians may not initiate follow-up if the individual does not fall into well-recognized risk categories and prescribe watchful waiting rather than additional tests.

This process can fail as reflected in relatively high rates of uninformed patients. As part of a study of Black and White women with abnormal mammograms, patients were interviewed by telephone to find out why they did not adhere to follow-up: half of these women indicated that they thought their mammogram was normal (McCarthy et al., 1996, #517). Unfortunately, documentation that notification of abnormal result had been communicated to the woman was available from only 57% of medical records. Strategies developed to improve physician-physician and physician-patient communication will be an important area for additional research.

Caplan and colleagues recently reported on diagnostic delay in a subsample of women in the National Cancer Institute's Black/White Cancer Survival Study. Women who failed to receive follow-up care for abnormal mamogram within four weeks described physician inaction, and appointment delays as an important cause of the overall delay in diagnostic resolution (Caplan, 1996). However, relying on patient report after cancer diagnosis may complicate the interpretation of these findings. Women with advanced disease were more likely to attribute delays to themselves; delays were increased in women without palpable lumps compared to women with palpable lumps; and younger women (lower prevalence of disease) were more likely to experience delays than older women. Thus, the clinical relevance of physician delays is not clear from this study.

5.1.2.3 System Barriers to Realized Access to Follow-up Care

Features of the health care system have the potential to influence receipt of timely resolution of abnormal tests. As part of the National Cancer Institute's Black/White Cancer Survival Study, Caplan et al (1995) evaluated the role of system delay in diagnosis of breast cancer patients. Although the median system delay was longer for

black women than white women (2.7 weeks vs. 2.1 weeks), it was not statistically significant. However, system factors may differentially affect black and white women--use of a public clinic increased chances of delay for black women (Caplan et al, 1995).

Others have looked at system delays in greater detail (McCarthy, 1996, #517). In a survey of women both adherent and non-adherent to abnormal mammography follow-up, difficulty with getting medical appointments, having to wait a long time to get medical appointments, and being bothered by the length of the wait at the physicians office were all associated with an increased likelihood of delayed abnormal follow-up, although only having difficulty getting medical appointments was statistically significant.

Differences in follow-up for abnormal cervical screening have also been described by urban and rural residence (Fox et al., 1997, #1098) and clinic size (Webber et al., 1996,#1111).

5.1.3 Interventions to Increase Follow up

In the following sections, we present a review of interventions to increase adherence to follow-up after abnormal pap smear results as a case-study. We selected the follow-up of abnormal Pap smears since this area included the largest body of literature. Since issues affecting breast and colorectal cancer are likely to be different, it will be important to review interventions for breast and colorectal cancers as these data become available.

For the case study, we conducted a systematic review of the literature. Articles employing a controlled design are included. Additional details about the search strategy and study identification are included in Appendix B.

5.1.3.1 Patient-Targeted Interventions

The majority of interventions focused on increasing timely follow-up after an abnormal pap smear are targeted to patients. As in the section on asymptomatic screening, we have classified interventions as cognitive, behavioral, or sociologically based. Because of the large variability in the patient populations, control groups, settings, and outcomes measured, we did not perform a quantitative analysis. Instead, we provide qualitative reviews of the studies.

We identified six cognitive interventions targeted to patients to improve adherence to follow-up to abnormal screening result. These interventions used videotape (Marcus, 1992, #870), generic education (Marcus, 1992, #870), educational pamphlets (Paskett, 1990, #806), personalized letters (Marcus, 1992, #870), and telephone counseling (Lerman, 1992, #781; Miller, 1997, #1105). All strategies were compared against generic reminder letters or telephone appointments. Unfortunately, the one study using generic education wasn't effective; the authors speculated that clinic staff may not have complied with the intervention protocol — only 40% of the women randomized to receive the intervention indicated that they had actually had done so.

Table 5.2 Cognitive Interventions Targeted to Patients to Increase Follow-up After Abnormal Pap Smear

Generic Patient Education

	Intervention	Effect Size	95% CI
Marcus, 1992[1]	Slide-tape program playing in clinic describing cervical cancer and pap smear with culturally relevant narration vs. generic reminder letter	OR: 0.97	OR CI: 0.63, 1.49)

There were four cognitive interventions that used theory-based education to provide motivation to obtain follow up care (Table 5.3). Studies used different mechanisms to communicate to patients (telephone vs. letter), targeted different patient populations, and used different working definitions of abnormal pap smears. (Lerman et al.,1992, #781) identified women that had missed a colposcopy appointment. (Paskett et al, 1990, #806) identified women with either atypia or dysplasia that were advised to have colposcopy, and (Marcus et al.,1992, #870) identified women through cytology reports and included both women with unsatisfactory smears as well as women with smears suspicious of invasive carcinoma. (Miller et al., 1997, #1105) identified women who had received notification of abnormal result. Among the four studies, compliance was assessed within 4 months (Marcus et al, 1992, #870), 9 months (Paskett et al., 1990, #806), and at two time periods--immediately as well as at a 6 month follow-up after the initial abnormal screening test for individuals without clear evidence of cancer (Miller et al., 1997, #1105).

Table 5.3 Patient Targeted Cognitive Interventions to Increase Follow-up After Abnormal Pap Smear Theory-based Patient Education

	Intervention	Effect Size	95% CI
Paskett, 1990[1]	Pamphlet using psychological value expectancy theory with reminder letter vs. reminder letter alone	12.9	(-2.0, 28.2)
Lerman, 1992[1]	Telephone counseling to address barriers to adherence vs. telephone rescheduling call	23.8	(3.8, 44)
Marcus, 1992[1]	Personalized follow-up letter (in English and Spanish) vs. generic follow-up letter (usual care)	Odds Ratio: 0.9	CI for OR: (0.64, 1.27)
Miller, 1997	Personalized telephone counseling to address barriers to adherence vs. telephone appointment call	8	(0.05, 15.5)
Miller, 1997	Attendance at 6-month follow-up for personalized telephone counseling to address barriers to adherence vs. telephone appointment call	28.4	(6.6, 45.8)

None of the interventions which used a letter format led to a significant improvement in adherence to follow-up after abnormal screening test (Paskett, 1990,#806; Marcus, 1992,#870). Sending a pamphlet in addition to a reminder letter (based on psychologic value expectancy theory) led to a 13% increase in the number of women receiving follow up, but the relatively small sample resulted in a wide confidence interval surrounding this estimate (95% CI: -2.0, 28.2) (Paskett et al., 1990,#806). (Marcus et al., 1992,#870) compared a personalized follow-up letter sent in both English and Spanish to a generic letter requesting follow up. Women receiving the personalized letter were less likely to follow-up (OR: 0.9), but this effect was not significant (0.64, 1.27).

The two personalized patient-targeted interventions conducted over the telephone appeared to be effective in increasing the rate of follow-up for women with abnormal pap smears (Lerman et al., 1992,#781; Miller et al., 1997,#1105). Additionally, when assessed at the six month follow-up, the personalized telephone intervention appeared to have a lasting effect with almost 30% more women who received the personalized intervention participating in the six-month follow-up than women who received only a scheduling telephone call (95% CI: 6.6, 45.8) (Miller et al., 1997, #1105). Further, these two studies were conducted in low income minority populations indicating their effectiveness in vulnerable populations.

We identified three patient-targeted studies which attempted to increase follow up after abnormal pap smear by changing patient behavior (Mitchell et al., 1989, #784; Del Mar, 1995, #1113; Miller et al., 1997, #1105). These studies all used a patient reminder (Table 5.4). Two used a letter format (Mitchell et al., 1989, #784; Del Mar et al., 1995, #1113) and the other used a telephone reminder (Miller et al., 1997, #1105). Periods of 6 weeks (Mitchell et al., 1989, #784) and 28 weeks (Del Mar et al., 1995, #1113) were used to evaluate follow-up. All strategies had a positive effect on the rate of initial follow-up, although this was not statistically significant for the patient letters (Mitchell, 1989; Del Mar, 1995). However, use of a telephone confirmation of the follow-up appointment compared to usual care led to an 18% (95% CI: 8.9, 27.1) increase in follow-up (Miller et al., 1997,#1105).

Table 5.4 Patient Targeted Behavioral Interventions to Increase Follow-up After Abnormal Pap Smear

	Intervention	**Effect Size**	**95% CI**
Mitchell, 1989	Patient letter with message framed as loss vs. Patient letter with message framed as gain	5.3	(-10.7, 21.3)
Del Mar, 1995	Address verification for follow-up letter vs. letter sent to listed address	4.4	(-2.9, 11.7)
Miller, 1997	Telephone confirmation of appointment vs. usual care	18	(8.9, 27.1)
Miller, 1997	6-month follow-up for telephone confirmation of appointment vs. usual care	6.2	(-11.3, 23.7)

A single study also assessed the effectiveness of telephone confirmation of the appointment on patient adherence to 6-month follow-up (Miller et al., 1997, #1105). Although rates of adherence to 6-month follow-up were 6.2% higher, this effect was not statistically higher than for women receiving usual care (95% CI: -11.3, 23.7) (Miller, 1997, #1105).

We found only a single study that utilized a patient-targeted sociologically-based intervention to increase follow-up after abnormal pap smear (Marcus, 1992, #870) (See Table 5.5). In that study, provision of transportation incentives, in addition to a generic follow up letter appeared to increase the odds of follow-up compared to women receiving a generic letter alone (OR: 1.48; 95% CI: 1.06, 2.06). This study was performed in a multi-ethnic population of women where 70% had no insurance coverage indicating that other interventions which reduce financial barriers to care may also be potential effective in a vulnerable population. However, the effectiveness of transportation incentives was not replicated when added to a slide tape program or a personalized letter as part of a combined intervention strategy (See below).

Table 5.5 Patient Targeted Sociological Interventions
to Increase Follow-up After Abnormal Pap Smear

	Intervention	**Effect Size**	**95% CI**
Marcus, 1992[1]	Transportation incentives and generic follow-up letter vs. generic follow-up letter (usual care)	Odds Ratio: 1.48	CI for OR: (1.06, 2.06)

We identified three studies with seven distinct combined intervention strategies to increase adherence to follow up after abnormal pap smear (Manfredi et al., 1990; Marcus et al., 1992; Paskett et al., 1995, #777) (See Table 5.6). One study did not limit patients to those with abnormal pap smears and included patients with any abnormal cancer screening results (e.g., breast, cervical) (Manfredi et al, 1990, #1114), so the effectiveness of the strategy on increasing follow up of pap smear alone cannot be assessed. It is included here for comparison of trends only.

Interventions with transportation incentives as part of a combined strategy did not lead to improved follow-up (Marcus, 1992, #870). The combination of personalized follow-up and another format of information or reminder (e.g., telephone reminder or slide-tape program) appeared to increase rates of adherence to follow-up. Both of these interventions took place in primarily black or multiethnic populations where the majority of women were without health insurance indicating effectiveness in vulnerable populations.

Table 5.6 Patient Targeted Behavioral Interventions to Increase Follow-up After Abnormal Pap Smear

Combined Strategies

	Intervention	Effect Size	95% CI
Manfredi, 1990a[2]	Nurse-patient communication, patient form, reminder note, and telephone reminder vs. usual care	20.8	(13.1, 28.5)
Marcus, 1992[1]	Personalized follow-up letter (in English and Spanish) and slide tape program playing in clinic vs. generic follow up letter	OR: 2.3	(1.21, 4.34)
Marcus, 1992[1]	Personalized follow-up letter (in English and Spanish) and transportation incentives vs. generic follow-up letter	OR: 1.09	(0.67,1.76)
Marcus, 1992[1]	Slide tape program playing in clinic and transportation incentives vs. generic follow-up letter	OR: 0.87	(0.47, 1.59)
Marcus, 1992[1]	Personalized follow-up letter (in English and Spanish), slide tape program playing in clinic and transportation incentives vs. generic follow-up letter	OR: 0.44	(0.18,1.06)
Paskett, 1995[2]	Motivational brochures and clinic tracking system vs. clinic tracking system in family planning clinics	7.6	(-8.3, 23.5)
Paskett, 1995[2]	Motivational brochures and clinic tracking system vs. clinic tracking system in public health OB/GYN and dysplasia clinic	39.1 (rate declined in control)	(21.3, 56.9)
Paskett, 1995[2]	Motivational brochures and clinic tracking system vs. clinic tracking system in family practice	-1.8	(-18.4, 20.2)

1 Randomized controlled trial
2 Concurrent controls

In the study reported by (Marcus et al., 1992, #870) the combined intervention was one of seven potential combinations of personalized letter, slide-tape program and transportation incentives compared to usual care. Unfortunately the usual care arm was not sampled for multiple comparisons as we have reported here. One of the interventions, transportation incentives, was effective alone, but not in combination with a personalized follow-up letter or with a slide-tape playing in clinic waiting rooms. Given this unlikely result, a negative interaction between individual strategies (a positive interaction may be more realistic), issues associated with multiple comparisons may limit the interpretation of this intervention.

(Paskett et al., 1995, #777) also reported mixed findings of the same combination strategy implemented in three types of clinics (family planning, public health OB\GYN, and family practice) using concurrent control groups defined by clinic type. This strategy, consisting of motivational brochures and a clinic tracking system led to increases in the number of women receiving follow-up in family planning and public health OB/GYN and dysplasia clinics (7.6% and 39.1%, respectively). This effect was not significant in the family planning clinic (95%CI:-8.3,23.5) and although significant in the public health OB/GYN and dysplasia clinics (95% CI: 21.3, 56.9), rates of follow-up in the control clinics declined indicating potentially inappropriate control groups. In the family practice clinic, the combination intervention led to a slight decrease in follow up of abnormal results (1.8%) which was not significant (95% CI:-18.4, 20.2).

5.1.3.2 Physician Targeted Interventions

We found a single intervention targeted at physician behavior to reduce the rate of unresolved screening tests. We did not find any interventions targeted at improving physician-patient communication or physician-physician communication as a means to increase adherence to follow-up after abnormal test result.

(Monticciolo and Sickles, 1990, #1107) described a computerized follow-up system to aid physicians in tracking women with abnormal screening mammograms. Using two time periods, 1985-1987 and 1987-1989, and a pre-post design, the authors concluded that the computerized follow-up system reduced rates of unresolved abnormal mammograms. With the pre-post design, the role of secular trends associated with increased follow up after abnormal tests cannot be eliminated. Thus, interpretation of the effectiveness of this intervention is limited.

5.1.3.3 System Based Interventions

Despite several potential system barriers to follow-up of abnormal screening result associated with the type of clinic, complications with making appointments, or geographic location, we did not find any published system based interventions to increase adherence to follow up after an abnormal screening test. One NCI-funded study was funded to develop a hospital clinic-based tracking system to decrease rates of lost to follow-up among women with abnormal mammograms and Pap smears cared for in public hospitals located in area with high rates of late stage disease and cancer mortality. Preliminary results from that project indicate that such a system can increase follow-up rates after abnormal screens, but that success depends on availability of trained staff to operate the system and computer support systems to maintain it (Kerner, personal communication, 1998). Another strategy that has been used in under-resourced settings where difficulty negotiating that system may constitute barriers to follow-up is the use of a patient navigator assigned to the patient with the express purpose in assisting the patient in scheduling and receiving follow-up care. For example, the Harlem Cancer Education and Demonstration project developed a patient navigator program to assist patients in obtaining clinical follow-up following abnormal screening or cancer diagnosis. For patients with suspicious screening results, 87.5% that utilized the patient navigator completed breast biopsies, while 56.6% without the navigator completed biopsies (Freeman et al., 1995, #864).

5.1. 4 Summary

Now that increasing numbers of the general population are receiving cancer screening tests, additional resources need to be focused on ensuring that individuals with abnormal results receive timely evaluation and resolution. Research efforts in this arena need to include development of standardized process and outcome measures, focus on patient-physician and physician-physician communication, and assessment of the most cost-effective follow-up care algorithms and technologies.

5.2 PHASE 2 - ACCESS TO DIAGNOSTIC AND STAGING EVALUATIONS

Following confirmation of cancer detected through asymptomatic screening or symptom evaluation, additional diagnostic tests are used to further classify (e.g., hormone receptor status for breast cancer) and stage disease. These evaluations provide critical information for determining appropriate treatments Yet it has been reported that standard diagnostic work-up and staging is not performed consistently in all population groups (Lash and Silliman, 199X; Hillner et al., 1996, #1212; Liff et al, 1991, #269; Elixhauser and Ball, 1993, #446). For example, Hillner and colleagues (Hillner, 1996, #1212) reported that completion of breast cancer staging varied by patient age and ranged from 82% to 52% of women with local or regional breast cancer. Lack of complete staging has been shown to be independently associated with increased cancer mortality after adjusting for the effects of age and comorbidity (Lee-Feldstein et al., 1994, # 638; Lash, personal communication, 1998). Further, a lack of staging or understaging for those individuals with advanced tumors or limited life expectancy may still affect quality, if not quantity of life. To better standardize services delivered in this phase of care, clinical staging algorithms have recently been presented as practice guidelines (NCCN; 1997).

As described in Figure 6, outcome measures for assessing realized access to diagnostic work-up and staging are process measures—proportion of care that complies with guidelines for diagnostic and staging evaluation and rates of un-staged cancer cases (Mandelblatt et al., 1998, submitted). For example, recommended components of the diagnostic and staging work-up are for localized breast cancer include laboratory tests (e.g., CBC, platelets, liver function tests), chest x-ray and bilateral mammogram, and review of tumor characteristics for pathology, determination of estrogen and progesterone receptor status, S-phase determination, and evaluation of nodal status (NCCN, 1997, #1440, #1441, #1442, #1443, #1444, #1445, #1446, #1447, #1448). However, such staging paradigms are constantly evolving and are controversial in certain clinical situations. For instance, sentinel node biopsies have recently been suggested as an alternative to axillary dissection in breast cancer; this procedure has the advantage, if the sentinel nodes is negative, of avoiding full dissections, with their attendant high morbidity of decreased arm mobility and edema. However, the use of sentinel node biopsy has noted yet to be evaluated in clinical trials. The usefulness of axillary dissection for guiding treatment may be limited in certain groups, such as the very frail elderly, who are not likely to receive non-hormonal systemic chemotherapy.

Diagnostic work-up and staging informs estimates of prognosis, physician-patient communication about disease and treatment options, and the treatment decision-making process. In the future, outcome measures will need to be developed that consider clinical outcomes, patient preferences, patient participation in decision-making, satisfaction with care, and quality of life.

5.2.1 Barriers to Realized Access to Definitive Cancer Staging

We found very little published literature describing realized access to definitive staging. Therefore, we also examined SEER data for discrepancies in survival for unstaged and distant cancer cases for potential indications of inadequate access to staging care. In choosing this approach, we assumed that absence of pathological staging would be appropriate in cases of clinically apparent widespread metastatic disease, where additional data would not change treatment approaches, or where there is insufficient time for staging among patients presenting in figure 6 - domains for staging,moribund condition. In these cases, then survival of unstaged patients should be similar to, or worse than that for those staged with distant disease. Situations where 5-year survival for patients with unstaged cancer is higher than for patients with distant disease, and approaches that of regional disease, indicate a potential lack of realized access to quality staging and cancer care. These patients, had they been staged, and found to have regional disease, are likely to have been eligible for treatment to improve the duration and/or quality of life.

In the following sections, we summarize survival with unstaged disease, then review the published literature to describe patient, provider, and system barriers associated with limited realized access to diagnostic cancer care. Within each section, we identify areas where additional research might improve the quality of the diagnostic phase of cancer care. Finally, we summarize policy options which might improve utilization of appropriate and timely diagnostic work-up and staging.

5.2.1.1 Survival with Unstaged Disease

As described in Table 5.7, the tumor-specific five year survival rate for unstaged tumors was higher than for tumors diagnosed as distant for all sixteen tumor sites. Moreover, for cancer patients with unstaged cervical cancer, melanoma of the skin, and urinary/bladder cancer, 5-year survival was also higher than for patients initially diagnosed with regional disease, suggesting that many patients who would be eligible for treatment (i.e., for regional disease) are being inappropriately unstaged.

Reasons for under- or non-staging may be a result of patient preferences for care; alternatively, these patients may be receiving adequate stage-specific treatment, but are experiencing survival differences based on age or comorbidity. There is also the possibility that changes in diagnostic technologies have improved detection of "silent" metastases, led to reclassification of patients, and apparently improved survival (the "Will Rogers" phenomena)

Table 5.7 5-Year Survival Rate by Stage of Disease at Diagnosis (1986-1991)

	Localized	**Regional**	**Distant**	**Unstaged**
Breast	96.1	74.9	19.8	54.1
Cervix	90.9	49.9	8.6	61.1
Colon and Rectum	91.0	62.8	6.9	34.2
Esophageal	21.4	9.5	1.8	8.5
Kidney and Renal Pelvis	87.5	59.2	9.2	27.2
Liver/intrahepatic bile duct	12.9	7.3	1.8	3.2
Small cell lung and bronchus	18.6	9.5	1.7	7.1
Melanoma of the Skin	93.8	59.8	15.9	67.9
Oral cavity and pharynx	80.5	41.6	18.3	32.9
Ovary	90.9	49.5	23.3	26.2
Pancreas	12.0	4.8	1.6	4.2
Prostate	98.6	92.1	29.8	79.4
Stomach	59.6	22.1	2.2	12.1
Testis	98.5	97.1	71.6	92.4
Thyroid	100.0	93.5	46.5	76.6
Urinary/Bladder	92.8	48.3	5.9	63.5

NOTE: Rate is per 100,000 individuals. SOURCE: Kosary et al., 1996

(Feinstein, 1985, #1201). However, this would only affect patients that are currently staged by inflating their 5-year survival, indicating that the observed differences in 5-year survival rates for unstaged patients and patients staged with distant disease might be even higher. Unfortunately, there are insufficient data at present to determine test these different hypotheses. This will be an important area for additional research.

There are four tumor sites where 5-year survival is quite low across all stages— esophageal, liver and intrahepatic bile duct, small cell lung cancer and bronchus, and pancreatic cancer. For these tumor sites, fewer than

25 per 100,000 patients survive 5 years. Thus, where treatment has little impact on survival, regardless of stage of disease at diagnosis, being unstaged is unlikely to represent a barrier to realized access to care, when survival is the outcome. However, to the extent that lack of staging reflects undertreatment, this may impact patient quality of life. In these settings, patient preferences for care should guide treatment decisions.

5.2.1.2 Patient Barriers to Realized Access to Definitive Staging

As was the case in other phases of cancer cere, patient barriers such as age, gender, insurance, and race/ethnicity act as barriers to staging assessments (Figure 6).

5.2.1.2.1 Age

In both breast and ovary cancer (the two tumor sites where this information is readily available), a higher percentage of women over the age of 50 are unstaged than women under the age of 50, although the absolute proportion of women who are unstaged is small (4% vs 3% for breast and 7% vs 3% for ovary, respectively)(Kosary et al, 1995, #1100). Others have reported associations between increasing age and lack of definitive staging procedures within older age groups (Hillner et al, 1996, #1212; Lash and Silliman, 1997; Silliman et al, 1989, #973). For example, (Hillner et al., 1996, #1212) used tumor registry and Medicare data from Virginia to evaluate the process of care for women over the age of 65 with breast cancer. They found that 18% of women between the ages of 65 and 79; 33% between of 80-84; and 48% over the age of 85 did not have did not have axillary node dissection; this trend was significant.

The association between patient age and lower rates of diagnostic evaluations appears to differ across tumor site. In contrast to the situation for breast and ovarian cancer, (Guadagnoli et al., 1990, #1432) reported that increasing age was not associated with the diagnostic tests ordered for non-small cell lung and colorectal cancer patients. There may be few differences in staging across age groups for tumors with low expected survival (Guadagnoli et al., 1990), although this does not explain the lack of an age effect in colorectal cancer.

5.2.1.2.2 Gender

Tumors which affect both men and women are described in Table 5.8. For colorectal, esophagus, kidney, lung, pancreas, stomach, and urinary bladder tumor sites, the percentage of women that were unstaged is higher than that for men. Thus, issues associated with limited access to staging and diagnostic work-up may differ by gender.

Table 5.8 Percentage of Tumors Unstaged by Patient Gender (1986-1991)

	Men	Women
Colorectal	5	6
Esophagus	24	31
Kidney and Renal Pelvis	6	8
Liver	34	34
Lung	13	14
Oral Cavity and Pharynx	12	10
Pancreas	18	24
Stomach	13	16
Urinary/Bladder	4	6

SOURCE: Kosary et al., 1996

5.2.1.2.3 Insurance

(Riley et al., 1994, #637) reported on the stage of disease at diagnosis for Medicare benefitiaries over the age of 65 receiving care through traditional fee-for-service providers (FFS) and health maintenance organizations (HMO), and found that fewer patients receiving care through HMO were unstaged for tumors of the breast, cervix, colon, kidney and renal pelvis, melanoma, ovary and prostate.

5.2.1.2.4 Race/Ethnicity

There have been several reports of higher rates of unstaged cancer or lower rates of staging procedures in Black patients as compared to white patients (Liff et al., 1991, #269;Ball and Elixhauser, 1991, #627). This has been reported for bladder (Harris et al, 1997, #919; Kosary, 1996, #1100), breast (Harris et al., 1997; Kosary, 1996) colorectal (Ball and Elixhauser, 1991, #627; Liff et al., 1991, # 269; Kosary, 1996, #1100), lung/bronchus (Liff et

al., 1991, #269), uterine/corpus (Harris et al, 1997, #919; Liff et al., 1991, #269), uterine/cervix (Harris et al, 1997, #919; Liff et al., 1991, #269), renal (Kosary, 1996, #1100) and prostate cancers (Liff et al., #269).

Diagnostic work up and staging contains multiple components. In a study designed to evaluate the location of colorectal cancers from national hospital discharge data, Elixhauser and Ball (1996) noted that black colorectal cancer patients had a higher percentage of colorectal cancer tumors with unspecified sites (29% higher). When only hospitalizations where colorectal cancer was the primary diagnosis were evaluated, this difference increased and 40% more black than white discharges had unspecified tumor sites. Further, this difference was maintained across five patient age categories, gender, and expected 3rd party payor (Medicare, Medicaid, private payor or self-pay) and hospital type. These data might reflect later stage of diagnosis for Black compared to White colorectal cancer patients—indicating disease so diffuse that site of origin could not be determined. This, and other explanations, could not be evaluated from existing data.

Reports of differences in staging and diagnostic work-up for Black and White cancer patients were also reported in multiple studies of colorectal cancer (Elixhauser and Ball, 1991; Liff et al, 1991, #403; Kosary et al, 1996)). Liff et al (1991, #403) reported racial differences in staging for prostate cancer and lung cancer patients that were not reflected in national SEER data (Kosary et al., 1996), potentially reflecting geographic variability. Thus, utilization of definitive staging procedures for cancer patients by patient race may differ based on the tumor type.

Patients that are unstaged for extent of disease are typically excluded from many analyses. Stratification of analyses so that unstaged patient could be assessed separately; and tumor types, geographic locations, or patient and physician characteristics could be identified might help focus future interventions to improve diagnostic work-up and staging.

5.6.3 Provider Barriers to Realized Access to Definitive Staging

Once abnormal test results are identified as cancerous, staging and diagnostic work-up is primarily the responsibility of the treating oncologist or surgeon. Variability in physician practice patterns may lead to a lack of adherence to definitive diagnostic staging. As part of a national survey to describe practice patterns for diagnosis and staging of prostate cancer among urologists, Plawker et al (1997) found significant variablity in the use of age-specific prostate specific antigen (PSA), use of sextant biopsy, radiologic imaging such as CT, bone scan, and MRI, and pelvic lymph node dissection.

Even though practice guidelines for prostate cancer exist, physician-associated variability in utilization of staging procedures may be greater where two specialties, urology and oncology, provide the same type of care for patients with suspected prostate cancer. Providers may base diagnostic decisions on distinct guidelines issued by different associations, different journals, or treat patients identified through different mechanisms.

We found little in the published literature describing physician characteristics associated with the performance of diagnostic work-up and staging or time to resolution following initiation of diagnostic tests.

5.6.4 System barriers to realized access to definitive staging

We identified a single system-related barrier to realized access to definitive staging—urban/rural differences in medical care. Liff et al. (1991(403)) assessed pathology records and discharge diagnoses of cancer in Georgia. Across all tumor sites, the percentage of white patients living in rural areas with unstaged tumors was double that of white patients living in urban areas (18.3 vs. 9.6). A similar relationship was reported for rural and urban black cancer patients (23.7 vs. 13.1). This same urban-rural difference has been observed for colon, lung/bronchus, breast, uterine corpus, uterine cervix, and prostate cancers for both white and black cancer patients. In fact, there was only a single tumor site identified by the authors without a urban-rural, and or Black/White difference in staging.

5.7 INTERVENTIONS TO IMPROVE ACCESS TO DEFINITIVE CANCER STAGING

We did not find any interventions addressing barriers to definitive staging procedures. Further, we found very little descriptive information identifying groups which receive more or less staging. Use of national data, such those included from SEER tumor registry reports may mask regional differences in staging. We found at least one tumor-type where smaller studies reported differences in staging for patient sub-groups not reflected in SEER data.

Since staging directly effects treatment decision making as well as survival following diagnosis (Lash and Silliman, 1998; Lee-Feldstein et al,. 1994 (524), additional descriptive work identifying populations unlikely to receive definitive staging, characteristics of providers which do not provide definitive staging, or system

characteristics could lay the groundwork for improving realized access to cancer care**.** Improvement in the provision of definitive staging will increase the amount and quality of available information with which providers can review treatment options and help patients make informed treatment decisions. Increased utilization of definitive cancer staging may also lead to improvements in the content of care for patients that receive cancer treatment, with increased attention to palliative care for patients diagnosed later in disease.

6.0 PHASE 3: CANCER TREATMENT

Following, appropriate diagnostic work-up and staging in phase two, patients, their families, and physicians have the opportunity to review treatment options and make decisions about treatment (Figure 7). Those decisions are individualized and are typically guided by patient preferences for expected survival and quality of life within the context of the clinical tumor characteristics.

The primary goal of local and adjuvant treatment is to cure the cancer while maintaining a reasonable quality of life. In cases where cure is not possible (e.g, advanced stages at diagnosis or cancer types with high case fatality rates), the objectives of therapy are to maximize life expectancy, preferably as disease-free survival, and to maximize quality of life. In either situation, palliative care (ie, treatment of symptoms related to disease or treatment) is delivered along side curative care throughout the course of disease. The balance between curative and palliative care often shifts over the course of illness, with a greater emphasis on cure in the beginning with receiving a cancer diagnosis, shifting to increased emphasis on palliation at the end of life for patients destined to die of their disease (Figure 7a).

For ease of presentation, we focus this section on barriers to curative primary and adjuvant therapy, highlighting areas where there may also be access problems for palliation. Palliative care is then discussed in greater detail in the section devoted to barriers to end of life care since there are many common issues in these two areas. Finally, while randomized controlled trials focus largely on primary and adjuvant treatment, this topic is presented separately, since their are unique barriers involved in accessing treatment in this setting.

In the following sections, we first identify methodologic issues associated with assessing realized access to primary and adjuvant cancer treatment, then describe patient, physician, and system barriers to appropriate treatment, and identify recent efforts for improving access to cancer treatment.

6.1 METHODOLOGICAL ISSUES

There are several issues which must be addressed in order to measure access for the treatment phase of care, including having an adequate data base for evaluation and filling gaps in knowledge about treatment (e.g., patient preferences for therapy), and defining appropriate outcomes of access. Existing data bases, such as SEER, are limited in data collection about this phase of care. For instance, while surgical and radiation treatment are recorded, data on adjuvant treatment is often incomplete, and treatments, such as tamoxifen are often not recorded. Data on tamoxifen and other out-patient medications are generally not included in claims databases either. In situations where cancer patients receive care through different institutions or health care systems, identifying all primary and adjuvant treatments is complicated, at best. Even in cases where these data are available on whether or not patients received adjuvant care, assessment of the completion of a recommended course of therapy is limited.

Even when adjuvant care is clearly documented, it is difficult to ascertain the source of a barrier to adjuvant therapy. For example, adjuvant therapy may either not have been offerend to the patient, or have been recommended by the treating physician, but patients may not understand the recommendations, may not have adequate health insurance, or may choose not to receive adjuvant therapy. Documentation of these various reasons, which have differing implications for access to care, is rarely available.

Large data sets also do not include sufficient clinical data to assess the denominator of patients that would have been eligible for a given treatment. For instance, in a recent study of all women with stage I or II breast cancer, 64% in Massachusetts and 38% in Minnesota received breast conserving surgery. When only women eligible for breast conserving surgery were assessed and included in the denominator (e.g., negative margins on excisional biopsy), these figures increased to 74% in Massachusetts and 48% in Minnesota (Guadagnoli et al, 1998). Decisions about treatment are generally made considering clinical characteristics of disease defined during the staging process, level of comorbid disease, underlying life expectancy, and patient functional status. Yet large claims data bases may not include these data. Further, advances in the use of prognostic and “treatment response” characteristics such as estrogen and progesterone receptor status, tumor expression of erb-B2, or sentinel node

biopsy, which may affect treatment decision making are not reflected in existing data sources. Chart reviews can be conducted to address these limitations in existing databases, but this is not feasible as a general solution. The development of the merged SEER-Medicare database has been an important improvement in the usefulness of both data sources for identifying poor outcomes among selected patient groups that may be a function of access to care; expansion of such a data source would facilitate important research and monitoring activities in access to care.

A related issue is the absence of data describing the patient impact of cancer and its treatment. It is possible, for instance, that a patient who appears to have been under-treated may actually be receiving the care that they preferred. Although tools developed explicitly to help individual patients make decisons about specific treatments are available (Scwitzer, 1995; Randall, 1993), their long-term use is limited by the treatment options available at the time of their development.

Other measures of patient preferences, also known as patient utilities, may be used to help providers understand how patients feel about different components of care, specific side effects of care, adverse events or other consequences which may be generalized to multiple therapies. Patient utility measures require individuals to value their current health or expected health outcomes, either implicitly or explicitly. These measures are based in the economic theory (von Neumann and Morgenstern, 1947), and are commonly used as the denominator in cost-effectiveness analyses. Descriptive measures such as the Health Utilities Index (HUI) (Torance, 1982), the EuroQol (The Euroqol Group, 1990), or the Quality of Well-Being (QWB) scale (Kaplan, 1982) assess functional status across specific domains and combines measures into a single score based on population values. Techniques such as the time trade-off (McNeil, 1981) or standard gamble (Torrance, 1986), require patients to evaluate their current health or hypothetical health state in relation to death and perfect health. The use of patient utility in cost effectiveness assessment as well as some of the methodologic controversies is reviewed in greater detail in Gold et al (1996).

Patient utility measures are also complicated to administer, time consuming, and require a trained interviewer making routine documentation of these data difficult. Weeks and colleagues recently developed a short six question tool based on the Spitzer quality of life index, and have assigned time-trade off weights to each for calculation of a patient utility, or preference (the “q-tility index) (Weeks, 1996 #1438). Routine use of such tools may make documentation of patient’s treatment preferences more feasible.

Developing outcomes measures for treatment require definition of the denominator - the group “eligible for of a given therapy” - and incorporation of patient preferences for outcomes. Current outcome measures, such as survival, disease-free survival, and time to progression do not consider these issues. Rather, survival is crudely assessed among groups of similar stage patients with the diagnosis; stratification by gross treatment categories is sometimes included. If preferences were available, one could calculate of a somewhat more refined measure, such as quality-adjusted life years following diagnosis. While survival is usually calculated accounting for age, comorbidity is rarely considered.

Defining the denominator of patients eligible for adjuvant treatment is closely tied to the adequacy of diagnostic work-up and staging and primary treatment for cancer. For individuals who do not receive complete staging and or do not receive primary therapy, the use of adjuvant therapy may be, by definition, inappropriate. Thus, assessment of realized access to adjuvant therapy must be conducted as part of the third step of a sequential process where eligible individuals are defined as those that have received appropriate and complete diagnostic work-up and staging as well as appropriate and complete primary treatment.

Other important outcomes of both curative and palliative care are quality of life and patient satisfaction (e.g., sexual functioning, impact of side effects, symptom control, and psychosocial well-being). Unfortunately, outside of some research studies, these are not routinely collected.

Finally, of a process measure, adherence with guidelines for treatment practice, could be considered for this phase of care. To apply such of a measure, first requires agreement on the most appropriate treatments. We found great variability in definitions of appropriate treatment for cancer. Once study addressed whether or not patients received any care for disease (de Riljke, 1996), whereas others assessed specific components of care such as whether or not chemotherapy regimens for colorectal cancer included 5-Fluorouracil (Grilli et al., 1991). Detailed treatment guidelines currently exist for breast, cervical, prostate, ovarian, pancreatic, and other cancers (NCCN, 1997); this have the potential to serve as an excellent source for defining appropriate care based on patient clinical characteristics.

Thus, evaluating access to treatment services is complicated by the lack of data available to accurately categorize patients, their therapy and preferences for the same, and refined outcomes measures. The next sections describe barriers to primary and adjuvant treatment based on the best outcome measures currently available.

6.2 BARRIERS TO TREATMENT

As described in Figure 7, there are several patient, physician, and system barriers to care. We used two outcome measures to describe realized access to cancer treatment care--the process measure of adherence to treatment guidelines for eligible patients and survival following treatment by stage of disease at diagnosis.

6.2.1 Patient Barriers to Cancer Treatment

We identified several patient factors likely to affect patient access to cancer care including patient age, gender, type of health insurance, social class, race, and individual context.

6.2.1.1 Age

Increases in patient age are generally inversely associated with receipt of definitive surgical treatment for cancer (de Rijke, 1996; Samet et al., 1986; Newschaffer et al., 1996). However, age effects vary by cancer type (Chu et al., 1987; Farrow et al., 1992; Newschaffer et al., 1996; Satariano et al., 1992; Greenfield et al., 1987; Silliman et al., 1986). For instance, in of a study of cancer cases reported to of a tumor registry in the Netherlands, regardless of age few patients with colorectal or breast cancer received no primary treatment (1%), but age significantly effected treatment of ovarian cancer patients, with 13% over 70 receiving no treatment, compared to 2% of those aged 50-59 (de Riljke, 1996). Differences in the treatment of non-small cell lung cancer with increasing age have also been reported (Smith et al., 1995). Older patients with localized or regional disease were less likely to receive any therapy; those that did receive therapy were less likely to receive thoracotomy, or surgery compared to radiation therapy. Older patients with distant disease were also less likely to receive any therapy (Smith et al., 1995). In of a study of hospital discharge data in several states, increasing age was also associated with lower odds of receiving bone marrow transplantation BMT for leukemia or lymphoma (Mitchell et al, 1997. # 477) compared to other therapies.

Much of the research addressing the relationship between age and the cancer treatment has focused on breast cancer; these data will be briefly reviewed here. Lower rates of primary surgical treatment for patients with breast cancer have been reported with increasing age (Samet et al., 1986; Newschaffer et al., 1996). Increasing age has also been reported to be associated with lower rates of breast conserving surgery than modified radical mastectomy in women receiving surgery (Chu et al, 1987; Farrow et al, 1992; Mor et al, 1985; Newschaffer et al., 1996; Satariano et al., 1992), and lower rates of radiotherapy among women that do receive breast conserving surgery (Greenfield et al., 1987).

In a study of age and breast cancer treatment for localized disease using data from a single state cancer registry and Medicare claims, use of adjuvant chemotherapy also declined with age. Among women with one or more positive nodes, use of adjuvant chemotherapy declined from 20% in the 65-69 age group to 4% in the 80+ age group, although adjuvant hormonal therapy was used at a similar frequency across all age groups (30-35%) (Hillner et al., 1996). Guadagnoli et al (1997) also described age-associated differences in the type of care received in a retrospective assessment of adjuvant chemotherapy, hormonal therapy or both in postmenopausal women with primary breast cancer. For women with negative lymph nodes, hormonal therapy and the combination of hormonal therapy with chemotherapy were used with similar frequencies across age groups. The likelihood of receiving chemotherapy alone declined with advancing age. Most women with positive lymph nodes, of all ages, received some adjuvant therapy (92%). The likelihood of receiving hormonal therapy increased with age and the likelihood of receiving chemotherapy or hormonal therapy with chemotherapy decreased with age.

Other studies have described decreasing rates of adjuvant chemotherapy or hormonal therapy with increasing age, but have not defined estrogen receptor status or menopausal status of women (Silliman et al., 1989; Allen et al., 1986; Chu et al., 1987), or have not separately assessed the use of adjuvant chemotherapy from adjuvant hormonal therapy (Silliman et al., 1989; Allen et al., 1986; Chu et al., 1987).

Differences in care by age are often be assumed to be associated with increasing levels of patient comorbidity. This assumption may not inappropriate. Newschaffer et al (1996) utilized records from of a single state cancer registry linked to Medicare Provider and Reimbursement data to assess the effects of age and comorbidity on treatment in localized and regional breast cancer. The claims of Medicare eligible women with newly diagnosed disease were assessed during the initial treatment period and 2 years prior to diagnosis to develop of a comorbidity index. Adjusting for the effect of stage of disease at diagnosis (localized vs. regional), patient race, residential location, marital status, and year of diagnosis, the women in the 85+ age category were 0.31 times as likely as women in the 65-74 age category to receive surgery (95%CI: 0.16, 0.60). Women in the 75-84 age

category were also less likely to receive surgery, but this effect was not significant. Inclusion of comorbidity in this model did not affect the estimates.

Among women that received surgery, those in the 85+ age category were 0.55 times as likely to receive non-breast conserving procedures (95% CI: 0.33,0.92). The odds of receiving radiotherapy following breast conserving surgery also declined with increasing age. Adjusting for the effect of stage of disease at diagnosis (localized vs. regional), patient race, residential location, marital status, women in the 75-84 age category were 0.23 times as likely to receive radiotherapy (95% CI: 0.10,0.54) and women in the 85+ age category were 0.03 times (95% CI: 0.01,0.13) as likely as women in the 65-74 age category to receive radiotherapy. These associations changed little when comorbidity was added to the model, indicating that age-related under-treatment was due to factors other than coexistent disease.

It is also assumed that the elderly either will not tolerance or desire aggressive chemotherapy. However, when doses are adjusted for physiological functioning, the elderly tolerate chemotherapy as well as younger patients (Begg and Carbone, 198X). Differences in use of adjuvant chemotherapy in older women with localized breast cancer, may also be due, in part to the perception that response and efficacy may vary according to menopausal status. Fetting et al. (1997) reported that the rates of chemotherapy in metastatic breast cancer, where responses are not related to menopausal status, also varied by patient's age. Among those patients, 74% under the age of 65; 42% in the 65-74 age group; and 12% older than 74 received chemotherapy. Event after adjusting for presence of comorbid conditions and treatment by a medical oncologist, this age effect was significant. Finally, contrary to expectation, when asked about preferences for treatment, the elderly choose aggressive life-saving chemotherapy for breast cancer as often as their younger cohorts (McQuellen, Muss et al, 1996; Yellen et al, 1996).

Thus, age appears to be of a barrier to adequate cancer treatment. Given the demographic forecast for the coming decades, where one in four to one in five adults will be over 65, and the dramatic increases in cancer risk with advancing age, further research is needed to understand the reasons and solutions for this apparent inadequate care of the aged.

6.2.1.2 Gender

While women are generally less likely than men to receive major therapeutic procedures (RCT refs; Harris et al,. 1997), we found only two studies that explicitly addressed differences in cancer treatment by gender, and neither found of a difference in the presence of a major therapeutic procedures for bladder or colorectal cancer (Harris et al., 1997 (919)), or receiving BMT for leukemia and lymphoma patients (Mitchell et al, 1997 (477). As described in Table 6.1, there are also few large differences in 5 year survival by stage of disease for men and women. Thus, using the measures of realized access to care that are currently available, gender does not appear to play of a large role in access to this phase of care.

Table 6.1-Year Survival by Stage of Disease at Diagnosis
By Patient Gender (1986-1991)

	Men	**Women**
Colorectal		
Localized	87.9	87.3
Regional	55.7	52.5
Distant	4.6	5.6
Esophagus		
Localized	23.3	17.2
Regional	10.0	8.2
Distant	1.9	1.5
Kidney and renal pelvis		
Localized	88.9	85.4
Regional	59.6	58.6
Distant	9.2	9.3
Liver and Intrahepatic bile duct		
Localized	9.1	18.9
Regional	4.6	12.6
Distant	1.6	2.1
Lung, small cell and bronchus		
Localized	16.5	21.1
Regional	8.1	10.9
Distant	1.4	2.1
Oral cavity and Pharynx		
Localized	78.9	83.4
Regional	38.8	47.7
Distant	16.5	23.1
Pancreas		
Localized	8	9
Regional	23	22
Distant	52	45
Stomach		
Localized	17	20
Regional	32	31
Distant	39	33
Thyroid		
Localized	99.9	100.0
Regional	90.7	94.6
Distant	43.1	48.6
Urinary bladder		
Localized	94.0	88.9
Regional	50.1	44.2

Distant	7.5	3.1

SOURCE: Kosary et al, 1996

6.2.1.3 Insurance

As in earlier phases of cancer care, insurance and type of insurance plan effect access to treatment services. For instance, one study assessed treatment and survival for female Medicare beneficiaries with localized breast cancer enrolled in two health maintenance organizations (HMOs) or traditional fee for service (FFS) plans in the two geographic areas (San Francisco-Oakland and Seattle-Puget Sound). A higher percentage of women enrolled in both HMOs received breast conserving surgery (BCS) than in the FFS plans in both geographic areas. Further, more of these women received radiation therapy following BCS. However, women in FFS were older with greater levels of comorbidity. Women enrolled in the Medicare HMO in San Francisco-Oakland and Seattle-Puget Sound were 0.7 and .75 times, respectively as likely to die of breast cancer within 10 years as FFS enrollees (95% CI:0.62,0.79 and 95% CI:0.63,0.90), adjusting for age and race. However, when the differences between HMO and FFS case-mix were considered (adjustment for age, race, stage, first primary, and comorbidity), the differences in survival remained significant in San Francisco-Oakland (RR: 0.71; 95%CI:0.59,0.87), but were no longer significant in Seattle-Puget Sound (RR:1.01; 95%CI:0.77,1.33). Survival following breast cancer treatment for women enrolled in HMO plans was as good, if not better than for similar women enrolled in FFS plans. Thus, when assessing differences between insurers, treatments, and survival, inclusion of comorbidity level is an important factor; differences in prior screening behavior, coverage treatment options, and other patient (e.g., income, education) and organizational characteristics that may be associated with insurance plan and treatment should also be considered in evaluating results of studies comparing treatment across insurance plans.

Using of a cancer registry and hospital discharge data from of a single state, Ayanian et al (1993) assessed survival stratified by stage of disease at diagnosis by breast cancer patients aged 35 to 64 with private insurance, Medicaid, or without insurance. Adjusted for the effect of age, median household income, race, marital status, number of coexisting diagnoses, survival for uninsured women, or those with Medicaid insurance, was significantly worse than for women with private insurance ($p<0.001$). When stratified by stage of disease at diagnosis, the authors found worse survival for uninsured or Medicaid insured women diagnosed with localized or regional disease ($p<0.001$). No differences in survival associated with insurance coverage were found for women with distant disease or between uninsured and Medicaid patients for any stage of disease (Ayanian et al., 1993, #570). Additional research is needed to document the effects of uninsurance on receipt of treatment services for other cancer sites.

Type of insurance affects access to standard as well high technology care. For example, of a study of access to bone marrow transplantation (BMT) for leukemia and lymphoma patients used discharge data from four states and two year time periods. Individuals with Medicaid, health insurance through an HMO, or who were self pay were significantly less likely to receive BMT than individuals with Blue Cross or other private commercial insurance (Mitchell et al, 1997 (477)).

6.2.1.4 Social Class

We found few studies describing differences in treatment for patients of different social classes. This is surprising considering the central role social class plays in screening, stage of disease at diagnosis, and longer term outcomes, including mortality. In contrast, there is of a large body of literature on race effects on access to treatment (see below). It is possible that much of these effects are mediated by unmeasured differences in social class. Further research in the role of social class in realized access to cancer treatment is clearly needed warranted.

6.2.1.5 Race

Differences in treatment according to patient race have been reported for colorectal (Cooper et al., 1996; Ball and Elixhauser, 1996), leukemia and lymphoma (Mitchell, 1997), myeloma (Savage et al, 1984), prostate cancer (Harlan et al., 1995; Gornick et al, 1996), and breast cancer (Satariano et al, 1992). In this section we highlight differences in stage-, race-specific survival (as of a proxy for access to treatment), and then describe the effects of race on treatment for selected cancer sites.

As described in Table 6.2, Black cancer patients diagnosed with localized or regional disease have lower survival than do White Cancer patients for most tumor sites. Exceptions are stomach and pancreas, tumor sites with uniformly high case-fatality rates. Similarly, there are few differences in survival by race for patients diagnosed with distant disease.

Table 6.2 Five-Year Survival by Stage of Disease at Diagnosis for Black and White Cancer Patients

	White	Black
Breast cancer		
Localized	93.7	89.0
Regional	76.4	60.3
Distant	20.2	16.1
Cervix uteri		
Localized	91.7	87.2
Regional	51.8	41.5
Distant	8.6	8.8
Colon and Rectum		
Localized	88.2	84.3
Regional	55.1	44.2
Distant	4.9	5.1
Esophagus		
Localized	24.7	13.4
Regional	11.0	4.5
Distant	1.8	1.6
Kidney and Renal Pelvis		
Localized	88.5	79.8
Regional	60.0	54.7
Distant	9.1	9.5
Larynx		
Localized	84.7	69.3
Regional	55.5	42.2
Distant	39.0	36.8
Liver/Intrahepatic bile duct		
Localized	13.7	10.7
Regional	8.1	5.0
Distant	2.6	0.0

Table 6.2 Five-Year Survival by Stage of Disease at Diagnosis for Black and White Cancer Patients (continued)

Small cell lung/bronchus		
Localized	19.1	13.6
Regional	10.2	5.2
Distant	1.6	1.7
Oral cavity and pharynx		
Localized	81.4	67.7
Regional	43.3	30.5
Distant	20.0	10.4

Ovary		
Localized	91.2	82.6
Regional	49.8	47.0
Distant	23.3	22.6
Pancreas		
Localized	11.8	11.2
Regional	4.3	7.8
Distant	1.5	2.0
Prostate		
Localized	99.7	89.8
Regional	93.6	78.3
Distant	30.6	24.8
Stomach		
Localized	57.4	57.0
Regional	20.6	23.3
Distant	2.1	3.3
Urinary Bladder		
Localized	93.5	79.0
Regional	49.2	38.0
Distant	6.6	3.5

SOURCE: Kosary et al., 1996 NOTE: Next draft will include assessment of statistical significance

Biological differences in tumor type have also been suggested as playing of a role in some of racial differences in mortality from cancer. For instance, in breast cancer, black women have been described as more likely to have tumors that were poorly differentiated, estrogen receptor negative, and progesterone receptor negative (Eley et al, 1994; Freeman and Wasfie, 1989; Fisher et al, 1993). However, of a study of colorectal cancer patients reported that although survival was lower for Black patients compared White patients, the grade of histology and lymphoid reaction, two biologic measures of tumor aggressiveness were lower for Black vs. White Patients (Chen et al., 1997). This implies that the role of other factors in decreased survival in Blacks following cancer diagnoses, such as realized access to cancer treatment, may play of a large role in racial differences in survival. The next sections briefly describe literature on treatment and race for selected cancer sites.

Colorectal Cancer

Several studies of colorectal cancer have described differences in treatment by race (Cooper et al., 1996; Ball and Elixhauser, 1996). In of a study of Medicare beneficiaries, patients with colorectal cancer were identified using ICD-9 coding from hospital discharge diagnoses from the Medicare Provider Analysis and Review data files. Controlling for the effect of gender, age, number of comorbidities, location of tumor, and extent of disease, Black patients were less likely to undergo surgical resection (OR=0.55, 95% CI: 0.51,0.59) than White patients. Among patients who underwent surgical resection, Black patients were more likely to die 2 years after surgery (OR=1.38, 95% CI: 1.24, 1.64) than White patients controlling for the effects of gender, age, number of comorbidities, location of tumor, and extent of disease (Cooper et al, 1996).

Similar results were reported from of a nationally representative sample of hospital discharges for surgery for colorectal cancer (Ball and Elixhauser, 1996). Black patients were less likely than White patients to receive surgical procedures controlling for differences in patient demographics, insurance status, clinical factors, and provider characteristics. Treatment was equivalent only for the sickest patients (Ball and Elixhauser, 1996).

Studies of colorectal cancer have described differences in survival by race as well (Cooper et al., 1996; Ball and Elixhauser, 1996). In of a study of Medicare beneficiaries, patients with colorectal cancer were identified using ICD-9 coding from hospital discharge diagnoses from the Medicare Provider Analysis and Review data files. Deaths following admission were greater for Black than for White colorectal cancer patients for 30 days (11.3% vs.

8.4%), 1 year (39.5% vs. 30.6%) and 2 years (52.0% vs. 42.2%) (Cooper et al, 1996). Similar results were reported from of a nationally representative sample of hospital discharges for surgery for colorectal cancer (Ball and Elixhauser, 1996). The odds of inpatient mortality were 59% to 98% higher for Black than White patients, controlling for differences in patient demographics, insurance status, clinical factors, and provider characteristics. Mortality rates were equivalent only for the sickest patients (Ball and Elixhauser, 1996).

Leukemia and Lymphoma

Black leukemia and lymphoma patients admitted to the hospital are less likely to receive bone marrow transplantation than White patients, although information on the types of care these patients did receive were not provided (Mitchell et al., 1997).

Prostate Cancer

Even in cases where there is some controversy over definitive care as in the case with prostate cancer (Chodak, 1994;Fleming, 1993), differences in the rates of treatment for specific population groups may indicate barriers in realized access to care. In an analysis of rates of prostatectomy and radiation therapy for prostate cancer patients diagnosed with localized disease, Harlan et al (1995, #468, #491) compared racial trends in treatment over time. For most years and in all age groups, more white than black men received radical prostatectomy and radiation therapy. Although the use of radical prostatectomy increased from 1984 to 1991 over time for White and Black men, the proportion of black men aged 50-69 that received radical prostatectomy was lower than in similar white men in all years. Similar proportions of white and black men 70-79 received radical prostatectomy in 1984, but significantly more white men than black men in this age group received radical prostatectomy by 1991. The authors reported that whites and blacks had of a similar histologic grade of tumor at diagnosis. Within histologic grade, blacks were still more likely to receive watchful waiting than prostatectomy or radiation therapy (Harlan et al., 1995, # 468, #491).

In another study of prostate cancer patients receiving similar care through of a Veterans Affairs Medical Center in of a single geographic area, mortality in African American men was greater than for White men (Powell et al., 1995). In another study of prostate cancer patients identified through the Department of Defense tumor registry, race was not associated with survival. Here patients were active duty or retired military personnel or their dependents receiving medical care in receiving care at DOD facilities. of a critical difference between the two studies is that active duty patients were required to receive of a full physical examination biannually including of a digital rectal exam after the age of 40 (Optenberg et al., 1995). Thus, differences in primary care utilization and cancer screening may be responsible for some differences between these two studies of equal-access populations.

Differences in treatment by race have also reported for patients with advanced prostate cancer. Gornick et al (1996) linked Medicare administrative data on beneficiaries 65 and older to ZIP code level census data on medium income to assess the effects of income on service utilization. Rates of bilateral orchiectomy (surgical) were associated with income in both white and black beneficiaries. The same therapeutic result can be achieved pharmaceutically, but the quality of life decrement associated with the surgical approach is likely to be greater. Among white men, the rate of orchiectomy men declined from 1 per 1,000 for men living in areas where the median income is less than $13,100 to 0.7 per 1,000 for men living in areas where the median income was above $20,500. Among black men, the rate of orchiectomy was more U-shaped, and increased in the highest income group. The rate was 2.1 per 1,000 where median income was less than $13,100; 1.8 per 1,000 where median income was $13,101-16,300; 1.9 per 1,000 where median income was $16,301 to $20,500; and 2.2 per 1,000 where median income was greater than $20,500. Thus, the relation between race and treatment is complicated and may not be mediated solely through income differences for all tumor sites.

Breast Cancer

In of a study of black and white women with breast cancer treated in community hospitals affiliated with the NCI funded Community Clinical Oncology Program (CCOP), Diehr and colleagues assessed the quality of care received (1989, #395). There were many differences in care between white and black women. More black women had no health insurance or received health insurance through Medicaid than White women. Fewer black women saw of a surgeon and more saw of a medical oncologist. For those women that were seen by of a surgeon, the surgeon was more likely to have fewer years of experience. The hospitals where black women were treated were more likely to be teaching hospitals, provide care for predominately black patients, be government controlled, have more beds, have more discharges, more Medicaid admissions, have fewer Medicare admissions, and less likely to have radiation therapy facilities. After adjusting for age and stage of disease at diagnosis, black women with breast cancer were more likely to receive radiation therapy following mastectomy (considered to be inappropriate at the time the study data were collected) and less likely to be referred for rehabilitation following surgical treatment. Further adjustments for the type of hospital where these patients were treated did not change this pattern of inappropriate care (Diehr et al., 1989).

However, differences in treatment by race may be changing for breast cancer patients. Satarianio et al (1992) used data from tumor registry in of a single metropolitan area to identify women with early stage breast cancer and assess treatment. When the year of diagnosis was assessed, being treated in 1986 or 1987 compared to 1985 was associated with of a large increase in the increase in the odds of breast conservation with radiation therapy in black women (OR: 2.35, 95%CI:1.10, 5.0) and (OR:3.14. 95%CI:1.47,6.71), respectively).

6.2.1.5 Patient Attitudes

Patients' knowledge, attitudes, and beliefs are also likely to affect access to, and compliance, with primary and adjuvant therapy. For example, in a study of mostly minority breast cancer patients in lower social class groups, higher scores on the Mental Adjustment to Cancer (MAC) and the Affects Balance Scale were associated with greater compliance to chemotherapy regimen (Ayres et al., 1994). Further descriptive work among patients that receive adjuvant therapy and complete treatment regimens as well as patients that do not may help elucidate the role of patient characteristics in cancer care, and assist providers in the identifying patients which may require additional psychosocial support.

6.2.1.6 Individual context

of a number of contextual variables, including social support and limited access to transportation (Goodwin et al., 1996), characteristics of the context, or neighborhood of residence, and geographic locale are associated with barriers to treatment. Apart from the study by Goodwin and colleagues describing the effect of social support of treatment and survival, there is limited data on this topic. However, it is logical to assume that social supports would be a key determinant of access to treatment, particularly adjuvant treatment which requires longer-term disability and frequent visits for care. This hypothesis is supported by findings from a study of the sue of formal and informal social support by cancer patients, where more Black and Hispanic than White patients reported that participation in cancer support groups helped them to continue with their cancer treatment (Guidry et al., 1997). Smith and colleagues described individual context in the treatment of non small-cell lung cancer (Smith et al., 1995). The authors used tumor registries to identify newly diagnosed patients and merged information with Medicare claims, census and area resource files. Patients with localized or regional disease living in areas characterized by lower levels of educational attainment were less likely to receive any therapy and were also more likely to receive radiation therapy instead of surgery than similar patients residing in areas characterized by higher levels of education. Patients with localized or regional disease living in urban areas were less likely to receive any therapy (Smith et al., 1995).

Breast cancer patients with localized disease living in counties where lower percentages of individuals had completed college and in areas where larger percentages of the county lived below the poverty level were less likely to receive breast conserving surgery (Samet et al, 1994 (917)).

Differences in the rates of cancer patients receiving different therapies, or variation in care, are well documented across geographic region (Farrow, 1996; Harlan et al., 1995; Samet et al., 199X; Nattinger, 1992). Proximity to radiation facilities and cancer centers are also likely to affect access to care.

6.2.2 Physician Barriers to Cancer Treatment

Physician recommendation is generally the strongest predictor of patient treatment choice (Siminoff, 1989). This recommendation has been shown to be influenced by of a variety of factors including physician age (GIVIO,

1989 #836), gender (GIVIO, 1989), specialty (Deber and Thompson, 1987 #981), and beliefs in efficacy of care (GIVIO, 1989 #836). Other physician attributes that may affect realized access to cancer care are limited adherence to guideline recommendations and communication style.

6.2.2.1 Physician Specialty and Training

Deber and Thompson used breast cancer scenarios to assess treatment preferences in early stage breast cancer among three different cancer specialty groups - surgeons, surgical oncologists, and medical oncologists (1987 #981). Significantly more medical oncologists recommended breast conserving surgery (84%) than surgical oncologists (75%) or general surgeons (63%). Similar results have bene noted by others (Liberati et l, 1987; 1989).

Physician experience has also been reported to be associated with treatment. Using tumor registry data from of a single city, breast cancer patients treated by surgeons that performed more than 50 surgeries over of a two year period were 1.28 times more likely to receive partial mastectomy with radiation therapy compared to modified radical mastectomy (95%CI: 1.03, 1.58)(Satariano et al., 1992).

6.2.2.2 Physician attitudes and beliefs about treatment efficacy

In reviewing treatment options, physicians are responsible for communicating information to patients about the risk of recurrence, likelihood of side-effects, and expected impact on overall quality of life resulting from adjuvant care. The content and manner of this communication may plan an important role in patient perceptions of expected overall survival, morbidity, and quality of life during and following therapy. Rajagopal et al (1994) used hypothetical scenarios to assess physician recommendations for adjuvant therapy as well as improvements in disease-free survival necessary to provide such a treatment recommendation. Physicians recommended adjuvant treatment, but reported requiring of a greater improvement in disease-free survival as a result of adjuvant therapy than that described in published meta-analyses. Such physician overestimates of treatment efficacy may exacerbate patient tendencies to overestimate the benefit of adjuvant chemotherapy.

The influence of physician attitudes and beliefs on their recommendation of treatment has also been assessed using patient scenarios (Liberati et al., 1987;1989; GIVIO, 1991). Interestingly, physicians who felt hat patients should participate in treatment decisions were more likely to recommend breast conservation than surgeons who rated patient participation as less important. The vast majority of phsycians (97%) also indicated that they would recommend adjuvant chemotherapy in response to the scenario describing 35 year-old women but significantly fewer (66%) recommended adjuvant chemotherapy in response to a similar scenario describing a 60-year old woman. Thus, physician attitudes towards their patients can potentially act as barriers to care.

6.2.2.3 Knowledge and Adherence to Guideline Recommendations

Physician compliance with primary and adjuvant treatment guideline recommendations or results of consensus conferences is poor (Grilli et al, 1991, #394; Kosecoff et al., 1987; Nattinger et al., 1992, #692; Schleifer et al, 1991) For example, Grilli et al (1991) assessed the impact of physician practice guidelines for breast, colorectal or ovarian cancers on practice patterns for these patients in Italy (394). The authors assessed physician knowledge of and familiarity with treatment guidelines using physician surveys and physician patterns using hospital records for the treatment of cancer patients. Awareness of practice guidelines for breast cancer was reported by 60% of physicians; colorectal cancer, 47% of physicians; and ovarian cancer, 44% of physicians. For physicians treating breast cancer patients, awareness of guidelines was associated with increased compliance for guideline recommended surgery and post-surgical treatment. Awareness of guidelines was also associated with increased recommendations of surgical therapy among physicians treating colorectal cancer patients and ovarian cancer patients.

Following release of guidelines, compliance with recommended treatment for breast, colorectal, and ovarian cancers was variable. Compliance with recommendations for surgical therapy ranged from 30% to 84% among breast cancer patient and was 68% among colorectal cancer patients. Compliance with chemotherapy and/or radiation therapy ranged from 52% to 86% for patients with breast cancer, 25% to 90% among patients with colorectal cancer and 34% to 91% among patients with ovarian cancer.

Similar delays in adaptation or lack of compliance with guidelines has been described in the US as well (Nattinger et al., 1996 #1217, Nattinger et al., 1992 #692). For example, following reports in the early to mid 1980s of comparability of breast conserving surgery followed by radiation therapy as modified radical mastectomy for early stage breast cancer (Veronesi et al, 1981; Sarrazin et al., 1984; Fisher et al., 1985), the NCI released of a consensus statement recommending use of breast conservation for stage 1 and 2 disease. However, in 1986, national rates of breast conserving surgery ranged from 3.5% to 21.2% across the states (Nattinger et al., 1992), and had only increased to 29% by 1990 (Nattinger, 1996).

Physicians have also been noted to be non-adherent to chemotherapy regimens. For example, Schleifer and colleagues noted that 52% of patients had their chemotherapy modified by their physicians in ways that were considered inappropriate. Non-adherence to the proscribed regimen were noted to be more prevalent for older patients, for non-academic physicians, and for physicians treating patients with psychiatric problems (1991). The authors suggested that in-service education might help physicians overcome some of these barriers.

6.2.2.4 Physician-Patient Communication

Communication between physicians and patients and their families can facilitate or impede access to adequate treatment. Good communication is the foundation of a shared clinical decision-making process and is crucial for the maximization of patient benefit from treatment for cancer. Yet, patients with cancer and their physicians have reported differences in their interpretation of the content of their interactions (Mackillop et al, 1988; Mosconi et al, 1991; Siminoff et al, 1989), in their estimation of patient participation in the decision making process (Strull et al, 1990), and in their expectation of treatment benefits (Mackillop et al, 1988; Mosconi et al, 1991; Siminoff et al, 1989).

Physician-patient communication has also been implicated as playing of a role in patient compliance with health care or healthy behaviors (Fox, 1994; Carter, 1982; Inui, 1982) and patient satisfaction with the interaction (Comstock, 1982; Ley, 1982; Wartman, 1981), and is likely to effect compliance with lengthy or difficult regimens. Physician-patient communication has also been described as playing of a role in clinical outcomes (Greenfield, 1988; Mumford, 1982), patient quality of life or health status (Greenfield, 1988; Kaplan et al., 1989), and patient adjustment to cancer (Roberts et al, 1994)

Choice of surgical approach is associated with physician communication of treatment options for patients with local stage breast cancer. For instance, 27% of women who underwent mastectomy in Minnesota and 15% of women who underwent mastectomy in Massachusetts stated that their physicians did discuss breast conserving alternatives with them. Among women that discussed both options with their surgeons and chose mastectomy, the two most frequent reasons for this choice were the fear that breast-conserving options would not “get it all” and that the surgeon recommended mastectomy (Guadagnoli et al., 1998).

The content of physician communication has also been shown to differ by patient age, across patient social class or education, race or ethnicity, and expected prognosis (Waitzkin et al., 1985).

Finally, physicians serve as gatekeepers to adjuvant care, by providing recommendations for additional systemic therapy, or recommendations to additional specialists for assessment. For example, following surgery, a breast cancer patient might be referred to a radiation oncologist for radiotherapy. Following completion of radiotherapy, the patient might then by referred to a third specialist, a medical oncologist, for additional evaluation. Thus, at every step in the process, physician-physician communication and physician specific factors have an opportunity to facilitate or interfere with completion of adjuvant therapy. To date, little work has been done to specifically address physician communication and realized access to appropriate cancer care. Further research into the role of physician-patient communication in cancer care is warranted.

6.2.3 System Barriers to Cancer Treatment

The main barriers to realized access to cancer care associated with the health care system are geographic, types of hospitals, and the organization of care. For example, Harlan et al. (1995, 491,468), reported significant geographic variation in the rates of radical prostatectomy among men with localized or regional prostate cancer in the nine areas that compose the SEER tumor registry. For men treated in Utah, approximately 48% received prostatectomy, while less than half that amount, 23%, received prostatectomy in Connecticut. The percentage of men treated with radiation therapy ranged from 17% in Utah to 35% in San Francisco.

Nattinger et al. (1992) reported that the percentage of women aged 65-70 with localized or regional breast cancer receiving breast conserving surgery identified through Medicare claims varied widely by geographic region. In Kentucky, 3.5% of women received breast conserving surgery, while in Massachusetts, 21.2% of received breast conserving surgery. More recently, Guadagnoli et al (1998 (918)) reported that 74% of the women identified as being eligible for breast conserving surgery in 18 hospitals in Massachusetts versus 48% of women identified in 30 sites in Minnesota received it.

Geographic variation is also associated with geographic differences in survival following diagnosis with cancer. The biggest differences in survival were for prostate cancer and cancer of the uterus. Geographic variation in 5-year survival rates were not affected by adjustment for age, sex, and surgical treatment (Farrow, 1996).

There are also consistent differences in care common to characteristics of the geographic area. Patients with localized breast cancer identified by SEER tumor registries who resided in counties where there was of a cancer center, where there was of a city of more than 100,000 within the county, or where there were more physicians were more likely to receive breast conserving surgery than other types of surgery. When these factors and each of the SEER tumor registry locations were included in multivariate analyses, having of a cancer center in the county and living in of a county with of a large city were statistically significant (Samet et al, (917)).

In addition to being treated in of a hospital proximate to of a large of metropolitan area, higher rates of breast conserving surgery have been found for patients treated in hospitals with of a medical school affiliation (Nattinger et al., 1992 (692), with radiation facilities (Nattinger et al., 1992 (692); (Lazovich et al., 1991 (974)), and geriatric services (Nattinger et al., 1992 (692)).

6.3 INTERVENTIONS TO IMPROVE ACCESS TO TREATMENT

There are few interventions that have been designed to specifically improve access to treatment services. We briefly describe some recent efforts. To decrease the financial burden of cancer, some drug companies which belong to the Pharmaceutical Research and Manufacturers of America (PhRMA) have programs which provide prescription drugs, including cancer therapies, free of charge or at reduced rates for the medically indigent. Eligibility is typically based on insurance status and income level of the patient (PhRMA, 1998). No data on the number of cancer patients receiving care through these programs is currently available.

To standardize delivery of cancer care and improve outcomes, several cancer centers have joined together to develop guidelines for care and measures of the outcomes of this care, and to collect data to evaluate the impact of these guidelines (the Network of Comprehensive Cancer Centers; NCCN). Data collection and analysis is in the early stages; these data, and responses to the use of practice guidelines, will be interesting.

6.4 SUMMARY

There are some documented barriers to cancer care and treatment services, including apparent agist biases, differences in care by race, insurance coverage and type, physician characteristics, and regional resources and standards of care. Unfortunately, there are limited data on additional areas, such as social class and social supports, which are also likely to affect access to treatment care. Assessment of barriers to this phase of care is also limited by the absence of comprehensive outcome measures, including patient preferences, and detailed data collection.

6.5 CANCER TREATMENT IN RANDOMIZED CLINICAL TRIALS

Although randomized controlled trials (RCTs) can provide access to care along the entire spectrum of cancer services, from primary prevention to end of life care, for this review we concentrate on barriers to primary and adjuvant treatment RCTs. This decision was driven by pragmatic concerns - this was the phase of care with the largest body of relevant literature concerning access to RCTs for cancer; where data are available we highlight barriers to participation in RCTs for other phases of care.

As part of the primary and adjuvant treatment decision making process, patients may also be eligible to receive treatment as part of a RCT. Realized access to clinical trials can be measured through rates of patient recruitment, enrollment, and adherence to the study protocol. As with other outcome measures, the challenge in implementing these process-level indicators is delineation of the appropriate denominator. In his case, age-adjusted rates among eligible cancer patents would seem to be the best denominator, although, as noted previously, determination of eligibility is not always clear in all data sets.

As described in Figure 8, there are important patient and individual contextual factors, cancer care provider characteristics, and characteristics of the medical environment which can affect access to clinical trials. In the following sections, after an overview of cancer clinical trials, we describe the patient, physician and system barriers to clinical trial participation. In each section we highlight areas where additional research is needed. Finally, we review recent innovative studies developed to overcome barriers to clinical trial participation.

6.6 OVERVIEW OF CANCER CLINICAL TRIALS

Clinical trials are the mechanism through which new technologies, pharmaceuticals or therapeutic strategies are evaluated against current standards of care in individuals who have disease or are at risk of developing disease. It is through this process that new therapies or technologies are recognized as efficacious, approved by the Food and Drug Administration (FDA) for patient use, and diffuse into general practice.

RCTs of new therapies are conducted in a sequential manner. Following testing in animals, new cancer drugs are tested in humans with disease. For those therapies with tumor killing activity, Phase I trials are conducted in the sickest individuals to assess toxic and pharmacologic effects. Phase II trials are next conducted to assess dosing, effectiveness and safety, and may not include a comparison group. Phase III trials are larger scale randomized controlled trials. Typically, new therapies are initially tested in individuals with advanced disease, where effective standard therapies may not exist. If efficacy is shown in these patients, new indications may be tested in patients with more localized disease.

Clinical trials of new cancer therapies are largely sponsored by the National Cancer Institute through cooperative groups of 194 universities and 1839 hospitals (Tejeda, et al, 1996). These cooperative groups are listed in Table 6.3.

Recently, Community Clinical Oncology Programs and the Cooperative Group Outreach Program (CCOP) were developed to make clinical trials more accessible in the community. The NCI also developed an initiative in 1990, the Minority-Based CCOP, to specifically expand the clinical trials network and address the prevention and treatment need in minority patients, their physicians, and institutions (Kaluzny et al, 1993).

The pharmaceutical industry also sponsors large numbers of clinical trials of new cancer therapies, but data from these trials are not easily accessible until after FDA approval.

Table 6.3. National Cancer Institute Clinical Cooperative Oncology Groups
Brain Tumor Cooperative Group (BTCG)

Cancer and Leukemia Group B (CALGB)
Children's Cancer Study Group (CCSG)
Eastern Cooperative Oncology Group (ECOG)
European Organization for Research and Treatment of Cancer (EORTC)
Gynecologic Oncology Group (GOG)
Intergroup Rhabdomyosarcoma (IRS)
National Surgical Adjuvant Breast and Bowel Project (NSABP)
North Central Cancer Treatment Group (NCCTG)
Pediatric Oncology Group (POG)
Radiation Therapy Oncology (RTOG)
Southwest Oncology Group (SWOG)
National Wilms' Tumor Study Group (NWTSG)

Based on concerns that participation of vulnerable populations in clinical trials was limited, The NIH Revitalization Act of 1993 specified that women, minorities and subpopulations must either be included in all phase III clinical trials, or justification for their exclusion be documented (NIH, 1994). This legislation does not apply directly to trials sponsored by the pharmaceutical industry. According to information from the Food and Drug Administration (FDA), a guideline published in 1993 encourages pharmaceutical companies to include sufficient numbers of women in drug development programs to evaluate gender differences in response to drug treatment, but there is no specific guideline on inclusion of vulnerable populations in clinical trials. There is no requirement from either the NIH or the FDA on inclusion of patients based on age.

For patients, participation in clinical trials can result in access to a standard quality of care and early access to potential "break-through" therapies. For researchers and clinicians, the participation of vulnerable populations in clinical trials offers the opportunity to identify factors that may require modification of treatment protocols and alert clinicians to issues in patient management that may be unique to these populations.

6.7 BARRIERS TO PARTICIPATION IN CLINICAL TRIALS

In the following sections, we review patient, physician and system barriers to participation in clinical trials.

6.7.1 Patient Barriers to Participation in Clinical Trials

In general, few cancer patients enroll in clinical trials. It has been estimated that anywhere from 2 to 20% of all cancer patients participate in clinical trials (Goodwin et al, 1988). In our review of the literature, we identified age, insurance status, gender, race, and patient knowledge attitudes and beliefs as potential barriers to participation in clinical trials.

6.7.1.1 Age

Historically the elderly have been excluded form cancer clinical trials. Lack of data from this age groups severely limits the ability to disseminate results from trial participants to elderly populations, the group at highest risk of having cancer, since the elderly are physiologically heterogeneous, and may require different regimens, have different disease complication rates, may be more or less affected by side effects, and require specific care giver or social supports. This is especially critical in tumors that occur primarily in the elderly, such as breast, colorectal, and prostate cancer.

There are striking variations in age-specific rates of participation in cancer clinical trials (Tejeda et al., 1996). For instance, while more than 70% of cancer patients aged 0-19 participate in clinical trials; only 1.5% of those aged 50 and over participate in cooperative group clinical trials (Tejeda et al., 1996). Those over 60 are enrolled at the lowest rates of all groups, despite accounting for more than half of cancer cases.

In a review of cancer patients in the state of New Mexico between 1969 and 1982, only 868 of 42,724 (2%) cancer cases registered in the New Mexico Tumor Registry participated in Southwestern Oncology Group (SWOG) protocols. Evaluating only protocols without explicit age restrictions, Goodwin and colleagues compared age of patients on SWOG protocols with the age of cancer patients in the state of New Mexico. In the 15 tumor sites evaluated individually, the percentage of non-SWOG patients over the age of 65 was approximately two times higher than the percentage of SWOG patients in this age group. For breast cancer, 33% of non-SWOG patients were over the age of 65, while only 3% of SWOG patients were in this age group (Goodwin et al, 1988).

The elderly may also have many specific concerns about participating in clinical trials. When comparing the recruitment rates in nursing home populations, the type of message by recruiting staff has been reported to be associated with participation rates. In studies where a direct benefit to the patient resulting from clinical trial participation has been described, the percentage of patients recruited is approximately two to three times greater than studies without a direct benefit (Lipsitz, et al., 1987). In addition to being concerned about personal benefit, the

elderly may be particularly concerned about treatment complications or side effects and problems with transportation. However, when offered aggressive treatment, the elderly may still accept this care (Muss, 1996; McQuellon, 1995; Yellen et al, 1995).

As noted above, concern about treatment complications or side effects, comorbid conditions, and interactions with current medications has led to age-based exclusions of patients in RCTs. Although these exclusions may no longer exist to the same extent, addressing issues associated with participation in clinical trials and directly funding trials in the elderly will be an important area for additional research.

6.7.1.2 Gender

Prior to the NIH Revitalization Act of 1993, some clinical trials explicitly excluded women from participation. This issue has received a lot of attention in cardiovascular disease, especially because of differences in treatment of women and men in procedures such as revascularization and coronary bypass surgery (Tobin, et al., 1987; Ayanian and Epstein, 1991; Krumholz et al, 1992). Unfortunately, we did not find any studies describing differences in realized access to cancer clinical trials for women and men.

6.7.1.3 Insurance

Insurance coverage of clinical trials is limited, especially for phase I or phase II trials. In this section, we review policies for insurance coverage of cancer clinical trial participation for major providers.

The health care delivery system in the US has changed dramatically within the past decade. Emphasis on cost containment may affect not only which services are covered, but also the policies which guide decisions to cover specific services. The majority of private insurers, especially managed care organizations (MCOs) don't cover the cost of clinical trial participation, as a matter of policy. However, decisions to cover the cost of treatment in a clinical trial for an individual patient make take place on a case by case basis.

Government financed insurers (e.g., Medicare and Medicaid), and providers for the armed services have more explicit policies. The Medicare program has a Cancer Therapy Evaluation program, in conjunction with the NCI, which can provide coverage for some cancer drugs when used as a last resort. These are Group C drugs; defined as having completed almost all clinical effectiveness testing requirements for FDA in NCI monitored protocols and not having a having a drug company marketing plan (Bagley and McVearry, 1998). Thus, Medicare beneficiaries may receive coverage for therapy that is being evaluated in the clinical trial, but not the trial itself (e.g, ancillary research tests and evaluations).

Clinical trial reimbursement policies for Medicaid vary widely across the states. In Oregon, for example, autologous bone marrow or stem cell transplants are covered within the environment of a sanctioned clinical trial (Glass, 1998). In other states, coverage of specific therapies or specific patient populations, is not specified.

In 1997, the Veterans Health Administration VHA began increasing access for eligible veterans for NCI sponsored prevention, diagnostic, and treatment trials. Additionally, access to NCI-sponsored trials performed at civilian centers may be granted under specific circumstances (Wilson and Kizer, 1998). The Department of Defense (DOD) provides coverage for members and retirees from the Uniformed Services, their families, as well as others that receive health care through the DOD in Civilian Health and Medical Programs of Uniformed Services (CHAMPUS). In 1996, access to NCI-sponsored phase II or III clinical trial became available for CHAMPUS (Browne, et al., 1998)

There are also two on-going clinical trials where the trials themselves are sponsored by insurers. US HealthCare funded the administrative costs of a phase III trial of high dose chemotherapy with bone marrow support vs. standard dose chemotherapy in women with metastatic breast cancer (JNCI, 1995). Notably, high dose chemotherapy for breast cancer patients trial is area where insurers have faced considerable litigation, where payment for treatment was initially denied.

The Health Care Financing Administration (HCFA) is sponsoring a clinical trial for Medicare beneficiaries with emphysema. For patients enrolled in the trial, Medicare is providing coverage of the cost of treatment (surgical lung volume reduction vs. standard care). No trials of cancer treatment are currently sponsored by Medicare. Some payors may be willing to provide coverage of trials where the outcomes affect the costs of providing patient care (ie, are cost-effective compared to standard treatments).

Regardless of the payor, insurance generally will not cover the additional physician visits or treatment of side effects associated with the therapy under evaluation. Further, there may be substantial indirect costs associated with participation in clinical trials, such as transportation to the clinical site, temporary housing, or time lost from work for care givers. This barrier is especially problematic for patients with limited resources.

6.7.1.4 Social Class

Even though the clinical development of new therapies may initiate in patient populations with advanced disease (who disproportionately include lower social class groups), trial inclusion criteria may specify complete diagnostic work-up and staging, appropriate primary and adjuvant treatment; areas where individuals from lower social class or minority groups may experience significant barriers to care. Further, clinical trials typically have exclusion criteria based on presence of other comorbid conditions and performance status; requirements, which may differentially exclude members of lower social classes, who have been described as being in poorer health than higher social class groups.

For patients that are diagnosed late in their disease and do not receive appropriate care early in the cancer care pathway or who have significant other impairments, clinical trials may not be an option for care. However, such patients represent more "typical" cases in the general population. Thus, the generalizability of clinical trial results to these groups may be limited and may adversely affect the quality of care provided to these patients.

In order to identify patient groups that may be under represented in clinical trials more detailed comparisons of trial participants and cancer patients in the general population are needed by gender, age group, tumor site and stage of disease at diagnosis. Modification of tumor registry reporting to include socioeconomic factors such as income level, educational attainment, and type of health insurance might expand identification of under represented patient groups. Some of this work is currently under development using zip-code based surrogate socioeconomic status measures (Albain, 1997).

6.7.1.5 Race/Ethnicity

Although lower rates of participation in clinical trials by members of minority groups has been hypothesized (Svensson , 1989), evidence from studies of participation in cancer treatment and prevention trials sponsored by the NCI is mixed (Bleyer , 1997a; Bleyer, 1997b, Tejeda, 1996; Thompson et al., 1995; Chlebowshi, 1993; JNCI, 1996). Similar data with which to assess participation in cancer trials sponsored by the pharmaceutical industry are not readily available.

Researchers have used the Surveillance, Epidemiology, and End Results (SEER) tumor registry to develop national and regional estimates of the race-specific cancer incidence with which to compare participation in NCI sponsored cooperative clinical trials (Bleyer et al., 1997a; Bleyer et al., 1997b; Tejeda et al., 1996). For instance, Tejeda et al (1996) compared the racial distribution of 5 tumor types by patient age group (0-19, 20-49, and >=50) in the general cancer population and in patients participating in NCI sponsored treatment trials. Racial distributions of incident cancer in the general population and racial distributions of patients participating in NCI trials were similar (Tejeda et al., 1996). Bleyer et al (1997a; 1997b) also found that the proportion of minority patients with cancer under the age of 20 from the tumor registry and the proportion of minority patients participating in the Children's Cancer Group (CCG) or the Pediatric Oncology Group (POG) to be similar (Bleyer et al., 1997).

Thus, it appears that on a population basis, minorities are represented in trials in proportion to their age-specific rates of cancer. However, use of broad age categories, such as 0-20, to compare race-specific incidence and participation in NCI trials may be limited. Adolescents (aged 15-20) compose a small percentage of cooperative group participation compared to younger children (aged 0-14), but a larger percentage of tumor registrants (Bleyer et al., 1997b). Thus, access to clinical trials for minority adolescents may still be limited. Further analyses of patients by age and stage of disease might be help to identify patient populations with limitations in access to clinical trials. Additionally, evaluation of loss to follow up or protocol adherence may provide better data for the evaluation of realized access to clinical trials. These will be important areas for additional research.

In contrast to treatment trials, under-enrollment of minority groups has been well-documented in chemoprevention and screening trials (Thompson et al., 1995; Chlebowshi et al., 1993; JNCI, 1996). According to the National Cancer Institute, minority enrollment in the Prostate, Lung, Colorectal and Ovarian screening trial (PLCO) fell short of representation in the overall population (JNCI, 1996). In the Breast Cancer Prevention Trial (BCPT), recruiters have been able to encourage women from under served populations to participate in assessment of eligibility, but have been less successful in increasing trial enrollment for those that are eligible (JNCI, 1996). For example, a mock recruitment for the BCPT was performed with minority women with newly diagnosed breast cancer at a surgical breast clinic. Of the 126 patients identified from clinic records as sources for familial referral, 52% could be contacted and 25% of these patients were lost to follow-up. Only 24 of the original 126 patients could identify a female relative in the area that might be interested in participating in a chemoprevention trial (Chlebowski et al., 1993). Further, it is likely that all 24 of the identified population would not agree to participate and complete the study.

Recent results of the Tamoxifen chemoprevention trial in women at risk of breast cancer were favorable (NCI, 1998). As chemoprevention becomes more integrated into the cancer care pathway, further analyses of participation in chemoprevention clinical trials, loss to follow up, or protocol adherence patients by race and age might be help to identify patient populations with limitations in access to clinical trials. Interventions which improve enrollment, retention, and protocol adherence will also ensure that results of such trials are generalizable to these patient populations.

6.7.1.6 Knowledge, Attitudes, and Behaviors

Other patient based barriers can be grouped into general categories including attitudes towards health and the medical profession, and lack of awareness of clinical research. Many of the cultural knowledge, attitudes, and beliefs about cancer and cancer prevention activities will also present barriers to participation in clinical trials. Elmer Huerta, involved in the PLCO recruitment for the Washington Hospital Center, speculated that *fatalismo*, the belief that one's fate cannot be altered, may prevent Hispanic populations from enrolling in cancer clinical trials (JNCI, 1996). This may especially problematic for cancer screening or chemoprevention trials.

African American patients, their friends, and family may have a historically grounded fear or discomfort with the medical profession in relation to clinical research (Mouton et al., 1997; Harris et al, 1996; Robinson, 1996, #1190; Millon-Underwood, 1993, #1191). The Tuskegee Syphilis Study is a well-known example of mistreatment of black research subjects under the guise of medical research. The study was conducted from the early 1930s until the early 1970s to observe the untreated course of syphilis in black men. It was continued long after the development of treatment and clear standards of ethical research (Gamble, 1997 #1479).

In a study of attitudes of women who did not respond to initial mailing for the Women's Health Initiative, a multi-center trial of cancer prevention therapy, Mouton et al found several attitudinal differences between White and

Black women (Mouton et al., 1997). The population of women between the ages of 50 and 79 were similar by most demographic and medical characteristics: most had at least some college education; more than half had annual incomes over $25,000, about two-thirds rated their health as good or very good, and more than 80% had a private physician. Most women of both races either agreed or strongly agreed that participation in clinical research benefits society. However, Black women were still more likely to agree or strongly agree that scientists cannot be trusted, it is better to be treated by doctors who are researchers, and that they prefer studies headed by black scientists. After adjusting for education, marital status, and retiree status, Black women were more likely to have a negative attitude to clinical trials. Thus, despite many demographic similarities, perception of clinical trials split along racial lines.

Similar negative attitudes towards medicine and medical research were reported from a series of focus groups of African-American men questioned about prostate cancer clinical trials (Robinson, 1996, #1190). Concerns about being a guinea pig, loss of potency, or treatment side effects were also expressed. However, some men indicated that they would be willing to participate if they felt the investigator were competent, the trial was conducted at a black facility, and the medical center had a strong research record (Robinson, 1996, #1190).

Patients from vulnerable populations may also have less exposure to the clinical trial process and may require more input and guidance from a referring physician. In focus groups of African-American men, being informed about cancer risks, having knowledge of clinical trials, and being confidence in the treating clinician were all associated with greater stated willingness to participate in cancer clinical trials (Robinson, 1996, #1190). Unfortunately, many of these patients may not have an established relationship with a primary care provider, are typically dissimilar from the recruiting physician, and may feel uncomfortable asking questions. A lack of familiarity with the clinical trial process combined with low-level reading skills in some patient populations may complicate the informed consent process. In situations where clinicians may be disinclined to enroll patients in clinical trials, lack of patient knowledge and familiarity with clinical research may reinforce physician attitudes.

6.7.2 Physician Barriers to Clinical Trial Participation

Because of responsibilities for referring patients into treatment, the treating physician acts as a gatekeeper to clinical trial participation. Foley and Moertel (1991) conducted surveys of the Community Clinical Oncology Programs and found that the main reason for not entering eligible patients on clinical trial protocols was that the physician decided not to enroll the patient. Physicians were concerned about patient age, frailty, inadequate health insurance coverage, ability to travel to clinical center, and patient burden.

Physicians have also reported being concerned about the amount of time (patient and physician) associated with participation in clinical trials (Farrar et al., 1991; Kaluzny et al., 1993), being uncomfortable with discussions of uncertainty of the trial treatment (Taylor et al., 1984), and being concerned about changes in the physician role as a result of trial participation (Taylor et al., 1984). Patients entered into cancer clinical trials generally have another physician with primary responsibility for their cancer care, which can lead to another layer of complexity in the physician-patient relationship. When entering patients into clinical trials, physicians must also balance their responsibility for care to an individual patient currently undergoing treatment against concern for an unknown future patient who might benefit from the results of the trial.

Some of the issues described above are likely to be exacerbated for physicians without affiliations with CCOPs or cancer centers. Physicians in rural clinical centers or in centers without a strong research tradition may not receive support from their institution to enroll patients in clinical trials. Further, pressures to maintain patient volumes and comply with an increasingly complex series of reimbursement systems may limit the amount of time physicians can devote to enrollment of patients into clinical trials.

Research into physician attitudes about clinical trials is critical to increasing clinical trial enrollment. Educational programs focussed on increasing physician communication skills about randomized controlled trials and the informed consent process might increase physician comfort with clinical trial referral and increase patient enrollment. Educational programs have been used previously to increase physician communication skills in identification and counseling for risky sexual behaviors (Boekeloo et al., 199X). These programs might be adapted to increase patient referral into clinical trials.

For example, in our review of interventions to enhance utilization of mammography screening in phase I, we noted that cognitive interventions directed at changing physician knowledge and interventions adding reminders to the patient charts directed at changing physician behavior during the patient visit increased rates or mammography screening. Development of cognitive interventions such as educational programs to address physician and clinic staff attitudes to clinical research might improve realized access to clinical trials. Additionally, behavioral interventions, such as the review of patient charts following diagnostic work-up and staging by clinical coordinators and notations of appropriate trials prior to the visit where treatment is decided may also improve patient access to clinical trials. All of these areas for additional research might be especially useful in the CCOP and MBCCOP networks.

6.7.3 Medical System/Institutional Barriers to Clinical Trial Participation

As described above, clinical trials of new cancer therapies are sponsored by the National Cancer Institute through cooperative groups (Tejeda, et al, 1996). Clinical trials of cancer therapies may also be sponsored by the pharmaceutical industry in university and hospital networks. The medical infrastructure for universities and hospitals participating in RCTs, however, may be not provide strong incentives for patient referral into clinical trials. The increasingly competitive health care industry may exaggerate this effect--site investigators may have little time to discuss trial procedures with patients due to increasing emphasis on maintaining patient volumes and may be disinclined to offer trials to patients without insurance coverage. Coverage of patient care for those that do have health insurance may be complicated by low negotiated rates or non-coverage of participation.

Many of the hospitals that treat under served populations face additional financial problems that restrict research participation. Support staff such as study nurses and research coordinators or data collection and management resources may be very limited or non-existent. Institutional Review Boards (IRB), which certify ethical conduct of research in clinical trials, may not exist in these institutions. Finally, community investigators may not have experience in administering research protocols or participating in collaborative research.

Organizations such as MBCCOP, the Drew-Meharry-Morehouse consortium cancer center, and SOCRATES, a group formed by minority physicians to ensure access to clinical trials, as leads for future research efforts may be particularly useful resources for community centers with little research experience. Further, many patient-reported barriers to care are associated with the convenience of receiving care at study clinics. Interventions focussed on addressing the provision of transportation to clinics, expanded clinic hours, use of satellite clinics, and use of on-call study staff to increase subject enrollment and retention in clinical trials could be developed and assessed.

As mentioned in the review of patient barriers to participation in clinical trials, few insurers provide coverage for costs of care. Costs associated with clinical trials (e.g., additional physician visits, additional laboratory tests) are rarely reimbursed. The lack of reimbursement for this care leads to individual barriers to participation in RCTs. Payors may not cover participation in clinical trials because of a perception that care received in a clinical trial setting may be more expensive. Future research could address these concerns by funding three-arm cost effectiveness studies where patients are randomized into usual care outside a clinical trial, care within a clinical trial and the new intervention, care within a clinical trial and the standard therapy. This may be an important application of future cost-effectiveness research.

Institutional barriers are also important in primary prevention trials, such as the chemoprevention trials mentioned previously. Since these trials typically require long follow-up periods and are done in patient populations without signs of disease, the potential for patient loss to follow-up is greater. Improved follow-up through integrated tumor registries (e.g., clinical trial data as well as traditional tumor registry functioning) might address problems with long-term follow-up.

6.8 INTERVENTIONS TO REDUCE BARRIERS TO CLINICAL TRIALS

Many strategies have been suggested to overcome the major barriers reviewed above to increase the participation in cancer clinical trials (McCabe et al, 1994; Foley and Moertel, 1991; Harris et al., 1996). Strategies have been focussed on community education, reducing patient barriers to participation, physician education, and increasing institutional commitments to enrollment of all populations, including under served groups. Very little information is available on the effectiveness of these strategies in increasing enrollment of target populations. Once enrolled, there are virtually no data on the effectiveness of efforts directed to patient retention and reduction in loss to long term follow-up. This section summarizes some recent efforts to improve participation in clinical trials. Interventions are presented as community-focused, patient-focused, provider-focused, and system-focused.

6.8.1 Community Focused Approaches to Increase Clinical Trial Participation

Historically, the perception of clinical trials, particularly in the black community, has not been favorable. As mentioned above, this may provide a significant barrier to clinical trial enrollment, retention, and adherence to follow-up regimens. Interventions developed specifically to improve the image of clinical research may help allay fears and distrust of clinical trials and enhance enrollment. Stoy et al (1995) described a pilot to increase minority accrual based in the religious community. Investigators worked closely with the Congress of National Black Churches and clergy at four pilot churches that agreed to assist in recruitment. Others have reported that involvement of trusted religious leaders (Petrovich et al., 1991) or use of theater (JNCI, 1996) in study recruitment has led to positive responses from potential research subjects. Use of community leaders from other sectors may also help change attitudes to research. However, this approach is resource intensive and may require a substantial time commitment to complete patient enrollment. Further, at present, the effectiveness of this strategy in increasing patient enrollment and retention has not been reported.

Others have suggested that public presentations and targeted use of mass media may help to raise community awareness (Swanson and Ward, 1995). Table 6.4 describes local recruitment strategies used in a study of elderly and black hypercholesterolemic subjects into an intervention trial (Cholesterol Reduction in Seniors Program (CRISP)) (Stoy et al., 1995). Investigators used direct mass mailing to age-specific individuals identified from lists of previous studies of the elderly, membership lists from senior organizations and churches, the department of motor vehicles, and geographic areas with high percentage of elderly. Public service announcements, paid advertising, and interviews with study investigators were released through print and broadcast media. Additionally, some mass media was targeted to black communities. The study also sponsored mass cholesterol screening at retirement homes, community based health fairs, and senior centers.

Mass screening and mass mailing had the highest contact rates, 25% and 26%, respectively. Newspaper and radio/TV advertisements led to relatively low contact rates (10% and 2.4%, respectively), but high eligibility for the study in those that contacted the study (35% and 36%). However, the most effective community based strategy will be based on the desired population characteristics for the trial. For example, the CRISP study abandoned the mass screening approach for patient recruitment. Although it generated relatively high subject contact rates (25% of total contacts), the majority of the subjects were ineligible because they did not meet screening requirements (i.e. only 4% of subjects were eligible for the study). Also, strategies focussed on the church are likely to recruit women and men with healthy behaviors (ie, less likely to smoke or abuse alcohol) (Brown and Gary, 1994). This self-selection to community sites by risk status needs to be considered in light of the trial objectives to ensure external validity of results.

Table 6.4. Recruitment of subjects in the CRISP study

	Recruitment Source at Contact	Eligibility Rate by Source
Mass mailing Participants from other cohort studies Membership list from senior organizations and churches Lists from Department of Motor Vehicles Geographic lists **Targeted Mailing or Telephone Contact** Hospital Pathology Labs Health Maintenance Organizations Outpatient Clinics	783 (26%)	15%
Study Sponsored Mass Screening Screening at Retirement Homes and Senior Centers Screening at Health Fairs	764 (25%)	4%
Newspaper	317 (10%)	31%
Local Physicians and Medical Societies	404 (13.2%)	20%
Word of Mouth	237 (7.7%)	21%
Radio/TV	72 (2.4%)	36%
Other	477 (15.6%)	16%
Total	3061 (100%)	

Source: Stoy et al., 1995

6.8.2 Patient Based Approaches to Increase Participation in Clinical Trials

We found several strategies which addressed patient education and the provision of culturally sensitive materials to reduce barriers to participation in clinical trials. For instance, as part of the MBCCOP, consent forms and educational materials have been translated for low-literacy and non-English speaking populations (Kulzny et al, 1993). However, we did not find a formal assessment of the impact of these forms on patient enrollment, retention, and completion of cancer clinical trials.

Use of patient advocates have also been suggested as a mechanism to increase recruitment to trials. For example, when patents are making treatment choices, a patient advocate who has had the same cancer can encourage

new patients to consider RCT treatment, using their own positive experiences (personal communication, Margaret Borwhat, 1998).

The Patient Accession Core at the Lombardi Cancer Center at Georgetown University Medical Center is another mechanism that can be used to explicitly recruit under represented populations in trials. For instance, funding from the Department of Defense has allowed intensive recruitment for women at risk for, or with breast cancer to a treatment trial, a diagnostic trial, and an educational study of genetic testing. Investigators developed a Community Advisory Board to open dialogue about patient barriers to participation in clinical trials and increase patient accrual (Jon Kerner, personal communication, 1998). Data are not yet available to assess the effectiveness of this approach.

Gordon and Houser (1997) developed a world-wide-web based clinical trials directory, called Breast Cancer Answers, specifically to provide women information about choices for breast cancer care. In addition to providing information about available trials, this system uses patient age, stage of disease, and treatment history to link individuals with institutions with appropriate trials. Data on the number of women enrolling in these trials is not currently available, but the authors noted that the site is visited more than 200 times monthly. Obviously, this type of strategy will reach populations who have computers and Internet access.

The National Cancer Institute also sponsors the Cancer Information Service (CIS), which is a hotline for patients and the general public to access information on cancer treatment and clinical trials. This service can be accessed by a toll-free number or through the Internet, and has prevention and treatment related information organized by tumor site. In the period between 1989 and 1992, over 500,000 calls were made to CIS annually (Manfredi, 1993). As part of a study of the reasons for, and content of, these calls, researchers recontacted callers from a regional CIS office. Among patients seeking information, 21% indicated that they were calling to receive information about experimental treatment and 18% were calling to receive information on referrals to cancer experts. Thus, the CIS appears to be an excellent source of information about clinical trials for the general public. Data on the number of clinical trial referrals that lead to enrollment following CIS contact are unavailable, however.

6.8.3 Provider Based Approaches to Increase Participation in Clinical Trials

In our review of the medical literature, with one exception, we did not find any strategies specifically targeted to providers for increasing enrollment and retention in clinical trials. The NCI's CIS also sponsors a comprehensive cancer clinical trials registry called the Physician Data Query system (PDQ). This database can be accessed by telephone or via the Internet. It includes abstracts of trials that are open and approved for patient accrual as well as those that are completed or no longer accepting patients. Considering the key role that providers play in referring patients to clinical trials, additional research in this area is needed.

6.8.4 System Based Approaches to Increase Participation in Clinical Trials

Despite widespread systems barriers to RCT participation, with the exception of the community oncology cooperative groups, we did not find any other strategies targeted to decreasing system-based barriers. Although we did identify two trials where sponsors provided at least partial insurance coverage (JNCI, 1995; Bagley and McVearry, 1998), these approaches were not developed to explicitly increase patient participation. As a result, no information on enrollment and completion of insurer-sponsored trials compared to trials without insurer support is currently available. Development of strategies to decrease system barriers to care will be an important area for additional research.

6.9 SUMMARY

We reviewed the published literature describing barriers to participation in cancer clinical trials. The majority of cancer patients do not participate in clinical trials, although assessment of differential participation by patient subgroups is complicated by a lack of data. The majority of research we have reviewed in this section addresses enrollment in clinical trials. There is a paucity of information available about barriers to adherence to study protocols and completion of the trial. From the studies we reviewed, patient barriers to enrollment in treatment trials include age, and knowledge attitudes, and behaviors toward cancer and its treatment. Patients of minority groups are less likely to participate in chemoprevention trials; assessment of minority participation in treatment trials is limited by a paucity of good quality data. There are no data to assess whether additional barriers, such as financial, insurance, and gender barriers, are operating in obtaining access to RCTs.

Physicians act as the gatekeepers to clinical trials, with concerns about patients (e.g., age, frailty, lack of insurance), changing physician-patient relationships, and excessive time requirements for participation providing major barriers to patient enrollment. Changes in financing and reimbursement of care which affect physician behavior and system organization can also limit participation in clinical trials.

Underlying assumptions about the generalizability of clinical trial results are suppositions that patient populations are representative of the general populations. Depending on the recruitment strategies used and mix of subjects in the trial, this may or may not be true. For instance, if the elderly have not be included in a trial of chemotherapy, it would be difficult to disseminate effect treatments to this age group, where pharmacokinetics may vary from those in younger populations.

Currently, strategies that address communities and specific patient groups have been implemented to improve clinical trial enrollment; not all of these have included an evaluation of effectiveness. Very little work has been done to increase physician participation in or in reducing system barriers to clinical trial enrollment.

Appendix B: Cervical Cancer Screening Follow-up Case Study

We utilized the (OVID) search mechanism with MEDLINE in the years 1980-1998 to identify published English language articles on interventions to increase medical follow-up after an abnormal test result.

The search strategy was as follows: we used the terms "mass screening" or "vaginal smears" (N=16,789) and combined "cervix neoplasms" or "cervix dysplasia" (N=20,643) to identify the subset of studies focused on abnormal results of screening (N=2,384). We then developed a series of terms to identify characteristics and settings where interventions could take place: "primary health care", "preventive health services", "preventive medicine", "health promotion", "physicians practice patterns", "continuity of patient care", "communication" or persuasive communication", "reminder systems", "pamphlets", "patient education", "patient acceptance of health care", "patient compliance", or motivation (N=69,140).

The combination of these two searches (abnormal results of screening and characteristics or settings of interventions) yielded 104 studies. To be eligible for inclusion in our review, studies had to be randomized controlled trials, or concurrently controlled trials. Uncontrolled trials or pre/post studies were excluded. Thus, to assess study design, abstracts and MEDLINE terms (e.g., random allocation, longitudinal studies, intervention studies, prospective studies and follow-up studies) were reviewed for evidence of prospective follow-up with either randomized assignment to an intervention or control group. Published abstracts were excluded as they were judged to have too brief a description of methods for assessment.

From this list 10 studies were selected for further review. Reference lists of these studies were also searched to identify other eligible studies. A total of eight studies met the stated criteria and are included in our review. Because these studies used a variety of definitions of abnormal test result, included different periods for assessment adherence to follow-up, and used different outcomes, we did not perform a quantitative analysis. Studies are described qualitatively only.

7.0 PHASE 4: ACCESS TO POST-TREATMENT SURVEILLANCE AND RECURRENCE CARE

Following definitive primary and adjuvant treatment in phase 3 of cancer care, patients are monitored for signs of disease recurrence and psychosocial distress associated with survivorship. Monitoring or surveillance tends to be more intensive for the first several years when the probability of recurrence and adjustment difficulties may be greatest, but may continue many years beyond initial diagnosis. Patients that experience recurrence may return to phase 3 to receive potentially curative treatment, or depending on the extent of disease, tumor type, and preferences for care, enter the final phase of the disease continuum, the end of life.

Very little work has been performed to assess the efficacy or effectiveness of any surveillance strategies for cancer patients. Despite this, published guidelines for the surveillance of patients following definitive treatment typically recommend the content, frequency, and duration of follow-up examinations and diagnostic tests (NCCN, 1997; Virgo, 1996; Fischer, 1996). Similar guidelines for surveillance of individuals with genetic predisposition to cancers are also available for heredity nonpolyposis colon cancer (HNPCC) (Burke et al., 1997) and BRCA1 and BRCA2 (Burke et al., 1997). Establishment of evidence-based guidelines for patient surveillance following definitive treatment or following identification of genetic predisposition to cancer is a critical area for additional research to ensure that recommended follow-up strategies reflect meaningful clinical and patient-based outcomes. Likewise, there are little data on the longer-term psychosocial needs of cancer survivors.

As described in Figure 9, one process-based measure, compliance with examination

figure X

and testing frequency as recommended in evidence-based guidelines, and one outcome- duration of survival following recurrence stratified by stage and adequacy of primary and adjuvant treatment - can be used to assess realized access to cancer surveillance. As more data on post-treatment quality of life become available, such measures should be integrated into the assessment of realized access to cancer surveillance and recurrence treatment.

Even in the absence of evidence-based guidelines and clear outcome measures, geographic variability in the content of follow-up care (Virgo, 1995; Johnson, 1996a; Johnson, 1996b), higher rates of recurrent disease (Gordon, 1992), and lower levels of long-term quality of life among certain patient subgroups (Ganz, 1998) indicate potential limitations in realized access to this phase of cancer care. In the following sections we review several issues underlying the assessment of realized access to cancer surveillance and recurrence therapy. We then describe patient, physician, and system barriers to realized access to surveillance following definitive treatment. We identify areas where additional research may improve realized access to effective cancer surveillance and follow-up after definitive treatment and describe several policy options to improve access to effective cancer surveillance.

7.1 METHODOLOGICAL ISSUES

There are several methodological challenges which must be resolved prior to full assessment of the impact of barriers to this phase of care, including the efficacy of cancer surveillance, the integration of patient-based outcomes, and other methodologic problems associated with the assessment of realized access to cancer surveillance.

7.1.1 Effectiveness of Cancer Surveillance

The effectiveness of intensive surveillance in improving disease-free or overall survival has yet to be demonstrated for most tumor types. Even less is known about the impact of intensive surveillance on patient quality of life. Surveillance following definitive cancer treatment is based on the premise that intensive scrutiny will result in improved survival, disease-free survival, or patient quality of life. This assumes that surveillance will detect recurrent disease early in its the natural history, that treatment exists that can improve survival or symptom control for recurrent disease, and that earlier treatment will improve patient outcomes.

First, in order to detect recurrent disease early in the natural history while patient is asymptomatic, diagnostic tests must exist that are both sensitive and specific to recurrent disease. That is, tests should be able to accurately identify patients with recurrent disease (sensitivity), and identify patients without recurrent disease (specificity). Yet, several follow-up studies of breast cancer have reported that most recurrences are symptomatic and detected by the patients between visits (Schapira and Urban, 1991;). As few as 15.4% of breast cancer recurrences are detected by physicians in asymptomatic patients (Schapira and Urban, 1991). In a retrospective follow-up of patients treated for non-Hodgkin's lymphoma and in complete remission, 91% of relapses, were detected at unscheduled visits where patients presented with symptoms (Weeks et al, 1991). In the two examples described here, diagnostic tests for disease recurrence do not appear to be particularly sensitive.

Even in cases where a tumor marker, such as prostate specific antigen (PSA) identifies patients with recurrent disease, it may not be very specific. There have been several reports of elevated PSA levels in men treated for localized disease lasting for several years without detection of disease recurrence (Lightner, 1990; Frazier, 1983). In these cases, aggressive use of surveillance can result in unnecessary investigation and distress.

Second, in order for surveillance to have an impact on patient outcomes, effective treatment of recurrent disease should be available. For example, among patients initially treated for localized testicular cancer, the cure rate associated with systemic therapy following recurrence has been reported to be as high as 99% (Williams, 1987). On the other hand, for patients initially treated for localized small cell or non-small cell lung cancer, treatment of recurrence has little impact on overall or disease-free survival (Virgo, 1995).

Third, in order for surveillance to be effective in improving patient outcomes, treatment of asymptomatic disease should be greater than that for symptomatic disease, exclusive of any lead time, length, or detection biases. However, there are few differences in survival for symptomatic and asymptomatic diagnoses of recurrence for patients treated with curative intent for endometrial cancer (Agboola et al., 1997), breast cancer (GIVIO, 1994; Del Turrcio Rosselli, 1994), or Hodgkin's disease (Radford et al., 1997). In a study of intensive follow-up for breast cancer, adding annual chest roentgenography and bone scan every six months to routine physical exams and mammography led to the detection of more intrathoracic and bone metastases in the intensive follow up group, but no significant differences in 5-year mortality (Rosselli Del Turco, et al., 1994). A similar study randomized patients into two follow-up groups, a group receiving routine physician examination and mammography and an intensive follow-up group adding chest roentgenography, liver echography, bone scan. Type of recurrence (e.g., local-regional, contralateral breast, or distant metastases) did not differ by type of follow-up (GIVIO, 1995); thus

intensive followup did not improve patient survival. Follow-up for more than five years for either of these two studies has not been reported.

Finally, the underlying risk of recurrent disease, which also varies by tumor site and stage of disease at diagnosis, must be considered along with the factors mentioned previously. Surveillance will be most useful in situations where the risk of recurrence is high, diagnostic tests are specific and sensitive, and treatment of asymptomatic disease is effective in improving patient outcomes. The interaction of these factors is rarely this clear, however**.**

Even though patients who receive definitive treatment for localized testicular cancer have a relatively low risk of recurrence, about 15%, sensitive tests for detection of recurrence exist (e.g., beta-human chorionic gonadotropin, lactate dehydrogenase, and alpha-fetoprotein), and treatment of recurrence is very effective, especially when tumor is low-volume (Williams, 1987). Thus, testicular cancer may be an especially good candidate for the evaluation of realized access to cancer surveillance.

Patients receiving definitive treatment for localized or regional breast cancer may experience moderate rates of recurrence, around 50% (Edelman, 1997), but are rarely detected symptomatically (GIVIO, 1995), have few treatment options, and treatment of asymptomatic disease rarely offers improved outcome over that treated symptomatically. Thus, intensive surveillance of breast cancer to improve disease free survival or overall survival does not appear to be warranted.

However, even if intensive surveillance does not increase patient survival, it may serve other important functions. For instance, with more frequent contact with the medical care team, patients may receive more attention to psychological distress, better rehabilitation, or may simply prefer the added reassurance of intensive surveillance. This may impact overall quality of life during the post-cancer survival period. However, in the only randomized study of quality of life and breast cancer surveillance, the GIVIO Investigators did not report differences in quality of life among patients undergoing intensive vs. more routine surveillance. Unfortunately, the study was not powered to detect differences in patient quality of life, so the reported lack of differences may be attributable to insufficient sample size. Additionally, these authors reported that the majority of the patients included in this study (70%) preferred intensive follow-up even when they were asymptomatic (GIVIO, 1994).

Conversely, intensive surveillance could also increase psychological distress of waiting for test results. In cases where diagnostic tests are not particularly specific, intensive surveillance may lead to more false positive tests. Among non-cancer patients, receipt of a false positive test result has been described as introducing psychological distress (Lerman et al, 1991); the impact of a false positive indication of cancer recurrence is likely to have a greater adverse effect. This is an important area for additional research.

7.1.2 Outcome Measurement

As noted in the introduction, outcomes for surveillance and recurrence treatment include process measures of rates of proscribed care and quality of life and survival outcomes. There are, however, several methodologic challenges that must still be overcome to develop adequate outcomes measures for this phase of care, including integration of multi-disciplinary measures of patient quality of life and the ability to stratify the denominator for survival rates into groups that are homogeneous with respect to stage, tumor characteristics, and prior treatment. Such separation of groups is necessary to segregate the effects on survival of initial treatment from those attributable to recurrence care.

Very little work has been done to assess the long-term impact of surveillance for recurrence, treatment of recurrence, or surviving cancer on patient quality of life. Fears of disease recurrence, concerns about long term effects of therapy, physical impairment, loss of role functioning, lower thresholds for anxiety or depression, changes in relationships with family and friends, spirituality, and social support are among some of the domains likely to affected for cancer survivors. There are also important practical problems which all patients may face following primary treatment—modification of life, health, or funeral insurance policies and employability issues (Greaves-Otte, 1991). In a recent review of studies of long term quality of life in cancer survivors conducted by Gotay and Muraoka (1998), only a single quality of life instrument had been developed and validated for this population of cancer patients.

Further validation of quality of life assessment following definitive cancer treatment may be required beyond that typically conducted in clinical trial follow-up. For example, Fowler and colleagues surveyed randomly selected Medicare beneficiaries who had undergone prostatectomy for prostate cancer two to four years after treatment. Most men reported some problems with urinary incontinence and sexual function, and at rates much higher than available at the time of publication (Fowler et al., 1993). Additional research in long term impact of cancer and its treatment on patient quality of life should be conducted in the general population of cancer survivors, using sufficient samples to detect differences, compared to age-adjusted healthy controls (which could include non-

recurring cancer patients or the general population), with instruments appropriate for the tumor site, and sensitive to detecting clinically meaningful changes over time in both healthy and very ill populations (ie, not subject to ceiling or floor effects).

As noted above, survival should be assessed in groups that are similar to in age, stage, tumor characteristics, and prior treatment to segregate the effects on survival of initial treatment from those attributable to recurrence care. Unfortunately, there may be insufficient information routinely collected in public data sources that can be used for this purpose, and review of medical records (often from multiple sources) is generally not feasible. Tumor registry data identify patients at the time of diagnosis, and describe staging, first course of therapy, and mortality. Tumor registries may not always provide information on the timing or treatment of recurrence. Other sources of patient data, such as administrative claims, lack clinical precision in defining tumor characteristics, patient characteristics, and treatments received. Data describing patient quality of life while under surveillance are generally unavailable. Thus, the framework for accurately assessing access to this phase of care needs to be expanded to more clearly delineate and evaluate barriers to access.

7.2 BARRIERS TO SURVEILLANCE AND RECURRENCE CARE

In the following sections we describe the existing research on patient, physician, and system barriers to realized access to cancer surveillance and recurrence care, using crude indicators of access such as differences in quality of life, content of care, or risk of recurrence across patient subgroups.

7.2.1 Patient Barriers to Realized Access to Surveillance and Recurrence Care

We identified several patient issues associated with differences in care likely to be associated with realized access in this phase of care including patient age, insurance status, race, and social class.

7.2.1.1 Age

Long term quality of life impacts of cancer appear to vary by patient age. For example, less favorable physical function scores have been reported in older breast cancer survivors than younger patients, but younger women fair less well in other domains, including emotional well-being, role function-emotional, and depression (Ganz et al., 1998). These data were reported only for women that received BCS and the quality of life values were compared to healthy age-matched women. Thus, differences in quality of life concerns for different patient age groups are unlikely to be associated only with aging. These quality of life concerns may reflect unmet needs associated with patient age, such as physical rehabilitation or psychosocial care following cancer treatment.

7.2.1.2 Insurance

Following initial treatment, the content of cancer surveillance may vary by presence and type of insurance. Although we did not find any studies specifically addressing surveillance care among patients with and without health insurance, it is logical to assume that patients without insurance are likely to have barriers to obtaining follow-up visits and tests; out-of-pocket cots may also be a barrier to seeking care once symptoms of recurrence appear. Thus, uninsured, or underinsured groups may be at risk for poorer post-recurrence survival, to the extent that detection and treatment is effective.

Among insured groups, the content of patient care may vary by type of insurance. This is suggested by the fact that immediate post-surgery care does vary by health plan. For instance, using hospital charts, Retchin et al (1997) compared post-initial treatment care for colorectal cancer patients receiving surgery in Medicare FFS or Medicare managed care settings (e.g., independent practice associations, group, and staff models). Patients receiving care through managed care plans had lower surgical risk than patients in FFS plans, but other clinical characteristics did not differ by group. Following definitive surgery, patients enrolled in managed care were less likely to receive patient-controlled analgesia, post-operative chest radiographs for patients with fever, and were more likely to be discharged home than to a nursing home than were patients receiving care through FFS plans, adjusting for baseline clinical characteristics. The authors did not discuss the optimal rates of utilization for these services; clearly, the risk of overutilization is important as well. The results of this study highlight the need for quality of care standards in longer-term post-treatment care by type of health plan.

7.2.1.3 Race

We identified two studies that assessed patient race in relation to risk of detection of disease recurrence (Gordon et al, 1992; Moul et al., 1996, #459) and another that assessed patient race and utilization of formal social support mechanisms (Guidry, 1997).

Risk of recurrence was assessed in a study of white and black men treated with local prostatectomy within the US military health care system (Moul et al., 1996, #459). All patients received bilateral pelvic lymphadenectomy, clinical and pathological staging, as well as follow up quarterly for the first year, bi-annually for the second and third year, and annually from year 4 onward. Prior to treatment, more black men than whites were

identified through elevated PSA tests (69.6% vs. 47.3%), had hypertension (62.5% vs. 35.2%), or had diabetes (17.0% vs. 5.3%). Black patients were also more likely to have positive tumor margins and higher tumor volume. Black prostate cancer patients were also more likely to experience detected recurrences, however, after adjustment for initial tumor characteristics (organ confinement, radical prostatectomy grade, pretreatment serum PSA, acid phosphatase, and surgical positive margins), the risk associated with black race was no longer significant ($p>0.05$). From these data, where equal access to early detection and treatment services were available, race was not a barrier to surveillance and recurrence detection. However, since minority cancer patients are more likely to be from a lower social class and to be uninsured than whites, race-associated barriers to surveillance care may exist in other health care settings.

7.2.1.4 Individual Context

Realized access to surveillance care includes multiple dimensions. Social support may play an important role in maintaining patient quality of life. Differences in the use of and reliance on informal social networks and social support by patient characteristics, such as race, have been reported (Burton, 1997). In one study of patients living with cancer, more Hispanic than White or Black cancer patients reported being asked to join a support group by their providers. Over 80% of these patients reported that support groups helped them cope with cancer by providing emotional support. When describing other sources of support, White patients were more likely to report that relatives were not helpful than black or Hispanic patients, and black patients were more likely to report that a spouse was not helpful than white or Hispanic patients (Guidry, 1997). The results of this study appears to support the hypothesis that use of formal and informal support may differ by patient race. Unfortunately, despite significant differences in factors that may affect participation and usefulness of support groups such as age, gender, marital status, educational attainment, household income, tumor site, and duration of cancer among the patients included in the study, the authors only presented univariate data. Thus, uncontrolled confounding is likely to play a large role in these results.

Some characteristics of individual context which may not routinely be available can be assessed through linkage with census data. For instance, in a study of extended follow-up of breast cancer patients entered into clinical trials, census data describing individual context--educational attainment in census tract, median family income, per capita income, and percentage of individuals living in census tract below the poverty line--were added to data describing patient clinical characteristics, duration of disease-free survival and survival. In univariate analyses all individual context variables were associated with overall survival and duration of disease free survival. In multi variate models, percentage of the census tract of the patients residence living below the poverty level predicted overall survival, and the percentage of census tract with a college education predicted disease-free survival. Interestingly, when these data were stratified by the race of the patient, individual context (percentage in census tract in poverty or without a college degree) was associated with disease free and overall survival only in white patients. The clinicial characteristics used to classify patients at entry into the trials, number of positive nodes and ER+ status, were associated with disease free and overall survival for both races. Thus, individual context appears to play a significant role in survival and disease-free survival following cancer treatment and these effects vary by patient race (Gordon et al., 1992). Although at the time of the trials, unmeasured factors associated with prognosis were likely to be balanced by treatment arm as a result of randomization, the authors did not state whether or not assignment to treatment arms was stratified by race. Since the authors report differences in treatment outcome for at least one of the trials (Crowe, 1990), this may affect interpretation of results.

7.2.2 Physician Barriers to Realized Access to Surveillance and Recurrence Care

Even though evidence-based guidelines for cancer surveillance do not currently exist, variability in the content of patient care point towards potential physician barriers to realized access to cancer surveillance. For instance, there is variability in frequency of testing and intensity of follow-up care has been reported after lung and colorectal cancer surgery (Virgo et al., 1995), and weak associations are also reported by geographic region (Johnson et al., 1996a; Johnson et al., 1996b).

Experience and training may play a role in explaining some of the variability of surveillance care. For example, in a study of practice patterns for colorectal cancer surveillance among members of either the Society of Surgical Oncology or the American Society of Colon and Rectal Surgeons, year of completion of training was significantly associated with the content of follow-up recommendations (Johnson et al, 1996). Development of evidence based practices guidelines may help to reduce some of this variability. Additional research is needed to describe the effects, if any, of other physician characteristics on barriers to this phase of care.

7.2.2.1 Patient-Physician Communication

Communication between providers and patients may also play a role in the outcomes of cancer surveillance and recurrence care. For instance, in a survey of cancer patients, Guidry et al reported that most providers do not encourage patients to join social support groups. However, most patients that did belong to support groups found

them useful, and over 90% would recommend them to other cancer patients. Although not all patients will find support groups useful, physician-patient discussion about formal and informal support as well as overall quality of life may be important components of cancer surveillance, in addition to the medical history, physical exam, and diagnostic testing. This may reflect a lack of attention to psychosocial care following cancer treatment.

7.2.3 System Barriers to Realized Access to Cancer Surveillance and Recurrence Care

We did not identify any studies that documented system barriers to cancer surveillance and recurrence care. As in other phases of care, it is possible that regular recall systems and coordination of care by multi disciplinary teams could reduce system barriers to care, if they do exist. These areas will be important for additional research.

7.3 SUMMARY

As advances in initial cancer treatment result in an increased the number of cancer survivors, realized access to surveillance and recurrence care will be increasingly important component of cancer care. There are, however, several methodologic issues which will need to be resolved prior to conducting systematic research and evaluation for this domain of care, including development of evidence-based guidelines, development and validation of multidimensional outcome measures describing patient quality of life following initial treatment, and the creation of data collection infrastructures for monitoring of outcomes.

Using crude measures of realized access, we identified several instances where the receipt of care varies by patient group which may reflect patient barriers to surveillance and recurrence care, including patient age, type of health insurance, and individual context. Physician characteristics associated with variability in surveillance care included training and physician-patient communication skills. System barriers have not been studied to date and we there are no interventions that we are aware of that have been developed to improve realized access to surveillance and recurrence care.

8.0 PHASE 5: END OF LIFE CARE

Despite many recent advances in cancer detection and treatment, in 1998 approximately 550,000 cancer patients will die from their disease (NCI, 1998). Unfortunately, many of these patients will suffer avoidable pain and distress (Cleeland et al., 1994, #727; Passik et al., 1998, #1014) indicating limitations in realized access to care. The current debate over physician assisted suicide further highlights limitations in the perceived quality of end of life care (Foley, 1997, #(589).

For the purposes of this review, we use the term end of life care to refer to the care of cancer patients with an extremely low probabilities of cure as they approach the possibility of death from their disease. While the balance of care in this phase is shifted away from curative care to an emphasis on palliation, many patients approaching the end of life continue to opt for receive aggressive treatment with a curative intent. In this latter situation, palliative care should be delivered alongside the curative therapy. This relationship between curative therapy and palliative care is illustrated in Figure 10. As illustrated in Figure 11, patients may enter this phase at any time following diagnosis of cancer, from recognition of widespread disease in phase two or after failure to respond to treatment of recurrence in phase four.

In this section, we identify gaps in the assessment of the quality of end-of-life care which need to be addressed prior to being able to fully characterize access problems, develop a working definition of realized access to end of life care, and describe patient, physician, and system barriers to end of life care in cancer. We also identify areas for additional research in this phase of cancer care, and describe recent efforts to improve patient access to end of life care. Finally, we summarize recommendations for improving realized access to end of life care.

8.1 METHODOLOGICAL ISSUES

In attempting to describe barriers to this portion of cancer care, we identified three critical outstanding issues which need to be addressed prior to being able to fully characterize access problems: the practical implications of differences in the philosophy between traditional medicine and palliative care, the lack of a comprehensive definition of end of life care, the absence of multi-dimensional outcome measures for realized access for end of life care, and the lack of data on effectiveness of interventions to improve aspects of care at the end of life.

Underlying the structure and delivery of end of life care is a philosophical distinction between traditional medicine and palliative care. Under the traditional medical model, the main goal of therapy is maximizing patient survival through the cure of disease (curative care). The main goal of the palliative care model is maximizing patient comfort and quality of life (Fox, 1996; #729). Meeting this goal requires knowledge of the individual patient, their subjective complaints, their interaction with their environment, and their preferences for outcomes.

Goals of the two models of medical care can, and ideally, should coexist throughout the cancer care process. Attention to issues such as symptom control, patient quality of life and general well-being, and patient satisfaction only at the end of life implies that these issues are not as relevant to care earlier in the natural history of disease. Similarly, exclusive attention to palliative care at the end of life implies that curative care is inappropriate for, or not desired by, these patients. Neither of these extremes are true, and failure to integrate curative and palliative care over the entire disease continuum, in and of itself represents a barrier to quality care throughout the cancer care pathway.

The conflict between these two models of care is exemplified in the design of clinical trials of treatment for recurrent or metastatic cancer, where the probability of a sustained response to therapy is low. Although palliation should be considered a major goal such therapy, these studies typically use tumor response to therapy or disease-free survival, rather than patient quality of life, satisfaction with care, or palliative endpoints to assess treatment outcomes. Although more recent studies of treatment for recurrent or metastatic disease are beginning to use quality of life endpoints to assess treatment outcomes (e.g., Tannock et al., 1989; 1996), they are likely to be secondary endpoints, and are not used to develop sample size estimates. In these situations, undetected differences in patient quality of life, satisfaction with care or palliation across treatment arms may be attributable to insufficient sample size. Thus, even though active or life-sustaining therapy may lead to improved palliation of pain or other symptoms, use of crude measures, such as time to disease progression, severely limits the ability to draw conclusions about other domains.

Although several guidelines have been developed to address management of specific aspects of end of life care, such as pain control (AHCPR, 1994; Levy, 1996, #731; WHO, 1990), management of specific symptoms such as anxiety, anorexia, or cachexia (Bruera, 1997, #726), or management of generalized patient distress (NCCN, 1998), these recommendations do not provide a comprehensive definition of end of life care.

Despite the absence of a consensus definition of end of life care for cancer patients, the American Society of Clinical Oncology Task Force on Cancer Care at the End of Life (1998 #456) has developed a set of principals to guide end of life care: 1) cancer care at end of life should be based on a ongoing relationship between the patient and the primary oncologist and a physician with training in end of life care; 2) cancer care should be responsive to patient wishes, or in situations where the patient is a child, parent wishes; 3) end of life cancer care should include adequate provider communication with patient and family; and 4) cancer care should be focused on maximizing patient quality of life through attention to physical, psychosocial, and spiritual needs of the patient and family (J Clin Oncol, 1998, #456).

Thus, any working definition of realized access to end of life care must be highly individualized for each patient and measured from the patient perspective using outcome measures such as satisfaction, quality of life, and patient utility (also referred to as patient preferences). Effective symptom control, care giver support, and patient participation in decision making about care are among the critical domains also suggested for measuring access to quality of care at the end of life (Lynn, 1997; Donaldson and Field, 1998).

Development of appropriate outcome measures for end of life has many inherent methodologic challenges including selection of the most salient domains, relevance for patients that choose to seek aggressive therapy as well as those that choose a non-curative approach, ability to integrate patient and family preferences for care, identifying the appropriate period for initiation and termination (e.g., inclusion of bereavement) of measurement, and measuring care experiences across multiple settings. Measures of patient outcomes should also be sensitive to changes in preferences associated with disease progression (Gaskin et al., 1998). Finally, since patients at the end of life rate their quality of life as higher than care givers do (Rothman, 1991), use of proxy respondents to assess patient outcomes may not be appropriate.

Several groups (including Last Acts, Center to Improve Care of the Dying) are currently developing outcomes and evaluation tools for palliative care, although they are not focusing explicitly on patients with terminal cancer. As these projects may be in preliminary stages, specific information on these measures is unavailable. This work is funded by Andrus Foundation, AHCPR, the Nathan Cummings Foundation, and the Robert Wood Johnson Foundation. This will be an extremely important area for future research.

8.2 BARRIERS TO END OF LIFE CARE

This next section describes patient, physician, and system barriers to end of life care and interventions to improve access to care. As described in Figure 12, realized access to end of life care is affected primarily by selected characteristics of the patient, cancer care providers (including the palliative care team), provider and provider-patient communication, and the medical care environment.

8.2.1 Patient Barriers to End of Life Care

Several domains in the patient and individual context arenas are particularly relevant in discussing barriers to end of life care including poor understanding of patient decision making at end of life; patient knowledge, attitudes, and beliefs about cancer; and a lack of or inadequate health insurance.

8.2.1.1 Patient Decision Making

At all phases of care, patients are more willing than providers expect to undergo aggressive treatment with high morbidity and low expected benefits (Slevin et al., 1990; Meystre et al, 1997). Related to this, one of the most critical patient barriers to end of life care is the reluctance to acknowledge terminal disease and to turn to a focus on palliation. This may be reflected in pursuit of curative therapy despite high treatment associated morbidity and very low probabilities of benefit. For example, to assess treatment preferences at the end of life, McQuellon and colleagues surveyed breast cancer patients using scenarios describing advanced metastatic disease. The majority of these patients indicated that they would prefer aggressive treatment, and that between 54% and 78% of patients would elect to initiate treatment even without symptoms of metastatic disease (McQuellon et al., 1995). Such patients may not be adequately prepared to discuss their prognosis, participate in effective communications about treatment options, and develop informed treatment preferences.

That this does occur is suggested by a recent study Weeks and colleagues noted that terminally ill patients who over-estimated their life expectancy were more likely to chose aggressive therapy than those who more accurately assessed their prognosis (1998).

8.2.1.2 Knowledge, Attitudes and Behaviors

Patients' attitudes towards the sick role can act as barriers to care. For instance, if patients feel that being a "good" patient requires stoicism, then they are at risk of being under-recognized and treated for symptoms such as pain, nausea, or depression. Other beliefs, such as concern about becoming addicted to pain medications can constitute barriers to care (Ward et al., 1993). For example, in one study of the adequacy of analgesia (as calculated from patient self report on the Brief Pain Inventory (BPI) and a Pain Management Index), patients that were under-medicated were more likely than patients appropriately medicated to be concerned about opioid addiction, developing tolerance to analgesics, side effects of pain medication, being a good patient, and that the acknowledgment of pain signifies disease progression (Ward et al., 1993). Older patients, women, and patients with less education were more likely to be concerned that being a good patient meant not complaining of pain. Patients with less education were also more likely to feel that pain is an inevitable part of cancer (Ward et al, 1993). Some of these differences may be cultural—more Hispanic patients have reported being concerned about taking too much analgesic medication and being concerned about side effects than Black patients (Cleeland et al, 1997). These concerns have been reported elsewhere (Rimer et al., 1987; Levin et al, 1985). All of these factors may lead to under-treatment of pain.

Patients may also not express their symptomatic concerns to their physicians. For example, Passik et al found that while 36% of the cancer patients exhibited symptoms of clinical depression, fewer than 3% of patients were seeking care from a mental health professional (Passik et al., 1998). Patient reluctance to communicate symptoms is a barrier to the ability of providers to recognize these symptoms and ensure quality cancer care. Communication may also be complicated by gender, social class, cultural, or ethnic differences between patients and treating physicians. Patients may also be reluctant to discuss symptomatic concerns with their physicians for fear of diverting provider attention from the pursuit of cure (Diekmann et al, 1989; Ward et al, 1993).

Patients in vulnerable populations (ie, elderly, low social class, minorities) may also be less likely to have a regular clinician with whom they are comfortable discussing end of life issues. Reluctance to seek care for common symptoms of terminal illness may be further complicated by cultural beliefs, such as *fatalismo*, or the belief that one's fate cannot be altered.

Additionally, fear and distrust of the medical profession may lead some patients to think that a treatment strategy exclusively employing palliative care is a means for physicians to hasten death. Patients and their families may lack information or sources of information about palliative care. In patients with little knowledge of cancer or its detection (and therefore more likely to be diagnosed with advanced disease), debilitating treatment may occur before a single conversation has taken place about terminal care.

8.2.1.3 Insurance

Patients in vulnerable populations may also lack or have inadequate health insurance coverage, which may further limit access to aspects of end of life care. In hearings sponsored by the American Cancer Society, patients these individuals were described as not being able to afford outpatient nursing, nutritional supplements, or pain medication (Underwood, 1995). However, we did not find any studies specifically addressing outcomes of end of life care for individuals without health insurance compared to similar individuals with health insurance or by different type of health insurance.

Even for patients that have insurance, the costs of end of life care may be burdensome. As part of the SUPPORT study, Covinsky et al (1994) assessed financial and family care giving burden in relation to the treatment seriously ill patients. The vast majority of patients in this study had health insurance (96%), yet more than half of the families reported at least one severe burden ranging from loss of family savings, loss of income, to changes in future educational plans or employment status. Out-of-pocket costs of pain, and other medications are likely to be a barrier for all but the wealthiest groups of patients.

8.2.1.4 Individual Context

There have been several reports linking social support or family presence to cancer mortality and treatment decision-making (Yellen and Cella, 1995). Social supports are clearly a key contextual factor affecting end of life care, we did not find any studies explicitly assessing the role of social support, community support, or the family in realized access to this phase of care. This will be an important area for future research.

8.2.2 Provider Barriers to End-of Life Care

Despite the use of interdisciplinary teams in end of life care, physicians play the role of gatekeeper to services, thus, most of the barriers to end of life care are associated with physicians. They hold primary responsibility for recognition and treatment of common symptoms of terminal cancer, attention to psychosocial care, effective physician-patient-care giver communication, referral to specialists and/or hospice care, and maintenance of an ongoing relationship with the patient and a multi disciplinary team of specialists.

Primary among provider barriers to realized access to quality end of life cancer care is the ability to recognize an individual patient at the end of life. Although population data may be available for median survival or median disease free survival for most cancers, the application of these data to the individual patient is complex. By definition, some patients with similar clinical profiles will have longer and some will have shorter survival when compared with the mean or median. Yet physicians are asked to certify that patients have a six-month expected survival and may be held accountable when these values are longer than expected. Other physician barriers are summarized below.

8.2.2.1 Symptom Management

Patients with metastatic or recurrent cancer are likely to experience a variety of symptoms. The most frequent is pain—pain is estimated to affect as many as 80% of patients with advanced disease (ref). Uncontrolled pain can cause suffering, decreased ability to sleep, reduced physical functioning, and diminished patient quality of life. Thus, pain control represents an important component of quality of end of life care in cancer patients and one where there are management guidelines (AHCPR, WHO) and effective pharmacologic strategies (Levy, 1996).

Unfortunately, providers—primary care physicians, oncologists, and nurses-- may under treat cancer pain (Levin et al., 1998; McCaffery and Ferrell, 1995). For example, Cleeland et al. compared patient reported pain, treatment for pain, and physician assessment of pain in over 1300 recurrent or metastatic cancer patients (Cleeland et al., 1994). Patients completed several pain assessment scales and their physicians provided information about the patient's treatment for pain, described the patient's performance status, assessed patient pain control and the interference of pain on activity and sleep. The investigators computed a pain management score using the World Health Organization's guidelines for management of pain in cancer and congruence between patient's level of pain and current pain therapy. They found that 42% of patients that had pain were inadequately managed. Physician-patient discrepancy in the rating of patient pain was closely associated with inadequate pain management (Cleeland et al., 1994). McCaffery and Ferrell (1994) also reported that 16% of registered nurses surveyed in 1994 believed placebos could be used to determine if patient-expressed pain is real.

Moreover, as noted above, the elderly, women, and minorities may be more likely to have inadequate pain management (Cleeland et al., 1994; Bernabei et al, 1998; Cleeland et al, 1997). In a follow-up study designed to address treatment for pain in minority populations, Cleeland et al (1997) reported similar results. Minority patients were more likely to be under medicated, and report needing more medication than their physician provided than non-minority patients; and Hispanic patients were more likely to have lower levels of pain relief than Black patients. Recognition of pain and its management appears to be less than optimal for all patients, and particularly for the elderly, women, and minorities.

In a survey of physicians affiliated with ECOG, self-reported barriers to pain management included concerns about side effect management, patient tolerance to analgesia, and regulatory scrutiny of narcotics prescribing (Van Roenn et al., 1993).

8.2.2.2 Psychosocial Care

The focus on disease management may overshadow the provider's attention to disease-related psychological distress and depression. Further, side effects of treatment or increasing symptoms of disease, such as a loss of appetite or inability to sleep, are difficult to distinguish from symptoms of depression. Passik et al. (1998), described a large study evaluating physician's ability to recognize depression in over 1,000 cancer patients. Following an office visit, cancer patients were screened for depression and physicians were asked to evaluate each patient for depression and rate the patient's symptoms. Physician and patient scores were similar, but most of the agreement was where both patients and physicians both indicated that the patient did not have depressive symptoms. In the 159 cases where patient scored moderate to severe depression, physicians only identified 20, or 13%, of these patients (Passik et al., 1998). We were unable to find data describing the degree to which cancer patients with depression actually receive treatment, are referred to support groups, receive family counseling or other psychosocial care.

Unrecognized depression, its treatment, or utilization of other psychosocial care may be even more limited for under served populations where patients are more dissimilar from treating physicians (ie, knowledge of cultural norms may increase difficulty in recognizing depression). Even for those patients that are recognized as suffering from depression or in need of other psychosocial support, under treatment may result from a lack of coordinated care or non- coverage of mental health services, or among the uninsured financial burdens of such care.

8.2.2.3 Provider-Patient Communication

Effective end of life care requires frank and empathetic discussion of the expected course of illness. Physicians and other providers may need to take an active role in encouraging patients to discuss issues such as advance directives with their families. Yet, as a group, physicians may be ill-prepared for this task. Historically, physicians have not disclosed the diagnosis of cancer to patients. As late as 1960, Oken reported that as many as 90% of physicians had a tendency not to tell the cancer patient of their diagnosis (Oken,1961). Even though most physicians are now discussing cancer diagnosis and prognosis, patients continue to report perceptions of their disease or treatment goals that differ from their physicians (Mackillop et al., 1988; Mosconi et al., 1991; Weeks et al., 1998).

A study of seriously ill patients in teaching hospitals found that physicians infrequently discuss advance directives (SUPPORT, 1996). When they are discussed, there is considerable disagreement to the interpretation of the discussions between physicians and patients. Further, even when some patients explicitly requested that CPR be withheld, do-not-resuscitate (DNR) orders were not written in the patient's chart (SUPPORT, 1996)

Thus, physician-patient communication, or lack thereof, has serious implications for how patients are treated. In the SUPPORT study, Weeks et al (1998), described the effect of discrepancies between cancer patient's and their physician's estimates of expected survival on treatment preferences, choice, and outcomes. In 82% of physician-patient pairs, patients had higher estimates of 6-month survival than did their physicians. In situations where the discrepancy between patient and physician estimate of expected survival was the highest, patients were 8.5 times more likely to favor curative over palliative care. Favoring life extending, curative therapy was associated with receipt of aggressive treatment. For the group of patients as a whole, survival did not differ for patients who favored life-extending therapy and patients that favored palliative care. It is possible that knowing that receipt of curative intent therapy would not improve survival may have altered decision-making. This is a critical area for additional research.

Physicians also serve as gatekeepers to hospice care, coordinated delivery of services for the terminally ill, by certifying that the patient has expected survival of less than six months. However, Christakis and Escarce (1996) recently reported that most hospice patients live for less than two months indicating that physicians may delay in referring patients for care. Delay in hospice referral may be due to the lack of clear indication that a patient has expected survival of 6 months or less, lack of physician knowledge of hospice services, poor communication with the palliative care team, or physician reluctance to engage in uncomfortable discussions or feelings that discussing terminal disease may eliminate patient hope.

Physician reluctance and discomfort in discussions of disease progression or expectations from treatment may be even greater when the patient is dissimilar—elderly, female, member of a low socioeconomic class or minority group (Fox, 1994; Waitckin, 1986).

Communication issues are not limited to physicians. Even though the most basic nursing philosophies are consistent with attention to patient quality of life, satisfaction, and preferences for treatment, communication between nurses and patients may also introduce barriers to end of life care. In a survey of hospice patients with cancer and their nurses, Meystre et al. (1997) reported that, despite agreement between patients and nurses on patient performance, patients were more likely to describe rescucitation, operation, chest radiography, and other procedures as acceptable interventions than were their nurses.

Hansen and colleagues recently published an overview of clinical interventions to change **patient care at the end of life via the use of advance directives** (Hansen et al., 1997). They reviewed studies that targeted patients, physicians, or both and found that even in cases where increased discussion of patient preferences for end of life care took place, changes documented in the medical record were limited. Thus, additional research in provider-patient communication must include all care providers and an assessment of behavioral changes in care delivery and their impact on patient outcomes.

8.2.2.4 Provider-Provider Communication

As components of an effective end of life care team, good communication among providers is critical. Unfortunately, this process may be less than optimal. As part of the SUPPORT study, study nurses communicated information on expected prognosis to patients and information about patient preferences to physicians; however, physicians reported that they received information on patient preferences in less than 40% of cases (SUPPORT, 1995). Additional research using interactive training for primary oncologists and palliative care teams will be important in addressing this barrier.

8.2.2.5 Provider Training

We identified potential gaps in education and training for all members of end of life care team, including primary care physicians, oncologists, nurses, and social workers. In a recent GAO report (GAO/HEHS-98-128), medical schools and residency programs were surveyed to determine availability of course work on palliative care between November 1997 and March 1998. Approximately 20% of medical schools did not offer classroom instruction in palliative care for chronic illness, symptom management for chronic illness, symptom management for terminal illness, or interdisciplinary health care for end of life. For those schools that did offer instruction, these topics were required.

Thus, attention to end of life care appears to be increasing in medical schools. For all topics, instruction has been added in at least 10% of schools. More than one-third of schools surveyed indicated that students need more exposure to patients with terminal illness, pain and depression due to chronic or terminal illness. Close to half of schools that responded to the GAO survey indicated that more training is needed in a hospice environment and as part of an interdisciplinary team providing end of life care. Recognition of these issues may lead to increased integration of end of life care in the medical school curriculum.

Although the number of residency programs that teach end of life care has increased from about 38% in 1994 to 50% in 1996, not all specialties have requirements for specific palliative care topics. Further, teaching of end of life care was variable among residency programs. In a 1996 American Medical Association (AMA) survey of physician residencies, among residencies in family medicine, internal medicine, or geriatric medicine over 80% of programs teach end of life care. However, in the specialities of pain management, hematology and oncology, oncology, urology, and pediatric oncology fewer than 65% of residencies teach end of life care (range 35%-63%) (JAMA, 1997).

Increases in the number of medical schools and residency programs incorporating end of life care in their curriculums is important for future physicians. Continuing Medical Education (CME) is the major mechanism for training practicing physicians. The GAO reviewed the AMA's database of accredited CME programs and found few courses that address palliative care. Also, few CME courses are available for doctors of osteopathy (GAO/HEHS-98-128). As the primary gatekeepers to end of life care, physician training will be a critical component for improving access to end-of-life care for all patients.

Variation in content and depth of curricula in end of life care in the training of nurses has been described as well (ANA, 1996). Nursing students are also reported to have limited supervised care with terminally ill patients (Dukes et al., 1995). Social workers may participate in the end of life care process by assisting with screening and assessment of the patient and family for psychological, social, and financial need. They are also likely to participate in helping patients and families access available services. However, education and training explicitly for end of life care in cancer is not always included in social work curricula.

Few educational or training programs have been designed explicitly to teach these care providers how to interact in multi disciplinary teams. We did not find any information describing the integrating of multi disciplinary teams in end of life care for cancer patients.

8.2.3 System Barriers to End of Life Care

The main health care system barriers to end of life care are rapid changes in the health care delivery system(s) over the past decade, limited availability and coordination of personnel or facilities, and fragmented coverage of care by insurers.

8.2.3.1 Changes in health care delivery systems

As part of the rapid growth in managed care within the past decade, plans of all types now aggressively compete to attract healthy patient populations, including offering benefits such as health club membership or preventive health care services. These same market forces are unlikely to result in specific benefits for chronic disease and end of life care (e.g., bereavement counseling) or drive innovation in the delivery of end-of-life care. The GAO recently reported relatively high rates of monthly enrollee turnover for Medicare benefitiaries receiving care through managed care (GAO/HEHS-98-142). Incentives to maintain quality care at the end of life may be dimenished in plans with high patient turnover. Some managed care organizations may approach hospice care only as a means to reduce expenditures. As more Medicare and Medicaid patients receive end of life care through managed care organizations, these issues will increase in importance.

8.2.3.2 System-Based Structural and Reimbursement Barriers to End of Life Care

Hospice care is one structure of care that can provide a coordinated and multi disciplinary approach to end of life care for cancer patients. Hospice is an umbrella term commonly used to describe the coordinated delivery of many services for the terminally ill patient and their family, and includes nursing care, physician services, homemakers and home health aides, physical, occupational, and speech therapy, and psychological counseling and social services. Bereavement care is also available for families (National Hospice Organization, 1998).

Outside of an organized hospice system, patients may receive care in a variety of settings including emergency rooms, acute care hospitals, doctor's offices, nursing homes and 24-hour home based nursing care. As part of the Survey of the Last Days of Life (SLDOL), Brock and Foley reported that more than 15% of all patients aged 65 and over had lived in three or more sites during the last 90 days of life. The impact of these multiple transfers on patient and care giver quality of life and well being, while unknown, is unlikely to be beneficial. Additionally, patients with multiple transfers are unlikely to have the same medical team attending to their needs, and patient and family wishes about advance directives may be less likely to be communicated. For instance, for patients that moved from the nursing home to the hospital, written advance directives were transferred with the patient in only 35% of cases (Danis et al., 1991). For patients that are initially hospitalized, ineffective discharge planning may leave patients without organized home care. This may result in problems with eating, mobility, pain control, or management of medications (Yost, 1995).

The availability of palliative care teams, nursing home beds, hospice beds, home care, or visiting nurse programs may be limited in some locations. Patients living in less heavily populated rural settings may not have the same options as similar patients in urban areas and may face serious limitations in transportation. Providers in non-hospice settings may not be well trained in pain management or other symptom control critical to the maintenance of patient well-being. Additionally, in situations where palliative end of life care resources do exist, they may not be organized for ease of patient utilization or physician referral. Patient distress may also be higher in situations were care is fragmented.

Medicare and Medicaid pay for the majority of end of life care. Each of these programs contains barriers for end of life care. For instance, Medicare reimbursement of medical services is typically broken into inpatient care and outpatient care (Part A and Part B), and does not cover most prescription medications under FFS plans. This can be a strong barrier for the terminal cancer patient choosing to die at home, since Medicare does not reimburse for outpatient oral analgesics, but will reimburse for pain management at an inpatient facility. Many managed care plans, however, include prescription plans as part of the benefits package. For patients receiving care through managed care plans, prescription medications included on plan formularies may be accessible.

There are also financial incentives which may limit patient referral for hospice care. For example, Medicare reimburses providers of hospice home care or nursing home care following an acute hospitalization at lower rates than similar care in non-hospice settings (United Hospital Fund, 1998).

Medicaid, the state-based health insurance programs, provides end of life hospice care for the impoverished in 43 states. Although state programs generally adopt the Medicare standard, the level of services offered varies by state. Additionally, the eligibility for Medicaid varies from <75% of the federal poverty level to >200% of federal poverty level. Thus, access to hospice care for vulnerable populations is variable through Medicaid.

The majority of employer sponsored health insurance programs offer some hospice benefits (Center for Survey Research, KPMG Peat Marwick, 1997). Although more than three quarters of workers covered by FFS and managed care plans were eligible for hospice benefits, 69% of workers covered by FFS plans versus 58% or workers covered by managed care plans were eligible for hospice benefits that included emotional, spiritual, or psychological support for patient and family. Loss of employment due to illness (and therefore employer contributions to the cost of health insurance) may limit the usefulness of hospice benefits for individuals with terminal disease. We found little information on hospice care for individuals without health insurance.

Characteristics of the hospice itself may also introduce barriers to end of life care. In order to participate in a hospice program, the patient must reject life-sustaining and curative treatment. Considering that most patients may be reluctant to acknowledge terminal disease, let alone reject life sustaining treatment, hospice care may not even be a consideration in their treatment decision making process. Further, the use of chemotherapy or radiation therapy is not always associated with curative goals. For instance, low doses of chemotherapy and radiation therapy for bone metastases are used to palliate symptoms. Depending on how these treatments are classified, for patients entering hospice care, access to these types of symptom management may be limited.

In 1996, hospice programs provided care for about 50% of cancer patient deaths (JCO, 1998). Very little information is available on the types of care received by the remaining 50% of dying cancer patients. Comprehensive data describing palliative care delivery to cancer patients seeking curative therapy toward the end of life has not been reported. For cancer patients without health insurance or from other traditionally vulnerable populations, it is likely that end of life care is suboptimal (Mor et al., 1992).

The existence of unstructured, fragmented care at the end of life implies that much of the care giving burden may fall on families and informal, unpaid care givers. The indirect costs associated with time loss from work in caring for a cancer patient at the end of life have not been well described, but they are likely to be substantial. This will be an important area for additional research.

8.3 INNOVATIVE STRATEGIES TO IMPROVE ACCESS TO END OF LIFE CARE

In the past several years, there have been several innovative projects to increase patient and physician awareness of issues in end of life care. There have also been several projects aimed at reducing system barriers to end of life care. Additionally, in 1997, Congress passed the Assisted Suicide Funding Restriction Act which authorized the Public Health Services to support public and non-profit organizations in increasing knowledge of pain management, education and training of health care providers in palliative care, improving access to hospice, and evaluation of different health care delivery systems in the quality of palliative care.

A recent Institute of Medicine project "Approaching Death: Improving Care at the End of Life" (1997) and a review by Wilkinson and colleagues (1998) contain comprehensive reviews of strategies to enhance end-of-life care. In this section we highlight several of these projects.

8.3.1 Projects Based on Reducing Patient Barriers to Care

The **S**tudy to **U**nderstand **P**rognoses and **P**references for **O**utcomes and **R**isks of **T**reatment (SUPPORT) funded by Robert Wood Johnson was a multi center study conducted in teaching hospitals to improve decision making and communication about end of life care (The SUPPORT Principal Investigators, 1996). Although the intervention to improve end of life care did not appear to affect the number of advance directives and other outcomes of interest, this was the first study devoted to collecting these types of data. Further, data collected as part of this study provide insight into physician and patient perceptions about terminal illness and decision making about end of life care (Weeks et al., 1998).

8.3.2 Projects Based on Reducing Physician Barriers to Care

Caring for the Dying, a two-part series completed by Christine Cassel and Linda Blank to address competencies and attitudes of clinicians caring for dying patients is an example of an educational intervention for end of life care. This series was supported by the American Board of Internal Medicine and has been distributed to Internal Medicine program directors (Steel, 1997). Information on the effectiveness of this approach in changing physician attitudes or on the care of patients is currently unavailable.

Trowbridge et al (1997) reported on an intervention to improve physician's treatment of cancer pain in the outpatient setting. All patients completed pain assessments with evaluation of pain relief from therapy. Patients were randomly assigned to have their assessments attached to the front of their chart. Inclusion of patient pain assessments led to significant increases in prescribed analgesia from the treating physician.

Janjan et al (1996) used a role model program in a workshop setting to increase knowledge of cancer pain management in physicians, nurses, and pharmacists. Improvement in attitudes and knowledge were reported immediately following the workshop as well as a year following the workshop (Janjan, 1996). This research was supported by the Texas Cancer Council and the National Cancer Institute. Evaluation of the effectiveness of this program on improving pain management in cancer patients has not been reported.

An evaluation of the US Medical Licensing Examination in testing student knowledge in end of life care issues is currently under way. This will include the development of a method of evaluating student performance. No data are currently available from this project.

The American Academy of Hospice and Palliative medicine has also developed a self- study course specific to palliative care. Evidence for effectiveness of this course in improving physician knowledge is currently unavailable.

8.3.3 Projects Based on Reducing System Barriers to Care

Recent restructuring of the Veterans Health Administration (VHA) has led to reorganization of their end of life care services. The VHA routinely provides hospice and palliative care services as well as nutritional support, social work, psychological counseling, inpatient and outpatient rehabilitation, and lodging for patients receiving extended treatment (Wilson and Kier, 1998). The charts of patients with cancer and three hospital admissions or one intensive care admission within a six month period are routinely screened for evidence of hospice admission or an individualized plan of care that includes discussion of resuscitation, evidence of symptom management, depression assessment, and referral for care giver support. Wilson and Kier (1998) reported that average compliance with these guidelines is 52% nationally, with a range of 32 to 82%. While promising, we did not find information describing the impact of this patient care oversight on patient outcomes.

The Joint Commission on the Accreditation of Heathcare Organizations (JCAHO), which is the accrediting body for hospitals and other health care organizations, recently introduced requirements for compliance with cancer pain management guidelines in metastatic lung, colorectal and breast cancer (JCAHO, 1996). We did not find data on the number of organizations compliant with these guidelines or changes in practice in these organization associated with the introduction of these requirements.

The Medicaring National Demonstration and Evaluation Project funded by Robert Wood Johnson Foundation is a program for delivery of multi disciplinary and comprehensive care for patients with terminal disease. Developed explicitly for advanced congestive heart failure and chronic obstructive pulmonary disease, unlike cancer care in the hospice, patients do not have to explicitly reject treatments that might sustain life (Medicaring, 1998; Lynn and Wilkinson, 1998, #1084). To date, there has been no evaluation of the effectiveness of this program on end of life care. If effective in improving patient outcomes, this model could be extended to cancer patients.

The Alabama Black Belt Cancer Linkage Initiative helps to coordinate cancer care for under served patients in rural Alabama. This National Cancer Institute funded project assists in arranging appointments with cancer specialists, arranging transportation for treatment, and linking cancer specialists with community physicians (Bryant, 1993). The effectiveness of this program in removing system based barriers to end of life care and improving care at the end of life also has not been reported.

As reported by the GAO, the Health Care Financing Administration (HCFA) is authorized to support demonstrations by states to obtain waivers and use Medicaid funds for home health care, attendant care or community living arrangements as mechanisms to improve end of life care in areas that are not normally covered (GAO/HEHS-98-128).

8.4 SUMMARY

Assessment of realized access to end of life care in cancer is complicated by many factors including the incompatibility of underlying philosophies of traditional medicine and palliative care, the lack of a comprehensive definition of end of life care, the lack of outcome measures to assess realized access to end of life care, and the lack of data on effectiveness of interventions to improve end of life care. Much work is needed in these areas.

We identified several key patient factors associated with barriers to high quality end of life cancer care including unwillingness to acknowledge end of life, limited knowledge of end of life care, incomplete communication with cancer care providers, and limited health insurance coverage. Providers play a critical role in ensuring access to cancer care at the end of life and are responsible for recognizing and treating symptoms of terminal disease, communicating with patients about disease and its treatment, and managing the overall process of end of life care. Although we found serious limitations in all of these areas, increased attention to education and training may begin to address these barriers.

Finally, the health care system itself introduces additional barriers to quality care at the end of life. Changes in financing and delivery of care place cancer patients at a distinct disadvantage at the end of life. Coordinated delivery of services at the end of life are available mainly through hospice care, but because of late referrals, patients may not benefit fully; patients are also forced to give up options for curative or other aggressive treatments to be eligible for hospice services. For patients that receive care through different avenues, that care may be inadequate, and the burden for that care may fall on the family and other informal care givers.

There appear to be many interventions in the early stages of development with the goal of improving the quality of care at the end of life. As these programs develop, it will be essential to submit them to rigorous

evaluation of patient outcomes aimed at improving the satisfaction with end of life care and quality of life among individuals with terminal illness.

9.0 SUMMARY

In this review we have used a conceptual framework for evaluating patient, provider, and system barriers to realized access to cancer care. Pervasive barriers to accessing quality care across the entire spectrum of cancer services. Some of these barriers cut across all phases of care, while others exert a stronger influence in a specific portion of the care continuum. For instance, several patient barriers, including age (and comorbidity), lack of health insurance, social class, race/ethnicity, and knowledge, attitudes, and behaviors play an important role in access to almost all phases of care (See Table 9.1). These are also the patient domains that have been most studied. Of note, data strongly suggested that many these patient barriers operate through the common pathway of low social class; and that race/ethnicity effects are often explained by culturally mediated norms and beliefs. These are intriguing areas for further research.

Some patient factors demonstrated effects on only selected aspects of care. For instance, we did not find strong evidence that gender was associated with barriers to primary and adjuvant treatment; but gender was described as playing a role in realized access to regular, on-going screening and diagnostic work-up and staging. Also, acculturation and language was only noted as a barrier to screening services. However, it is not clear if the lack of apparent effect of these (and other) variables on access to other phases of care reflects a true absence of effect, or is a function of a lack of investigation. Given the paucity of research in these, and other domains, the latter explanation is most likely. Research to fill such knowledge gaps will be important to achieving a full understanding of barriers to care.

Although provider characteristics are increasingly the focus of health services research, there are limited data specific to oncology providers. As gatekeepers to cancer services, oncology specialists are primarily responsible for diagnosing, describing options, and recommending therapeutic approaches. Not surprisingly, physician-patient communication was described as the most persistent barrier in almost all phases of cancer care (See Table 9.2). The next most frequently described provider barrier was knowledge, attitudes, and behavior. Physician-physician communication was also described as a barrier, particularly at care transition points, such as from primary care physician to oncologist after a cancer diagnosis is made, and end of life care where the oncologist shares patient responsibility with a multi-disciplinary team. Physician age and training were noted as barrier to some cancer treatments, and gender was implicated as being important for initiation and continuation of cancer screening. Barriers associated with all of these domains may be amenable to change through training. For example, communication skills are considered a “teachable” skill.

At a health care system level, several aspects of the organization and structure of care (e.g., managed care vs other delivery systems) acted as pervasive barriers to realized access to cancer care (See Table 9.3). A related system issue was the absence of comprehensive, routinely collected tumor registry data describing patient and tumor characteristics, adjuvant care, participation in trials, and recurrences. Without these data, assessment of realized access to cancer is limited.

Other system factors were barriers to more limited aspects of care. For instance, the absence of widely disseminated evidence-based practice guidelines may limit end of life care. The presence of conflicting professional recommendations about age of initiation and cessation of screening may also limit adherence to regular screening.

Very few studies included comprehensive outcome measures or examined multiple factors within a domain and across patient, physician, and system levels, so it is not possible to quantitate the relative contributions of individual factors to realized access to care. This will be an important next step in access research.

In addition to reviewing barriers to care, we also identified an important methodologic barrier to the assessment of realized access to care, the absence of defined outcome measures for each phase of care. As a result, throughout this report we have suggested phase-specific exemplar process and outcome measures of access to care (See Table 9.4). For example, in phase 1, an intermediate outcome of for regular mammography screening could be the number of annual mammograms (and clinical breast examinations) among age eligible women with one or more prior screens who have been receiving care for more than one (or two) years. This measure could then be stratified by patient characteristics to identify groups of women with sub-optimal access. Similarly, this measure could be used to assess the performance of physician groups and systems of care. Patient-rated quality of life and preference outcomes could also be routinely be measured over the course of cancer care to describe patient populations receiving insufficient care, and identify areas where patient concerns are not being adequately addressed.

Despite several decades of health care reform and cancer control research targeted to improving access to care, pervasive inequities in, and barriers to, cancer care persist. All interactions with the health care system represent a

potential opportunity to decrease avoidable cancer morbidity and mortality, particularly for populations at risk for poor cancer outcomes. At present, this goal remains elusive.

Table 9.1. Summary of Patient Barriers to Realized Access to Cancer Care

	Phase I: Asymptomatic Screening		**Phase II: Evaluation of Abnormal Screening**		**Phase III: Treatment**		**Phase IV: Surveillance**	**Phase V: End of Life Care**
	Initiation	**Interval**	**Follow-up of Abnormal**	**Diagnostic Work-up and Staging**	**Primary and Adjuvant Treatment**	**Randomized Controlled Trials**		
Patient Age	X			X	X	X	X	
Gender		X		X				
Health Insurance Uninsured Type of Insurance	X	X	X		 X	X	 X	X
Social Class Education Income	 X X	 X X	 X		 X			X
Race/Ethnicity	X	X	X	X	X	X		X
Knowledge, attitudes and behavior	X	X	X			X		X
Culture, language	X	X						
Individual Context Family, social Support Neighborhood income Neighborhood education	 X X X	 X X			 X		 X X X	

*Data for treatment trials do not show clear association between race and enrollment in RCTs. Data for chemoprevention trials indicate that African Americans are less likely to enroll in RCTs.

Table 9.2 Summary of Provider Barriers to Realized Access to Cancer Care

	Phase I: Asymptomatic Screening		**Phase II: Evaluation of Abnormal Screening**		**Phase III: Treatment**		**Phase IV: Surveillance**	**Phase V: End of Life Care**
	Initiation	**Interval**	**Follow-up of Abnormal**	**Diagnostic Work-up and Staging**	**Primary and Adjuvant Treatment**	**Randomized Controlled Trials**		
Age					X			
Gender	X	X						
Training				X	X		X	X
Physician-physician communication			X					X
Physician-patient communication	X	X	X		X	X	X	X
Knowledge, Attitudes, and Behavior	X	X			X	X		X

Table 9.3. Summary of System Barriers to Realized Access to Cancer Care

	Phase I: Asymptomatic Screening		**Phase II: Evaluation of Abnormal Screening**		**Phase III: Treatment**		**Phase IV: Surveillance**	**Phase V: End of Life Care**
	Initiation	**Interval Screening**	**Follow-up of Abnormal**	**Diagnostic Work-up and Staging**	**Primary and Adjuvant Treatment**	**Randomized Controlled Trials**		
Organization and Structure of Care	X	X			X	X		X
Reimbursement of care	X					X		X
Financial Resources						X		X
Practice Guidelines		X	X				X	X
Tumor Registry Infrastructure				X	X	X	X	X
Geography	X	X	X	X	X			
Type of provider or hospital		X	X		X			