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Patient Expectations Of Full Body CT Screening

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PATIENT EXPECTATIONS OF FULL BODY CT SCREENING

By

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Seton Hall University

Patient Expectations of Full Body CT Screening by Carole T. Kolber

ABSTRACT

Introduction: Despite limited scientific evidence on its risks and benefit, full body CT screening is available to self-referred individuals. The purpose of this study was to develop a scientific knowledge base on patient expectations of the procedure and to determine if characteristics of patients influence their expectations of its health benefits.

Methods: Six nationally representative facilities performing full body CT screening were used as study sites. A pretest-only, between-subjects, descriptive survey design was used to study 94 patients volunteers, scheduled to receive full body CT screening.

Data Analysis: Descriptive statistics were used in examining information on the demographic, health, and knowledge characteristics of the patients. The Chi Square Test for Independence and Spearman analyzed associations between patient characteristics and responses to expectation questions. An alpha of .05 was the level of significance.

Results: Survey participants were predominantly White, married, health conscious, 35-65 years olds with income and educational levels several times above national figures.

Patients' highest expectations related to consumer empowerment and lowest expectations related to the limitations of the procedure. The five patient characteristics found to have significant associations with patient expectations were gender; referral method; level of personal health concern; number of other health screenings; and patients' self-estimations of their current health status.

Conclusions: This study provided quantitative and descriptive data which were consistent with and added to the existing, primarily anecdotal knowledge base. The findings can be used in educating patients, prior to their providing informed consent for the procedure.

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DEDICATION

*This dissertation is dedicated to the cherished memory of my parents,
Jack and Anna Tanenbaum.*

Their infinite love, nurturance, personal sacrifices and encouragement of learning
have made an everlasting difference in the lives of their
children and grandchildren.

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Chapter I

INTRODUCTION

Background of the Problem

Full body computerized tomography (CT) screening is a radiological procedure in which multiple body organ systems are scanned to detect disease or other abnormalities. Prior to the year 2000, this procedure was rarely performed on healthy, asymptomatic individuals. Increasingly, full body CT screening has become available to the public. However, a standardized referral process has not been developed. Patients generally self-refer for full body CT screening, even though a physician's prescription is required for most other radiological procedures. Self-referral for full body CT screening may represent a problem within today's health care arena due to unrealistic patient expectations of the risks and benefits of the procedure.

CT screening encompasses both full body CT scans, as well as targeted CT scans of specific organs. Full body CT screening and targeted screening differ from diagnostic tests. Radiologists administer both diagnostic tests and screening tests. Diagnostic tests are usually used for patients who are in need of a medical evaluation due to specific disease symptoms. In contrast, screening tests are usually administered to asymptomatic individuals in order to ascertain if they have a specific disease (Siegel, 2001, p.1). While diagnostic tests are typically covered by insurance plans, only some targeted screening tests are covered. Self-referrals for full body CT screening are not covered by insurance and typically cost \$800-\$1500, (Pennachio, 2002, p.1).

The two most extensively researched targeted radiologic screening programs have been for breast cancer and lung cancer. To date, the only radiologic screening endorsed by the American College of Radiology (ACR) is screening mammography (Brandt-Zawadski, 2002a, p. 6). Breast cancer screening with mammography on an annual or bi-annual basis has been shown in clinical trials to result in a reduction in breast cancer mortality, although the matter remains controversial (Gates, T.J., 2001, p. 5). Interestingly, lung cancer screening using both chest radiography and helical CT has not been shown to lead to an overall reduction in cancer mortality, bringing into question the assumption that early diagnosis of lung cancer followed by early treatment will reduce lung cancer mortality (Swensen, 2002, pp. 7-8).

The FDA claims that no evidence has been presented to demonstrate that full body CT screening detects any disease early enough to make a difference in its overall management or outcome (USFDA, 2002, 1). Similar positions have been taken by The American College of Radiology, the American College of Cardiology, the American Association of Physicists in Medicine, and the American Heart Association (USFDA, 2002, 1). The American College of Radiology (ACR) is also reluctant to endorse any type of targeted CT screening due to inadequate cost-benefit data. The global issue of whether or not early detection with CT screening saves lives requires further testing (Brandt-Zawadski, 2002a, pp. 5-6).

Against this background of inconclusive evidence and controversy related to targeted radiological screening of specific organs, a new and possibly more controversial modality has been introduced, full body CT screening (Brandt-Zawadski, 2002a, pp. 5-6). To date, no randomized, controlled clinical trials of full body CT screening have been

performed or published in peer-reviewed journals (Rogers, 2002, p. 2).

Statement of the Problem (Purpose of the Study)

In order to make informed decisions and provide informed consent before receiving full body CT screening, patients need to have realistic expectations of the procedure. While physicians and patient educators have been primarily focused on the medical aspects of full body CT screening effectiveness, they also need to focus on patient expectations and perceptions. No published studies have examined patient expectations of full body CT screening, to date. Therefore, a need exists to develop a scientific knowledge base on patient expectations of full body CT screening and to determine if specific characteristics of patients influence their expectations of the health benefits of the procedure.

The proposed study would develop this knowledge base. As such, it would help physicians and patient educators to design educational programs which help patients make informed decisions about full body CT screening. Studies involving other screening procedures have used theoretical models to explain patient expectations and participation in other screening and preventive health practices. One such theory, The Health Belief Model was developed by Hochbaum and his associates working in the Public Health Service in the 1950's (Hochbaum, 1958, p.1; Hochbaum, et al., p. 305, 1992) to explain participation in public screening programs (National Institutes of Health, National Cancer Institute, 2003).

This model was recently applied to prostate cancer screening in a study by Clarke-Tasker (Clarke-Tasker, 2002). It suggests that willingness to take specific action regarding disease is influenced by factors in the target population which affect their beliefs and access to services. Perceived susceptibility to disease (Hochbaum, 1992, p. 305) is one

component of this model which may have direct relevance to patient expectations of the health benefits full body CT screening and is thus, being adapted for use within this study. For the purposes of this study, patients' characteristics which may be related to their perceived risks of contracting a health condition will be considered determinants of disease susceptibility. Such characteristics may include patients' ages, how they view their current health status; their preoccupations with health concerns; and the extent to which they engage in preventive health activities.

Therefore, a need exists to develop a scientific knowledge base on patient expectations of full body CT screening and to determine if adaptation of an established theoretical model may add to this knowledge base. The proposed study would develop this knowledge base. Explaining the relationship between patient's perceived susceptibility to disease and their expectations of full body CT screening would assist physician educators and patient educators in designing appropriate educational programs. This would help patients to make informed decisions regarding their participation in full body CT screening before providing informed consent.

Definitions

- 1) Screening - Systematic testing of asymptomatic individuals for preclinical disease.
- 2) CT Screening - Screening using computerized tomography (CT) as radiologic modality.
- 3) Targeted CT screening - Screening of specific organs such as lungs, colon, etc.
- 4) Full body CT screening - Screening of multiple organ systems generally within chest, abdomen, and pelvis. Coronary artery calcium detection and head scans may also be included as part of some full body CT screening studies (Brandt-Zawadski, 2002a p. 5).

- 5) Self-referred - Patient schedules procedure without physician prescription or other form of documented physician verbal or written approval.
- 6) Physician-referred-Patient schedules procedure with physician prescription or other form of documented physician verbal or written approval.
- 7) Patient Expectations-Perceptions and beliefs which patients hold regarding the health benefits of full body CT screening.
- 8) Patient Expectation Questions- Series of 15 statements regarding the health benefits of full body CT screening.
- 9) High Expectations-Patient "strongly agrees" or "agrees" with series of statements regarding the health benefits of full body CT screening.
- 10) Low Expectations-Patient "strongly disagrees" or "disagrees" with series of statements regarding the benefits of full body CT screening.
- 11) Realistic Expectations-Anticipated risks/benefits of full body CT screening procedure are consistent with expert medical opinion, as discussed within literature review.
- 12) Unrealistic Expectations-Anticipated risks/benefits of full body CT screening are inconsistent with expert medical opinion, as discussed within literature review.
- 13) Patient Expectation Dimensions- Six groupings of patient expectation variables, with each grouping corresponding to 2-3 of the patient expectation questions.
 - (a) "Reassurance"-Periodic affirmation of health status (Brandt- Zawadski, 2002a, pp.6), (Brandt-Zawadski, 2002b, pp. 1-3).
 - (b) "Cure"- Early detection may result in earlier treatment of disease and cure. (Mietten, & Henschke, 2001, pp. 3-4), (Obuchowski, N.A. et al. pp. 5-8), (Patz, et al., 2002, p. 2).

(c) "Prevention"-Facilitate preventive actions and prolong life (Mietten, & Henschke, 2001, pp. 2-4), (Brandt-Zawadski, 2002c, pp. 1-3).

(d) "Empowerment"-Promote consumers' control over their own health care.

(Brandt-Zawadski, 2002a, pp. 2-3), (Harris, 2002, p.10).

(e) "Satisfaction"-Positive perception of value of procedure in consumers' health care management (Brandt-Zawadski, 2002a, pp. 5-6), (Brandt-Zawadski, 2002c, 1-3.

(f) "Limitations"-Inconclusive scientific evidence of risks and benefits of procedure (Black & Welch, 1993, p. 10), (Obuchowski, N.A. et al. pp. 9-10),

(Siegel, 2001, p. 3), (Stanley, 2001, 990-991), (Patz, et al., p. 8),

(USFDA, CDRH, 2002, pp. 1-2).

14) Perceived Susceptibility To Disease-Subjective evaluation of the risks of contracting a health condition.

15) Determinants of Disease Susceptibility-Patients' characteristics which may be related to their perceived risks of contracting a health condition.

Hypothesis

There is a significant association between patients' perceptions of their susceptibility to disease and their expectations of the health benefits of full body CT screening.

Need

A practical and theoretical need exists for scientific studies on patient expectations of full body CT screening. Most of the current writings on full body CT screening are within the popular literature, rather than the professional literature. The few available professional publications are primarily opinion papers or editorials, not

scientific studies. Moreover, most of these papers do not exclusively or comprehensively focus on full body CT screening, but discuss the procedure within the context of other issues related to targeted CT screening. None of the papers have applied theoretical models related to participation in other screening procedures.

Patients rely on physicians and health care providers to mediate and supplement what they learn from the internet and read and hear in the popular media with professional information. A need exists to move the issue of full body CT screening from the popular literature to the professional literature.

Informed decision-making regarding participation in full body CT screening is predicated upon realistic patient expectations. Clinicians cannot facilitate informed decision-making in patients without an evidence-based knowledge of the patient's expectations of the procedure. This study would pioneer a new line of inquiry with respect to full body CT screening, while also contributing to the existing knowledge base on patient expectations of other screening and preventive health procedures. The findings derived from a study on patient expectations of full body CT screening may assist radiology educators and Continuing Medical Education (CME) educators to better prepare future and practicing physicians to address patient perspectives and perceptions. The study of this nature may also identify the critical information which must be communicated to patients when administering this procedure.

Most importantly, the study may help radiologists, primary care physicians, and other health professionals in counseling and educating patients who seek their advice regarding the risks and benefits of full body CT screening. By explaining how patients' perceived susceptibility to disease may effect their expectations of the benefits of full body

CT screening, preparatory information and education may more effectively incorporate the balanced presentation and clarity required for informed decision making and informed consent.

Chapter II

REVIEW OF LITERATURE

Overview of Literature Review

This literature review will focus on two areas of research relevant to full body CT screening and targeted screening, A) issues associated with screening effectiveness and B) patient expectations, attitudes, and perceptions of screening and related preventive medicine interventions.

Full body CT became the subject of articles in the popular press and the internet, beginning in the year 2000. Publications within the professional literature have followed, but are limited in number and are primarily subjective in nature. A significant body of professional literature does exist, however, on targeted screening programs. The issues examined in these articles and the studies presented on breast and lung cancer may serve as a basis for future work on full body screening.

To date, no professional research articles or studies were found specific to patient expectations of full body CT screening. Thus, professional literature related to a constellation of patient expectations, attitudes, and perceptions of screening and related aspects of preventive medicine will form the basis of this review. The focus of the discussion will be on previous methodologies and the identification of new methodologies which may be adapted to the study of patient expectations of full body CT screening.

The rationale for organizing the literature review within the two categories of screening effectiveness and patient expectations of screening is consistent with the purpose of this study. In counseling patients on the advisability of participating in screening and in

interpreting the patient's screening results, physicians and other clinicians need an evidence-based knowledge of screening effectiveness. After this knowledge base is established, physicians and other clinicians may additionally benefit from an evidence-based understanding of the patient's expectations of the screening procedure.

Issues Associated With Screening Effectiveness

Targeted screening has been wrought with controversy, since its inception in the 1960's for breast cancer and the 1970's for lung cancer. Many of the same controversies associated with targeted screening also extend to full body screening. They are as follows:

(1) Self Referral Process (2) Biases In Interpretation of Screening Studies; (3) False-Positives/False Negatives (4) Radiation Exposure (5) Cost-Effectiveness; (6) Medical Outcomes.

(1) Self-Referral For Controversial/Unproven Procedures

Proponents of the consumer's right to self-refer for radiologic screening contend that individuals willing to self-pay for screening tests should be allowed access to the procedures (Brandt-Zawadski, 2002a, pp. 2-3). This viewpoint is consistent with a recent cultural trend, toward consumer driven medicine. Proponents of consumer driven medicine advocate for individual empowerment in decisions regarding one's health care.

Brandt-Zawadski (2002a, p.5) has been a strong advocate for the consumer's right to self refer for CT screening. However, it must be emphasized that Brandt-Zawadski's (2002a) advocacy for self-referral pertains to targeted screening, not full body screening. He states that specific criteria have been developed for targeted CT screening programs (Brandt-Zawadski, 2002a, p. 5). However, full-body screening does not fall under the

same guidelines. Brandt-Zawadski (2002a) states that development of such guidelines for full body CT screening would be worthwhile.

The boomer generation's quest for wellness and longevity has been a major factor boosting the demand for full body CT screening (Brandt-Zawadski, 2002a, p. 2). The managed care environment restricts access to specialists and services desired by the consumer. However, higher standards of living have enabled many individuals to self-pay and seek health care outside the managed care system, (Brandt-Zawadski, 2002a, p. 2). The wealth of health care information provided through the internet and other media have also been major influences in motivating many consumers to take charge of their own health care. Some consumers may perceive self-referring and self-paying for screening as opportunities to assume this control.

The consumer empowerment issue is not universally perceived as a positive development. Harris (2001, p. 10), conversely, suggests that full body scans are designed for self-absorbed individuals seeking immortality. He indicates that the National Institute of Health (NIH) and National Cancer Institute (NCI) have not developed guidelines for its use. Harris contends that the only factor in determining individual eligibility is the ability to pay for the exam. He expresses great concern regarding the physical and psychological sequelae which may ensue from this haphazard testing. For example, patients may undergo further testing, biopsies, and invasive procedures for what is often benign disease (Harris, 2001, p. 10).

Rogers (2002, pp. 1-2) similarly questions the purpose and potential consequences of full body CT screening. He expresses particular concern regarding the consumer driven nature of the referral process. Rogers views self-referral for full body scans as a

commercial enterprise outside of conventional medicine. According to Rogers, no scientific studies have appeared in the peer-reviewed literature to support its use (Rogers, 2002, pp. 1-2).

(2) Biases In Interpreting Screening Study Data

Evaluating the efficacy of screening has remained problematic because survival data have been difficult to interpret due to the introduction of lead time, length time, overdiagnosis and selection bias. These biases frequently confound research results, making it difficult to obtain definitive efficacy data. Lead time, length time, overdiagnosis and selection bias are central to understanding the dilemmas in evaluating both targeted screening and full body CT screening (Stanley, 2001, pp. 989-991). They may be explained as follows:

Lead time is the interval between detection of a malignancy at screening and the time in which it is clinically diagnosed (Stanley, 2001, pp. 990-91). Lead time bias occurs when comparisons of screened and unscreened populations do not make adjustments for the timing of the diagnosis. Lead time is essentially a measure of the amount of time the diagnosis was advanced as a result of screening. Every patient screened has the time of his or her diagnosis advanced. Therefore, for screened patients, cause-specific survival is from detection on screening to death (Herman et al., 2002, p. 9). For unscreened patients, cause-specific survival is from clinical diagnosis to death. The screening test may inaccurately appear to prolong survival when all it has really done is moved forward the time of diagnosis. The impact of lead time can be accounted for or controlled by comparing age specific death rates, rather than length of survival from diagnosis to death (Herman et al., 2002, p.9).

Length time is the difference in growth rates of tumors in the same organs (Stanley, 2001, pp. 990-91). Length time bias occurs when comparisons of screened and unscreened populations do not take account of the variability of the rate at which the disease progresses. Diseases with long preclinical phases are more likely to be detected and are overrepresented in screening programs, when compared to diseases with shorter preclinical phases (Herman et al., 2002, pp. 9-10). Therefore, length time biases can erroneously lead to the conclusion that the screening test prolonged life, when it was actually the slow growing nature of the tumor. One way to control length time bias is to follow-up patients after the initial screening and compare them to patients with clinical-detected disease.

Overdiagnosis bias occurs when lesions which may never develop into a clinically manifested disease are introduced into comparisons of screened and unscreened populations (Stanley, 2001, pp. 990-91). These lesions are referred to as pseudodisease and refer to a sub-clinical condition that would not have produced signs or symptoms before the individual died of other causes (Black, 2000a, pp. 1-2). Patients with pseudodisease do not die from the disease under study (Obuchinski et al., 2001, pp. 9). Overdiagnosis bias is accounted for or controlled by using disease specific mortality, rather than years of survival as the end point for evaluating screening effectiveness (Black, 2000a, p. 3).

Selection bias occurs when volunteers in screening studies differ from the general population in ways that affect survival (Stanley, 2001, pp. 990-91). For example, volunteers may be in better health and more concerned with health maintenance

and prevention. Alternatively, they may be individuals who worry a great deal about their health and have family histories or medical or lifestyles factors that place them at greater risk for disease. Selection biases can be controlled by randomly assigning subjects to screened and unscreened groups after they agree to participate in the study (Herman et al., 2002, pp. 9-10).

The failure to adequately control for lead time, length time, overdiagnosis and selection bias has often resulted in weak study designs which may compromise the validity of the data. Herman et al. (2002, pp.1-2) contend that the limited definitive outcome data on costs vs. benefits of screening is somewhat attributable to weaknesses in study designs. Herman et al. discuss the pros and cons of three possible study designs to assess the efficacy of screening, correlational, observational, and randomization.

Correlational studies compare the relationship between screening and disease rates for different populations (Herman et al. pp. 2002, pp. 1-12). They are descriptive studies which may suggest a benefit from a screening program, but cannot test hypotheses. Observational studies are usually case-control or cohort. In the case-control study, individuals with and without the disease are compared based on their prior exposure to screening. In the cohort study, the case-fatality rate of individuals who chose to be screened is compared with the case-fatality rate of individuals whose disease was detected by the onset of symptoms. The validity of both types of case-controlled studies is highly dependent on the methods used to select cases. The authors indicate that it is only through randomized trials that the true benefit of a screening program can be studied because the correlational and observational designs do not allow for a valid comparison of the screened and unscreened cases (Herman et al. 2002, pp. 11-12).

In randomized trials, large populations control for the effects of confounding variables, as patients are randomly assigned (Herman et al. 2002, pp. 1-12). Lead-time bias can be controlled by adjusting for lead-time average in comparisons of survival rates of patients whose disease was detected by screening versus clinical detection or preferably by comparing age-specific mortality for the screened and unscreened groups. Length-time bias can be addressed by comparing the mortality rates of different groups after repeated screening. Although the best evidence comes from randomized trials, cost, feasibility and certain ethical considerations make this methodology controversial (Herman et al. 2002, pp. 11-12). The authors indicate that the challenge for the future is to identify new evaluation methodologies to determine which screening methods are most effective with specific populations (Herman et al. 2002, pp. 11-12).

(3) False Positive/False Negative Findings

False positive and false negative findings may represent the aspect of screening which holds the greatest potential harm for individual participants (Gates, 2001, p. 2). Most diseases on which screening is performed have a low incidence. Therefore, even the best screening tests may have low predictive values, generally in the range of 10-20%, (Gates, 2001, p. 2). Consequently, most positive results will be false positives, often resulting in unnecessary further work-ups). False negatives can also be extremely harmful. They provide false assurances and may result in the patient not receiving or delaying important treatment.

Black (2000, p. 3) has written extensively on the issue of overdiagnosis and resultant false positives. He cautions that overdiagnosis is one of the most significant side-effects of screening. It has frequently resulted in the screenee receiving unnecessary

and potentially dangerous treatments, such as cancer surgery, chemotherapy, and radiation.

Black and Welch (2000) argue that advances in diagnostic imaging may be leading to overestimations of disease and ultimately a "cycle of interventions" (p. 2). These interventions may confer limited or no benefit. In order for patients to receive the greatest benefits from screening, Black and Welch (1993, p. 10) have urged physicians do the following: (1) Resist the urge to aggressively intervene when disease is detected (2) Expect that advances in diagnosis will be accompanied by improvements in therapy; and (3) Maintain conventional protocols until random clinical trials indicate otherwise.

(4) Radiation Exposure

It has been estimated that of every 100,000 people undergoing screening, 40 will develop radiation induced cancers during their lifetimes (Siegel, 2002, p. 3). Of the 100,000 people, approximately 23,000 would be estimated to develop cancers from other causes. If the detection rate is low, 115 may benefit from the screening versus 40 who might develop spontaneously induced cancers. Siegel (2002, p. 3) indicates that although these figures may be viewed as theoretical, they do indicate that radiologists performing CT screening should understand factors relevant to radiation dose and implement programs to reduce radiation dose exposure.

According to literature published by the United States Food and Drug Administration, Center for Devices and Radiological Health (USFDA, CDRH) (2002, pp. 1-2) the radiation risk associated with CT procedures is generally much larger than the dose associated with regular X-ray procedures. The major risk of this exposure is the possibility that the individual may develop a radiation induced cancer at a later point.

This risk is basically very small. However, if a person manifests symptoms and requires diagnostic testing, this risk is more likely to be justified. The radiological testing may reveal a medical condition which is treatable, making the small risk of a radiation induced tumor possibly outweigh the benefit. If an individual has no symptoms, the risk of developing the tumor may outweigh any benefits to be derived from the test (CDRH, USFDA, 2002, 2).

Moreover, the public may not be aware that the FDA approves x-ray and CT units for use as diagnostic tools. The radiologist has the discretion to use the units for any purpose which appears medically justifiable. The FDA has limited authority to monitor or control the use of the radiological equipment (Lewis, 2001, pp. 1-2). According to the FDA, no manufacturer of CT units has submitted data demonstrating that full body screening is safe and effective. The agency indicates that any claims that a CT unit has been "approved, cleared, or certified" for such use are not true (CDRH, USFDA, 2002, p. 2).

An alternative view on radiation exposure is presented by Brandt-Zawadski (2002b, p. 5). Although stating that this issue is beyond the scope of his article, Brandt-Zawadski (2002b) indicates that there is no scientific proof that cancer can be induced in the 1-rem range used in most units. Brandt-Zawadski (2002a, p. 6-8) additionally argues that screening facilities using the newest technologies, often have units with far less radiation exposure than older units used in many hospitals. Using what he refers to as a simplistic analysis, Brandt-Zawadski (2002b, p. 8) cites figures to demonstrate that the benefits of early detection of cancer may outweigh the risks of radiation induced tumors.

(5) Cost-Effectiveness Is Not Known

There is no available evidence to prove that CT screening reduces costs of medical care (Siegel, 2001, p. 4). Full body CT screening is actually an example of where the opposite may be occurring. Consumers pay out of pocket for the initial CT screening, but the follow-up in terms of further diagnostic testing and other procedures is assumed by the health care system. If an invasive procedure is used and a complication occurs, this cost is also borne by private or government sponsored health insurance.

After conducting a meta-analysis of published screening studies, Obuchowski et al. (2001, pp. 2-10) identified criteria for effective screening, some of which have direct bearing on cost effectiveness. The authors state that the disease being screened should have serious enough consequences to justify screening from both a cost and emotional perspective (Obuchinski et al., 2001, p. 2). Moreover, the population being screening should have a high prevalence of the disease which the screening test can cost-effectively and accurately detect before signs and symptoms appear.

A screening test should also have good sensitivity and specificity (Obuchinski et al., 2001, p. 5). Sensitivity refers to the test's ability to detect true positive cases. Specificity refers to the test's ability to distinguish true positive from false positive cases. Increasing the specificity of a test will increase the cost effectiveness of the test. However, increasing the sensitivity of screening tests may not be cost effective because it may lead to an increase in detection of incidental findings that will not develop into disease or affect the patient's life (Siegel, 2001, pp. 2-3).

(6) Medical Outcomes

The evaluation of screening efficacy must ultimately come from the analysis of medical outcomes. The rationale for the use of a screening procedure rests on the ability of the test to detect disease before the critical point at which it metastasizes (Obuchinski et al., 2001, pp. 5-6). Moreover, a safe and effective treatment needs to exist (Obuchinski et al., 2001, pp. 7-8). The only statistical evidence found in a peer reviewed scientific journal to demonstrate the usefulness of full body scanning in detecting disease came from ancillary findings within a randomized controlled study at the Mayo Clinic using CT in lung cancer screening (Swensen, 2002, p. 3).

Swensen, (2002, p. 3) the investigator at the Mayo Clinic, utilized a protocol which included a low dose helical scan of the chest and abdomen through the level of the kidneys. In addition, to the 41 lung cancers which were found in the 1520 participants, four renal cancers, three breast cancers, one atrial myxoma, two gastric tumors, and 114 abdominal aortic aneurysms were found (Swensen, 2002, p. 3). Swensen states that these findings may indicate that whole body scanning may not only potentially save lives, but may also be cost effective. However, he cautions that it is too early at this time to draw a definitive conclusion.

Lacking any other statistical outcome data from scientific studies on full body CT screening, the studies on breast cancer screening and lung cancer screening will form the basis of the review on medical outcomes related to radiological screening studies.

Breast cancer screening with mammography: example of an effective, but controversial targeted screening program

As indicated in the introduction, mammography is the only radiologic screening modality endorsed by the American College of Radiology (Brandt-Zawadski, 2002).

Breast cancer screening on an annual or bi-annual basis has been shown in clinical trials to result in a reduction in breast cancer (Gates, T.J., p. 5). The five year survival rate for Stage I breast cancer is 97%, indicating that it may be possible to detect the disease when treatment is most effective (Obuchowski, N.A. et al. 2001, p. 6). Although breast cancer screening with mammography is one of the best documented radiologic screening procedures, controversy remains focused on two issues, (1) the age at which to start screening and (2) the design of the studies on which the positive evidence of mammographic screening is based.

Seven randomized trials on breast cancer screening with mammography were conducted, starting in the 1960's through the 1980's (Nystrom, Andersson, Bjurstam, Frisell, et al., 2002, p. 2). One study was conducted in the United States, a second in Canada, and the third in Scotland. The remaining four of the seven studies were conducted in Sweden. The Swedish trials were government sponsored with the goal of reducing breast cancer mortality.

The four Swedish trials are sometimes referred to as five trials because one trial, known as the Two County Trial, involved two parts, one conducted in the Ostergotland county and the other in Kopparberg county (Olsen, P.C. and Gortzche, O., 2000). The trials conducted in the United States, Canada, and Scotland evaluated mammography combined with breast self-examination, clinical examination, or both procedures (Olsen, P.C. and Gortzche, O., 2000). The Swedish trials only evaluated mammography.

The randomized breast cancer trials involved over half a million women in the United States, Canada, Scotland, and Sweden (Olsen, P.C. and Gortzche, O., 2000, pp. 129-134). These studies became the subject of significant controversy when several of the

methodologies and results were challenged in a meta-analysis published by Olsen and Gortzche of the Nordic Cochrane Center in Denmark (Olsen, P.C. and Gortzche, O., 2000, 355, 129-134).

Original papers authored by the investigators of these studies will be reviewed, followed by the findings of Olsen and Gortzche (2000) challenging the methodological quality of the studies. Counter reactions to Olsen and Gortzche (2000) will then be presented. The discussion will close with the review of two more recent papers. One is a follow-up to the Swedish studies (Duffy et al., 2002) and the other reports on a clinical trial from the Netherlands (Otto et al., 2003). Although most of the presented studies involved more than one outcome measure, for the purposes of this review, the primary outcome to be discussed will be mortality from breast cancer.

The earliest data available from a randomized controlled trial on the effect of screening on breast cancer mortality comes from the Breast Cancer Screening Project of the Health Insurance Plan (HIP) of Greater New York (Shapiro, 1977, p. 2772). Enrollment for the trial was from December, 1963 to June, 1966 and involved approximately 61,000 women, aged 40-64 who were members of HIP for at least one year (Chu, Smart, and Tarone, 1988, p. 1125). The study group consisted of 30,131 women who were screened for breast cancer using mammography and clinical examination. The women in the control group were not offered screening and told to follow their usual practices in receiving medical care.

Shapiro (1977, p. 2777) reported that nine years after the date of entry into the trial, the benefits of screening were significant for the women fifty years of age or over in the study group. These women demonstrated 30% less deaths than the women in the control

group. No benefit was found for women 40-49 years of age (Shapiro, 1977, p. 2777). The study also found that excluding mammography and only using clinical exam would have reduced the benefit of screening by one-third. Shapiro (1977, p. 2781) advised that a need existed for further research to assess the risks versus benefits of the radiation exposure from mammography, particularly in light of the advent of newer units, which possibly reduce radiation exposure (Shapiro, 1977, p. 2779) additionally suggested in 1977 that the issue of no benefit for women aged, 40-49 was not closed and that further studies were needed.

The further follow-up and re-examination of the age issue in the HIP study suggested by Shapiro was undertaken by Chu et al. (1988, p.1125). The authors looked at breast cancer mortality after eighteen or more years of follow-up. Using different statistical methods than those previously used for analysis of the age at entry cohorts, statistically significant benefits related to screening were demonstrated for both the 50-64 and the 40-49 age cohorts. This beneficial effect is first observed four years after entry to the screening program for the 50-64 age group, but is not apparent until nine years after entry in the 40-49 year old age group (Chu et al., 1988, p. 1127). Chu et al. suggested that extended follow-up might be required before the full extent of reduction in mortality for younger women could be demonstrated (Chu et al., 1988, p. 1131).

Delay in observable benefit from screening, particularly in younger women was also demonstrated in the Edinburgh trial, conducted between 1979 and 1981 (Roberts et al., 1990, p. 241). It involved 45,130 women in Edinburgh, Scotland, aged 45-64. The study design was a randomized trial. The objective was to assess the effectiveness of screening with mammography and clinical examination in reducing breast cancer mortality. After

seven years of follow-up, a breast cancer reduction rate of 17% was found in the intervention group (Roberts et al., 1990, pp. 244-245). When an adjustment was made for those study participants who entered the trial at age 50 or over, the reduction rate rose to 20%. However, these figures were non-significant for either participants over or under age 50 (Roberts et al., 1990, p. 245).

Although the initial findings in the Edinburgh trial were not significant, a fourteen year follow-up analysis, conducted by Alexander et al. (1999, pp.1903-1906), demonstrated significant reductions in breast cancer in the intervention group. The authors state that a limitation in the initial trial involved the failure to control for socio-economic status (Alexander et al., 1999, pp. 1903-1906). Using computer software not available at the time of the initial study, an adjustment was made for socioeconomic status. The application of this software to the data and extended follow-up of 7, 10, and 14 years has now brought the reductions in breast cancer in the screened group to 25-29% in women 45-64 years old (Alexander et al., 1999, p. 1907).

In contrast to the HIP and Edinburgh trials, the Canadian National Breast Screening Study did not demonstrate reductions in the death rate from breast cancer in either older or younger women (Miller, Baines, To, and Wall, 1992a, p. 1459). The study was conducted in fifteen urban study centers in Canada. The participants included 50,430 women who enrolled from January, 1980 through March, 1985 and were followed for a mean of 8.5 years. The study design was an individually randomized controlled trial. Participants with no history of breast cancer who had not received mammograms within the last 12 months were randomly assigned to receive mammography and physical examination or usual care after a physical examination. The objective of the study was to evaluate the efficacy of the

combined effects of annual mammograms, clinical examination of the breasts, and teaching of breast self-examination on the rate of breast cancer death.

Original results were reported in separate articles for women aged, 40-49 and women aged, 50-59 (Miller et al., 1992a, pp.1459-1476, Miller et al., 1992b, pp. 1477-1489). For the women aged, 40-49, the results demonstrated that screening with mammography and physical exam detected more node-negative small tumors than usual care, but had no impact on the death rate from breast cancer in the first seven years after initiation of screening (Miller et al., 1992, pp. 1459-1460, p. 1474). For the women aged 50-59, the results were the same. As with the 40-49 age group, screening with mammography and physical exam detected more node-negative small tumors than usual care. However, screening had no impact on the rate of death from breast cancer in women 50-59 (Miller et al., 1992, pp. 1477-78).

The next studies are often collectively known as the Swedish trials. Although starting and ending dates varied for each of the specific trials, the studies were conducted from the mid 1970's through the mid 1980's. The first study to be reported, the Malmo trial was initiated in October, 1976 and results are reported by Andersson et al. (1988, p. 943) through 1986. It was conducted in Malvo, Sweden to determine if breast cancer mortality could be improved by inviting women to have mammograms every 18-24 months. Women born in Malvo, from 1908 to 1932 were identified from the city's population registry. The first round of screening was completed in September, 1978.

The study design involved random assignment of age cohorts to screening and non-screening groups (Andersson et al., 1988, p. 943). Half the women born in each birth year cohort were randomly assigned to the study group and received mammography screening

with the remaining women placed in a control group in which they did not receive mammography screening. The study group comprised 21,088 women invited for screening and the control group comprised 21,195 women not invited for screening. All women were over age 45.

Five rounds of screening were completed (Andersson et al., 1988, p. 943). If breast cancer was detected, it was treated in accordance with the stage in which it was diagnosed. Cases were followed for a mean of 8.8 years. By the predetermined end of the study in December, 1986, no significant reduction in breast cancer occurred in the study group (Andersson et al., 1988, p. 946). The authors point out that this outcome was in variance with the results from the study conducted in the Swedish counties of Kopperberg and Ostergotland. The study did find differences in the effect of screening in older and younger women (Andersson et al., 1988, p. 947). Women in the study younger than 55 had a 29% higher mortality from breast cancer (Andersson et al., 1988, p. 948). Although the study showed no significant differences in mortality in the study and control groups after 8.8 years, it did demonstrate a 20%, non-significant reduction in mortality in women over 55 (Frisell et al., 1991, p. 50).

The authors of the Malvo trial point out that this outcome was in variance with the results from the study conducted in the Swedish counties of Kopperberg and Ostergotland (Andersson et al., 1988, p. 946). Koppersberg and Ostergotland, two counties in Sweden were selected as the site of the two county randomized controlled trial to investigate the effectiveness of mass screening with single view mammography (Tabar et al., 1985, p.829). The trial started in 1977 and enrolled 62,981 women, aged 40 or more living

in the two counties. Women in the study group were offered screening with mammography every 2-3 years while women in the control group were not offered screening.

Results at the end of 1984, seven years after the start of the trial, showed an overall 31% in reduction in breast cancer and a reduction of 25% in stage II or more advanced cancers (Tabar et al., 1985, p. 829). Age differences were also noted (Tabar et al., 1985, pp. 831-832). In the 50-74 age group, an overall reduction of 40% is seen. The authors point out that while no reduction in breast cancer is evidenced in the 40-49 age group, it may take further follow-up, such as in the HIP study before a reduction in breast cancer is evident (Tabar et al., 1985, p. 832).

Similar results to the Kopperberg and Ostergotland trial and in contrast to the Malmo trial were obtained in the Stockholm study. The Stockholm study was a randomized trial which began in March, 1981 and involved 60,261 women aged 40-64 at the start of the trial (Frisell et al., 1991, pp. 49-50). The study population comprised 40,318 women to whom single view mammography was offered (Frisell et al., 1991, p. 50). The control group comprised 19,343 women to whom mammography was not offered. Selection was random and assignment was made based on birthdates (Frisell et al., 1991, p. 49). The end-point in the trial was breast cancer death.

Results reported after a mean follow-up of 7.4 years, demonstrated a non-significant reduction of mortality of 29% in the study group (Frisell et al., 1991, p. 55). The cancer reduction rate among women over 50 years in the Stockholm study was 43%. The number of cancer deaths among younger women was too small to be able to draw definitive comparisons after 7.4 years (Frisell et al., 1991, p. 59).

Definitive results on the benefits for younger women were obtained from the Gothenberg breast screening trial (Bjurstam et al., 1997, p. 2091). This was a randomized trial to study the effect of mammography screening on breast cancer mortality in women, aged, 39 to 49 years old. The subjects were randomized to the study group between September, 1983 and April, 1984. This study group consisted of 11,742 women who were invited for two view mammography screening every 18 months. Another 14,217 women were randomized to the control group and not invited for mammography screening until the fifth screen of the study which occurred 6-7 years after randomization.

The primary outcome measure was mortality from breast carcinoma, up to and including the fifth screen of the study (Bjurstam et al., 1997, p. 2093). Mortality data up to December, 31, 1994 are available. The authors concluded that the trial added to evidence that a substantial mortality benefit could be achieved in women under 50, with strict adherence to an eighteen month mammography screening interval (Bjurstam et al., 1997, p. 2098).

Gotzsche and Olsen (2000) reviewed the methodological quality of the aforementioned mammography trials involving a half million women and showed these trials to be flawed. They examined each of the trials and concluded "screening for breast cancer is unjustified" (Gotzsche and Olsen, 2000, p. 133). The authors reviewed the methodological quality of the New York (HIP) study, the Canadian studies, the Edinburgh studies, and the mammography trials conducted in five cities involved in the Swedish studies, Malmö, Kopparsburgh, Ostergotland, Stockholm, and Goteborg (Gotzsche and Olsen, 2000, p.133). They also reviewed a Swedish meta-analysis of these trials and conducted their own meta-analysis. Gotzsche and Olsen (2000) focused their

study particularly on randomization methods and exclusions after randomization, as well as the outcome assessment. The authors indicate that the randomization methods in six of the eight trials did not result in equal groups. For example, in the New York trial, some pairs of women were matched and some were randomized (Gotzsche and Olsen, 2000, pp.129-103). There were also inconsistencies in the criteria for exclusion after randomization.

As previously discussed, in the Edinburgh trial, the study and control groups differed considerably in socio-economic at baseline (Gotzsche and Olsen, 2000, p. 130-131). In the Stockholm trial, inconsistencies were noted in reports of the numbers of women randomized to the study and control groups. In the Goteburg trial, randomization methods were inadequate, resulting in the study group appearing considerably younger than the control group. In Kopparsburg, and Ostergotland, a type of cluster randomization was used which is not adequately described.

The other flaw on which Gotzsche and Olsen's (2000, p. 131) analysis focused, pertained to masking analysis. Gotzsche and Olsen indicated that knowledge of whether the subjects were in the screened or unscreened groups may have affected judgment of cause of death. Therefore, it was necessary to have masked the screening status of the participant. The authors make note of the fact that the only two trials which were adequately randomized were the Canadian and the Malmo trials. Likewise, the only two trials in which masking of cause of death was used were the Canadian trial and the Malmo trials. Interestingly, these were the only two trials which found that screening had no effect on breast cancer mortality. The authors concluded, "our findings suggest that

only the trials from Malmö and Canada were unbiased" (Gotzsche and Olsen, 2000, p.131).

The results of the Danish study ignited a great deal of debate, as they significantly differed with the study interpretations of other experts. In an article representative of the counter view, Kopans (2003, pp. 5) states that the basic premise of the Gotzsche and Olsen meta-analysis that the breast cancer studies were flawed and biased was "highly questionable" (Kopans, 2003, p. 5). He further indicates that the breast cancer trials analyzed by Gotzsche and Olsen "have probably undergone greater scrutiny than any group of scientific studies" (Kopans, 2003, 5). Publication of the Gotzsche and Olsen meta-analysis in 2000 came at a point in which the randomized clinical trials had already been repeatedly reviewed (Kopans, 2003, p. 3). The only major controversy which continued into the 1990's, pertained to the age at which screening benefits begin.

In the years from 1993 and 1997, evidence had accumulated on women who had entered the clinical trials in their 40's (Eshenbach, 2001, pp. 2-3). An extensive review of this data on younger women was conducted at a National Institutes of Health consensus conference in 1997. After reviewing the evidence, the National Cancer Institute (NCI) and the American Cancer Society (ACS) recommended that screening mammography for women should start at age 40, rather than the previously recommended age of 50. Both agencies also emphasized the importance of informed consent in this process.

In response to the Gotzsche and Olsen study, the US Preventive Services Task Force (USPSTF) recently did another review of the evidence regarding the effectiveness of mammography, clinical breast examination, and breast self-examination in reducing breast cancer mortality (Anonymous, 2002, pp. 1-2). The (USPSTF) found fair evidence

from their own meta-analysis of breast cancer screening studies that screening every 12 to 33 months significantly reduced mortality from breast cancer. The evidence of benefit is greatest for woman aged 50 to 69. For women, aged 40 to 49, the incremental benefits are less clear because the incidence of breast cancer is lower than in older women.

The National Cancer Institute (NCI) of the National Institutes of Health has recommended that its established guidelines remain intact (Gangel and Preboth, 2002, pp. 1469-70). The NCI advises that women in their 40's should be screened by mammography every 1-2 years and women 50 years and older should also be screened by mammography every 1-2 years. Women under 40 with risk factors should consult with their physicians in determining at what age and how often they should be screened.

The benefits of screening were more recently confirmed in a review of studies in seven counties in Sweden (Kopans, 2003, p. 9). Duffy et al. conducted a meta-analysis of the data on the effectiveness of breast cancer screening derived from studies in seven Swedish counties, dating back to the late 1970's. The counties comprised approximately 33% of the eligible female Swedish population (Duffy et al., 2002, p. 458).

In doing their analysis, the authors attempted to control for two sources of contamination in previous studies (Duffy et al., 2002, p. 458). (1) Mortality in cases diagnosed in the period before organized screening needed to be separated from mortality of cases diagnosed in the screening period. (2) Cases diagnosed among unscreened women (non-attendees) needed to be separated from those women diagnosed among women who attended screening in order to control for self-selection. The authors' objective was to obtain an estimate of the reduction in breast cancer mortality that resulted from screening alone (Duffy et al., 2002, p. 464).

After correcting for these biases, the mortality adjustment for reduction of breast cancer in all seven counties for women actually exposed to screening compared with prescreening was found to be 44% (Duffy et al., 2002, pp. 458-459, 464-465). If all tumors were considered, both those women exposed and those of women unexposed to screening, counties with 10 or more years of screening demonstrated a significant 32% reduction in mortality. Those counties with 10 or less years of screening demonstrated a significant 18% reduction in mortality for the screening epoch compared with the non-screening epoch. After adjusting for non-attendees or self-selection bias during the screening epoch, a 39% reduction in mortality was demonstrated, as result of screening (Duffy et al., 2002, pp. 465-466). The authors concluded that the policy of offering screening is associated with a mortality reduction in breast cancer.

Another recently published study presented a retrospective review of 10 years of mammographic screening studies in the Netherlands (Otto et al., 2003, pp.1-9). Mammographic screening was initiated in the late 1980's and early 1990's (Otto et al., 2003, p. 1-2). The goal of the study was to assess the effect of the screening program on breast cancer mortality. Data on mortality was obtained from participating municipalities comprising more than 100,000 inhabitants. Data were examined for 27,948 women , aged 55-74 who died of breast cancer between 1980 and 1999.

Adjuvant therapy for breast cancer was introduced in the Netherlands in the early 1980's (Otto et al., 2003, p.4). In order to separate the effects of adjuvant therapy on breast cancer mortality from the effects of screening on breast cancer mortality, four categories of year clusters were identified, 1988-91, 1992-93, 1994-95, and 1996-1997. Using a Poisson regression model, the investigators were able to determine if upward

changes in breast cancer mortality were related to screening or the introduction of adjuvant therapy.

The authors concluded that the role of mammography was greater than adjuvant therapy in decreasing mortality (Otto et al., 2003, p. 7). This conclusion was based on the fact that by adjusting for the specific dates screening began in different municipalities, downward trends coincided with the introduction of screening. Also, the greatest benefits were demonstrated 10 years after the start of screening which was consistent with other studies (Otto et al., 2003, 7).

In addition to the recent American review of findings, a meeting was also held in February, 2002 in Stockholm to allow Gotzsche and Olson to present their data and to provide an opportunity for members of the trials to respond to their critics (Kopans, 2003, 9). According to Kopans, "it was clear that the concerns of Gotzsche and Olson were unfounded and their rejection of the benefits of screening unsupported" (Kopans, 2003, 9). The following March, the Swedish and Dutch governments rejected Gotzsche and Olsen analysis and reaffirmed the benefits of screening (Kopans, 2003, 9).

The preponderance of the evidence from the studies on breast cancer screening with mammography support its effectiveness (Eshenbach, 2001, pp. 2-3). The results of clinical trials have been extensively reviewed by respected bodies who have validated its overall efficacy. Controversies related to breast cancer screening may continue to resurface following re-analyses of data and changes in concepts of the disease and its treatment. Nevertheless, a level of consensus has been achieved regarding its efficacy, as evidenced the endorsement by the American College of Radiology (Brandt-Zawadski, 2002a, p. 6). Conversely, lung cancer screening continues to be a source of continued

contention in which limited resolution has been achieved, to date. Relevant studies on lung cancer screening using chest roentgenology and helical CT will now be reviewed.

Lung cancer screening with chest radiography: example of an ineffective screening program

Lung cancer screening programs, using radiographic screening were organized starting in the 1960's and conducted throughout the 1970's, into the 1980's. Gates (2001, p. 4) has referred to these trials as "the paradigm of an ineffective screening program. More recent lung cancer screening programs have used helical CT. Neither modality has demonstrated conclusive evidence of reductions in disease mortality rates (Swensen, 2002, pp. 7-8). However, advocates of helical CT have reopened the debate contending that it may still prove to be a useful lung screening modality, even if the clinical trials have not as yet demonstrated its efficacy (Mietten and Heineke, 2001, p.10) (Gates, 2001, p. 4).

Four randomized clinical trials of lung cancer screening were performed in the early 1970's (Patz et al., 2001, p. 6). Three were sponsored by the National Cancer Institute, the Mayo Lung Project, The Johns Hopkins Lung Project and the Memorial Sloan Kettering Lung Project. The Mayo Lung Project (MLP) was conducted within the actual clinical setting (Fontana et al., 1984, p. 561). All of the participants were high risk Mayo Clinic patients undergoing medical examinations. Starting in November, 1971 through July, 1976, 10,933 candidates were interviewed (Fontana et al., 1986, p. 747).

Inclusion criteria required candidates to be males, 45 or older, who had smoked at least 20 cigarettes or more daily over the last year and had no evidence of lung cancer (Fontana et al., 1984, 561). Prior to the actual study, candidates, participated in a "prevalence" (Fontana et al., 1984, p. 561) screening that included chest roentgenology and

sputum cytology. The purpose of the prevalence screening was to obtain a population suitable for the randomized controlled study by identifying and excluding those individuals who already had evidence of disease.

If either the chest x-ray or sputum cytology test proved positive, the candidate became a "prevalence" case (Fontana et al., 1986, p. 746). Detection of prevalence cases most frequently occurred through roentgenology. Ninety-one cases were detected. Overall, the resectability rate was 54% (Fontana et al., 1986, pp. 746-747). The five year survival for all causes of death among the "prevalence" group was approximately 30% . If only lung cancer deaths were considered, the survival rate among the "prevalence" group was approximately 40%.

Starting in November, 1971 through July, 1976, 10,933 candidates were interviewed (Fontana et al., 1986, p. 747). Of the 10,933 men who took part in the prevalence screening, only 9,211 also qualified for the MLP randomized trial (Fontana, Additional requirements for the randomized trial included a life expectancy of at least five years, sufficient respiratory reserve to undergo a lobectomy, if necessary, and completion of screening with evidence of being cancer free.

The 9,211 men who met the criteria were randomized to two groups, the screened group and the control group (Fontana et al., 1986, pp. 747-748). The screened group consisted of 4,618 patients who were reminded to have chest x-rays and sputum cytology studies every four months for six years. Efforts were made to ensure compliance through reminder letters. The control group consisted of 4,598 men who received an annual Mayo Clinic follow-up letter reminding them to have chest radiography and cytology studies, but no four month reminders about tests. Compliance was excellent with only 26 patients lost

to follow-up.

The results of the randomized trial showed that offering chest roentgenology and sputum cytology every four months to high risks patients conferred no greater mortality advantage over the standard medical practice of recommending annual testing (Fontana, et al., 1986, 746). The death rate from cancer was 3.2 per 1000 patients among those screened every four months and 3.0 among the control group (Fontana et al., 1986, 749). The authors concluded that the results do not justify recommending large scale radiological or cytological screening for lung cancer (Fontana et al., 1986, 749).

A follow-up study by Fontana, et al, published in 1986 demonstrated that even though the death rates from lung cancer and all causes were almost identical, study group participants showed significantly increased cancer detection, resectability, and longer survivorship from lung cancer when compared with the control group, (Fontana, et al. 1986, p. 749). The five year survival from lung cancer in the group screened every four months was approximately 35%, compared to approximately 15% for the control group.

A later follow-up by Marcus et al., was published in 2000 (Marcus et al., 2000 et al., p. 1308). The National Death Index (NDI), and the authors' own algorithm was used to follow-up individuals through 1996 whose death was of unknown origins (Marcus et al., 2000, pp. 1308-1310). The search identified 396 cancer deaths, bringing the lung cancer deaths to 337 in the intervention group and 303 in the control group. After a median follow-up of 20.5 years, the mortality rate was 4.4 per thousand in the intervention group and 3.9 in the control group. The authors concluded that the extended follow-up did not demonstrate a lung cancer mortality reduction.

The issue of the similarity in mortality rates, but longer five year survival rate in the screened group was also re-opened (Marcus et al., 2000, 1308). The authors suggested that some combination of lead time and overdiagnosis bias might be responsible for this finding. They further indicated that patient case survival is not a good measure of efficacy in lung cancer trials (Marcus et al., 2000, 1308). It is the overall reduction in mortality that makes the difference. The authors further suggested that the most probable cause for the discrepancy in individual case survival and mortality was attributable to the fact that some indolent lesions may have been incorrectly identified in the intervention group.

Similar findings to the Mayo Clinic trials were demonstrated in the Johns Hopkins Lung Project and the Memorial Sloan Kettering Lung Project, the other two studies sponsored by the National Cancer Institute (Fontana et al., 1986, p. 749). The Johns Hopkins Lung Project Study began in 1969 (Frost et al., 1984, p. 548). The study was a controlled clinical trial which enrolled 10,386 men, randomly assigned to two groups. (Tochman, 1986, p. 324S). The study population received dual screenings, consisting of chest roentgenograms and sputum cytology studies every four months. The controls only received annual chest roentgenograms. Initial prevalence studies were carried out similar to the Mayo study.

After 5-7 years of continued screening, the trial results showed that survival was similar in both the study and control groups (Tochman, 1986, p. 324S). Age adjusted lung cancer mortality was 3.4 per thousand in the screened group and 3.8 per thousand in the control group. This difference was not significant (Tochman, 1986, p. 324S). The authors stated that this study showed no benefit in reduction of lung cancer mortality (Tochman,

1986, pp. 324S-325S). Similar to the Mayo study, the researchers concluded that "mass screening for lung cancer cannot be recommended" (Tochman, 1986, p. 325S).

In the Sloan Kettering study, as in the Johns Hopkins study, a high risk population of male volunteers, 45 or older were recruited (Flehinger, 1984, p. 555). On the initial visit, each participant completed a questionnaire which provided demographic data, a history of cigarette smoking, and other information. The 10,040 male volunteers were randomly assigned by computer to a dual screen, involving x-ray and sputum cytology or a single x-ray only screen (Flehinger, 1984, p. 549). The same number of cancers developed in both the double screen and x-ray only groups, but the x-ray only group cancers were detected at a later date (Martini, 1986, p. 325S).

Similar results to the Mayo study were also demonstrated in a randomized, perspective study of lung cancer detection conducted in Czechoslovakia in 1976 (Kubit, et al. 1976, p. 2427). The objective of this study was to evaluate semi-annual screening with radiologic testing and cytologic studies administered at three year intervals and compare it to no screening in a control group. A total of 6,364 men, aged 40-64, who were heavy cigarette smokers received an initial screening (Kubit et al., 1976, pp. 2429-2430). Lung cancer was detected in 18 cases or 28% of those completing the initial prevalence study. The remaining 6,346 subjects not evidencing lung cancer were randomly assigned to either the experimental group or the control group.

The authors indicated that the study confirmed the ability of radiologic testing to detect early lung cancer and to identify patients with the best prognosis appropriate for re-section (Kubit et al., 1976, 2427). Subjects in the high risk population who were in the screening program did better than the control group, where the cancer was

diagnosed symptomatically, accidentally by x-rays, or autopsies (Kubit et al., 1976, 233-34). Of the 37 incidence cases detected by screening, 30% survived five years or more (Kubit et al., 1976, 2431-32). Of the 29 cases reported in the control group, 10% survived five years or more (Kubit et al., 1976, pp. 2433-34). Nevertheless, despite significant differences in years of survival between the study and control groups, there were no differences between these two groups in the number of patients dying specifically of lung cancer (Bach, 2003, p.3).

The Mayo Clinic, Johns Hopkins, Memorial Sloan Kettering, and Czech collectively enrolled 37,000 male smokers over the age of 45 (Patz et al., 2001, p.6-7). In reviewing the evidence from these trials, Patz (2001) states that each trial found an increased incidence of early stage cancer, more resectable cancers, improved survival rates in the screened, as opposed to control groups. Nevertheless, no trial found a statistical difference in lung cancer mortality when comparing the two groups. Patz and other researchers who have repeatedly analyzed the initial and long term follow-up results have concluded that the discrepancies in survival and mortality have been due to combinations of lead-time, length-time, and overdiagnosis bias.

Lung Cancer Screening With Chest CT: Example of An Inconclusive Screening Program

Researchers are now evaluating the efficacy of helical CT in screening for lung cancer. Two American trials are currently in progress, the Early Action Lung Project (Henschke et al., 1999) and the Mayo Clinic trial (Swensen, 2002). The results, to date of these two trials and one being conducted in Japan, (Sone et al.,) will be reviewed.

The Early Action Lung Cancer Project (EALCP) was initiated in 1992 to evaluate the usefulness of annual CT screening for lung cancer (Henschke, et. al, 1999, p. 100). Henschke, et. al (1992) developed a design which was intended to be quicker and less costly than the randomized clinical trial. The frequency of cure in high risk people was partitioned into three components, (1) frequency with which nodules were detected, (2) frequency with which these nodules represented malignant disease and (3) frequency with which malignant nodules were cured.

Participation in the EALCP was limited to 1000 volunteers who were 60 years of age or older and had a history of 10 pack years of smoking and no history of cancer (Henschke et al., 1999, p. 100). After a structured interview and informed consent, chest radiographs and low dose CT's were done for each participant. Two board certified radiologists read each CT scan separately. If they, disagreed on the findings, it was presented to a third expert reader and the adjudicated findings became the accepted ones.

The baseline findings very much confirmed the expectation that low dose CT, compared with chest radiography, increases the likelihood of detection of small non-calcified nodules (Henschke et al., 1999, p. 103). Non-calcified nodules were detected three times as commonly with CT than by chest radiography; malignant tumors four times as commonly; and stage I cancers, six times as commonly. While false-positive results

have been common in the study, they are usually managed with further non-invasive procedures, such as high resolution CT. The authors advise that further follow-up of participants with malignant disease is necessary to determine cure. Their non-comparative study is being used by other sites in the USA , as well as Israel and Germany (Henschke et al., 1999, p. 104).

Swensen (2002, pp. 1-2) reports on the results of a non-randomized trial at the Mayo Clinic which at the time of publication of this article was in Phase II. The study population was comprised of 1520 participants, who at enrollment were 50 or older and had smoked at least a pack a day for 20 years. After three years of screening, a total of 1.4% of the lung nodules found by the study were malignant. Swensen (2002) suspects that nearly 99% of the identified lesions are benign and false positive findings. Swensen further indicates that a low false positive rate is an important aspect of an effective screening test and that CT screening for lung cancer does not meet this standard.

Swensen (Swensen, 2002, pp. 7-8) concludes that for the detection of early lung cancers, CT is more sensitive than chest radiography. However, a lack of clarity exists regarding whether CT is an effective screening test. The many false positive findings raise questions regarding interference with one's quality of life due to unnecessary further interventions and radiation exposure. He specifically questions whether the morbidity and mortality for the screened group will actually be higher than the gains in disease specific mortality. He advocates for randomized, controlled trials as the best way to provide evidence on screening effectiveness.

In a study in Japan, which began in 1996, Sone et al. (1998, pp. 1-2) assessed the effectiveness of population based mass screening with spiral computed tomography in

detecting smaller lung cancers and decreasing mortality. Using a mobile CT unit, the authors screened 5,483 individual (smokers and non-smokers) from the general population of Matsumoto, Japan aged, 40 to 74 years. All participants received a low dose spiral CT of the thorax. The study population had previously undergone the standard procedures, annual chest radiography (miniature fluorophotography) and sputum cytology testing in the year before the CT studies and each study participant was found to be free of lung cancer (Sone et al., 1998, p. 4).

All patients gave informed consent and completed questionnaires relevant to medical and smoking history and demographic data (Sone, et al.1998, 2). Two controls from the annual general health survey were selected for each individual who underwent screening. The two controls and one study participant were matched by computer for sex, age within two years, smoking habits, and place of residence. The authors have reported on the one year follow-up three years after the initiation of screening.

The lung cancer detection rate for CT was 48%, compared to 3-5% for the standard x-ray screening scanning previously done in the same area of Japan (Sone, et al. 1998, 4). Therefore, CT scanning identified almost ten times as many cancers than standard mass screening previously done in the same area of Japan (Sone et al., 1998, 4).

In discussing the evidence to date, on the efficacy of lung cancer screening with helical CT, Patz et al. (2001) and Mietten and Heineken (2001) present two differing perspectives. Patz et al. (2001, p. 1) strongly urge that relevant hypothesis driven studies be performed before CT screening for lung cancer can be accepted as the standard of care. They indicate that for screening to be effective three conditions must be met. (1) Screening must be able to diagnose the disease before the patient becomes symptomatic.

(2) Earlier treatment must be more effective than later treatment. (3) The benefits of early treatment must outweigh the risks of screening.

Patz et al. (2001, pp. 4-6) suggest that survival is an inappropriate indice. They suggest that the least biased outcome measure is disease specific mortality because this can be used to measure populations from the time of screening (or no screening) rather than from the time of diagnosis. Disease specific mortality is not subject to lead time, length time or overdiagnosis. Moreover, they urge the use of the random clinical trial (RCT) to control for population selection biases.

Conversely, Mietten and Heineken (2001, p. 10) contend that the cautions regarding the ineffectiveness of lung screening are unfounded. They indicate that the MLP data does not lend support to not treating lung cancer in an asymptomatic individual. Mietten and Heineke indicate that 4-7 years represents too early a follow-up period and that the fatality reduction benefits of screening may not have been adequately demonstrated ((Mietten and Heineke, 2001, p. 6). Moreover, the authors contend that if we were to make all decisions regarding use of helical CT for lung cancer screening based on random clinical trials it would take approximately 30 years to determine if this procedure leads to reduced mortality. They urge radiologists to be critical thinkers in examining the evidence and not accept a position which may run counter to their own logic (Mietten and Heineke, 2001, p. 10).

Conclusions: Issues Associated With Screening Effectiveness

In evaluating screening, particularly full body screening, researchers and clinicians must consider the cultural, socio-economic, and medical-scientific domains in which these screening procedures have developed and continue to evolve. Each domain presents specific challenges which may influence conclusions on screening effectiveness.

The cultural domain which promoted consumer empowerment is reflective of a profound shift in the paradigm of the doctor-patient relationship (Kravitz, 1996, 1).

The ethical model of the physician-patient decision-making has evolved over the last three to four decades from a paternalistic to a contractual model. In the paternalistic model, physicians made decisions for patients based on what they perceived to be most beneficial to the patient (Veatch, 1996, 77). Alternatively, in the contractual or collaborative decision-making model, there is an exchange of information and sharing of decision-making between the physician and patient (Veatch, 1996, 79).

The 1960's is often considered the period in American history in which the paternalistic, beneficent paradigm of the patient-physician relationship began to shift to a model which has increasingly incorporated patient needs for greater autonomy (Veatch, 1997, p. 75). This paradigm shift was an outgrowth by what Kravitz (1996) refers to as the "biomedical revolution of the past half century" (p.1). As the options for the consumer expanded through technology, physicians and policy makers were faced with an unprecedented need to understand the "patient's concerns, desires, and expectations of health care," (Kravitz, 1996, p.1).

Increasingly, the model of shared decision making which evolved in the 1960's is undergoing further change. We may now be entering an era in which the balance in physician-patient decision making authority has shifted to the patient (Ubel, 1998, p. 2). Self-referral for targeted screening and full body CT screening may be representative of this new decision-making paradigm. Screening modalities give consumers greater choice and greater levels of control over their health maintenance. However, in the absence of scientific evidence or governmental or professional endorsement, this choice must also be considered in terms of its impact on socio-economic issues relevant to health care.

In examining the socio-economic domain, proponents for self-referral and self-payment for screening services have argued that consumers willing to pay-out-of-pocket have the right to exercise this choice. However, opponents would contend that if specific types of targeted screenings and full body CT screening are only available to self-paying individuals, it may exacerbate inequalities in the scope and availability of health services provided to different individuals in this society. If full body CT screening or another screening modality was ultimately found to prolong or save lives, this might confer an ethically unacceptable advantage to those individuals able to afford screening and an ethically unacceptable disadvantage to those individuals unable able to afford it.

Inequality in health resource allocation is a troubling, but not unusual situation in this society. However, it is particularly troubling in the screening context. The less privileged socio-economic classes are losing the potential benefits of specific screening procedures, while at the same time sharing the long range financial burdens of the procedures. If a finding on a CT scan of a self-paying individual requires follow-up, further interventions are generally financed by third party payers. In the case of private insurance, this may

mean higher premiums for individual subscribers or employers, who in turn may pass these costs on to employees. Alternatively, the costs may be assumed by public insurance and result in more limited resources for less privileged individuals and possibly higher taxes to finance health care.

As indicated, the cost effectiveness of screening has not been demonstrated, to date. Multiple factors impact short term and long term cost calculations. The propensity for false positives may result in immediate costs for unnecessary follow-up procedures. If complications or deaths occur from these procedures, the financial and human costs may exponentially increase. False negative findings may further contribute to the cost burdens, particularly if the disease could have been detected in an earlier and more curable stage. Other longer term financial consequences may stem from the sequelae of radiation exposure.

The most meaningful calculation of cost vs. benefit, however, may ultimately need to be determined from medical and scientific outcome studies. However, as clinicians and policy makers look to the medical-scientific domain, many of these outcomes are still somewhat elusive. They may wonder why the evidence remains controversial and inconclusive, despite years of clinical trials and other screening studies. As discussed, researchers have indicated that specific biases often distort the interpretation of findings and are not consistently controlled within study designs (Black & Welch, 1993, p. 5). For example, due to lead time bias, screening may appear to prolong survival, when in actuality, it only found the disease earlier. Due to length time bias, comparisons between screened and non-screened patients may not be adjusted for the rate of the progression of the disease (Black & Welch, 1993, p. 5).

Procedures to control these biases have been suggested, but require years of randomized clinical trials. In the interim, new technologies may be developed, concepts of the disease may be modified, and new treatments may be developed. Examples of lead and length time biases are provided in two of the trials previously reviewed studies, the Malmö breast cancer trial, and the Czech lung cancer trial (Black & Welch, 1993, 5). In both trials, fatality rate reductions were significant when the cancers diagnosed at screening in the screened groups were compared to cancers detected at the time of clinical diagnosis in the control groups. However, when the differences in mortality from breast cancer in the Malmö trial and lung cancer in the Czech trial were compared from time of randomization, there were no differences in breast or lung cancer mortality.

Overdiagnosis bias, is another formidable issue. Not only does overdiagnosis distort cancer statistics in clinical trials, but according to Black (2000, p. 3), it is one of the most significant side effects of screening for the individual. Whereas false-positives may cause an individual to worry and possibly receive an unnecessary follow-up procedure, overdiagnosis, may give an individual a cancer diagnosis for life and lead to continued unnecessary treatment. Overdiagnosis is considered to have been an explanation for one of the paradoxes in the Mayo Lung Cancer Project. The lung cancer mortality rate in the MLP was 11% higher for screened than unscreened patients (Black, 2000, pp. 3-4). Initial diagnoses of pseudodisease as lung cancer may have influenced subsequent reporting and cause of death on death certificates.

Although often controversial and inconclusive, a great deal of evidence has been accumulated on medical outcomes relevant to targeted radiological screening for breast and lung cancer. The positive potential of radiological screening to detect disease in

an early curable stage has been demonstrated in breast cancer screening trials. Conversely, the lung cancer screening debate is less settled. Consensus exists on the ineffectiveness of chest radiography, but lung cancer screening with helical CT remains the focus of the current screening controversy.

It is within the context of this debate over the value of lung and other targeted CT screening that the debate over full body CT screening is best understood. Black indicates that the negative effects of the Mayo Lung Project, do not preclude the possibility that screening with helical CT could still be very valuable (Black, 2000, 4). As discussed, clinical trials are in progress which are investigating lung cancer screening with helical CT (Henschke, et. al, 1999) (Sone, 1998) (Swensen, 2002). These studies may help resolve the current paradox which makes future studies on full body CT screening intriguing, but possibly frustrating to researchers.

The superior level of sensitivity of CT to detect disease in its earliest stages also increases the potential for overdiagnosis and false positives; and consequently the potential for many of the negative sequelae that have been reiterated throughout this discussion. The issue of cost vs. benefit of targeted CT has not been resolved. The assessment of cost vs. benefit of full body CT screening is even more challenging and its resolution is even more remote. In the interim in which researchers continue to accumulate evidence on CT screening, the focus of study needs to be medical outcomes, but also on issues related to the expectations of patients who are considering participation in full body and other CT screening studies. The next section will exam this integrally related issue.

Patient Expectations Of Screening & Other Preventive Medicine Practices

As indicated, scientific papers relevant to patient expectations have not been published, to date. However, published studies have examined patient expectations or related constructs relevant to screening and other preventive medicine practices. This section reviews the methodologies used in these studies. All of the studies used methodologies common to social science and educational research.

Of the twelve empirical studies reviewed, three used focus groups, five used survey methodologies, one used a pilot experimental-control group design, one used interview techniques, and two were meta-analyses based on existing literature searches. With the exception of the one experimental-control group design, all of the studies were descriptive. Outcomes were generally reported based on percentages of specific responses to written or oral surveys or discussed within narratives describing qualitative findings. With limited exception, there was rarely discussion of measurements related to internal validity.

Focus Groups

Of the three studies using focus group methodologies, two pertained to patient views of prostate cancer and prostate screening and one compared physician and patient reactions to Canadian government guidelines on preventive medicine. In the first paper, Clarke-Tasker (2002, p. 1) studied African-American males' knowledge, attitudes, and perceptions of prostate cancer and screening. The rationale for the study was based on the fact that African-American men have a 60% higher incidence of prostate cancer and are twice as likely to die from the disease than the general population. The goal of the study

was to obtain the necessary information to design culturally relevant interventions which might decrease prostate cancer mortality in this high risk population.

The theoretical basis of the study involved the Health Belief Model. This is a conceptual framework developed by Hochbaum and colleagues at the US Public Health Service in the 1950's to study behavior related to preventive health (Clarke-Tasker, 2002, pp. 1-2). The model contends that readiness to take appropriate action in preventing disease is based on each individual's perceptions of his or her susceptibility to the disease and perceptions of the severity of the disease. In the adapted version used in this study, perceived seriousness, perceived susceptibility, and knowledge of prostate cancer were used as determinants and predictors of health-seeking behaviors.

Clarke-Tasker (2002, pp. 3-4) recruited twelve African-American males, ages 38-80, from the local community to participate in the study. The methodology involved the use of two focus groups, each consisting of six men, as well as the principal investigator and a research assistant. The focus groups were used to: (1) identify local language and (2) obtain feedback from the participants on their perceptions of a prostate cancer video, digital rectal exam, blood drawing for prostate specific antigen (PSA), and the observation and direct handling of an anatomically correct prostate cancer model.

Clarke-Tasker (2002, pp. 3-4) developed open-ended questions to use with the focus group participants, as well as a set of problems, props, and tasks designed to help participants focus on prostate cancer issues. After obtaining informed consent, participants were audiotaped. A content analysis of the audiotapes was undertaken to identify key phrases and expressions used by the men in both groups. Participants also completed a survey questionnaire.

The results indicated that on the average, the participants believed in the efficacy of prostate cancer early detection methods (Clarke-Tasker, 2002, pp. 3-4. However, they also believed that physicians did not consistently screen or suggest screening. Participants were also concerned about possible changes in their sex lives, if diagnosed with prostate cancer. In addition, they considered the digital rectal exam to be embarrassing and uncomfortable, but necessary. Clarke-Tasker (2002, pp. 6-7) indicates that the study supports screening for prostate cancer and the need for education on its benefits.

In a second study using focus groups to study knowledge, attitudes, and beliefs about colorectal cancer and screening, Beeker et al. (2000, p. 2) identified barriers to screening and strategies for motivating and supporting behavioral change. During a four week period, 14 focus groups were conducted. Each of the focus groups had 10 or 11 participants. The groups met for two hours with a professional group moderator. In order to minimize bias, participants were selected from three different cities and included both African-American men and women and white men and women. Twelve of the groups were stratified by sex and age.

In analyzing the data, two of the investigators, sorted the responses, using categories or codes consistent with the major constructs in the conceptual model guiding the study (Beeker et al., 2000, p. 2). The qualitative findings obtained from the study indicated a number of barriers to screening. These included a lack of knowledge and confidence in the tests, negative attitudes towards the tests, and fear of the results and consequences of the tests. Beeker et al. (2000, pp. 7-8) suggest that decision aides might be useful in assisting both patients and providers in deciding between different screening options.

In the third study using a focus group methodology, Beaulieu et al. (1999, p. 1).

compared the clinical guidelines of the Canadian Task Force on Preventive Health on annual physical exams with the beliefs or perceived needs of physicians and patients. Physicians and patients participated in separate groups (Beaulieu et al., 1999, p. 1). The authors contacted ninety-six family physicians from a list of family physicians provided by the Federation des Medecins Omnipraticiens du Quebec (Beaulieu et al., 1999, p. 2).

All physicians received a letter asking them to participate in the survey, signed by the investigators and the chairperson of the regional medical association (Beaulieu et al., 1999, 2). This was followed by a phone call from one of the investigators inviting them to participate in the study. Of the original ninety-six physicians, only 25 were able to participate. This was balanced by a convenience sample of 10 additional physicians approached by the investigators, bringing the total number of physicians to 35. Physicians participants were offered continuing education credits.

Patients were recruited through the Montreal daily newspaper and local community papers (Beaulieu et al., 1999, 2). Participants had to be over 18 years old and have sought the services of a general practitioner at least once. Each participant received \$25. The focus groups were two hours in duration. The first part of each session was used to explore perceptions about preventive health. A vignette was then presented and discussed, representative of the recommendations of the Canadian Task Force on Preventive Health. The groups were led by a sociologist and also attended by one of the investigators and a research assistant.

Transcripts of group discussions were analyzed. Two coding systems were developed, one for physicians and one for patients (Beaulieu et al., 1999, p. 2). All transcripts were coded by one person. Beaulieu et al. (1999) analyzed the transcripts

independently to identify themes within different coding categories. A software package was used for data management. Several methods were used to ensure internal validity, including having one of the researchers who had not participated in any of the focus groups, analyze excerpts of the material.

Physicians and patients were found to share many of the same beliefs. Both patients and physicians favored the annual physical exam, indicating that it provides a more thorough work-up and builds trust within the patient-physician relationship. Patients considered tests more accurate than the history and physical (Beaulieu, 1999, p. 3). Very few patients indicated negatives of screening tests. In contrast, physicians placed greater value on the history and physical than tests results and were very concerned about false positive results. Beaulieu, et al. (1999, p.1) stated that physicians strongly disagreed with the Canadian Task Force on Preventive Health's recommendations that the routine annual physical be replaced with selected tests, specific to different stages of the individual's life cycle.

Focus groups provide an opportunity to obtain a great deal of information on patient perceptions, expectations, knowledge, attitudes, and related factors, directly from the individuals being studied. Through appropriate standardized questions, participants can expand on issues and personally provide information beyond that which can be obtained in survey methodologies. If this methodology is used, an adequate sample of participants should participate in order to best ensure that the views are representative of the population being studied.

Of the two focus group studies related to prostate cancer, the 14 focus groups

used by Beeker et al. (2000, p. 2) would appear to be the more representative sample. Twelve of the groups were also stratified by age and sex. In contrast, the Clarke-Tasker (1999, p. 1) study used only two focus groups, each consisting of six men. This sample size would not appear to have been representative. In the Beaulieu et al. (1999, p. 1) study, there was a discrepancy between the numbers in the physician and patient focus groups. There were thirty-five physicians in the physician focus groups and 75 patients in the patient focus groups. It is difficult to determine if the variation in the number of participants in each of these two groups, biased the findings.

The primary challenge in utilizing focus groups, pertains to data analysis. All three studies made fairly reasonable attempts to codify the verbal responses and produce outcome data based on a systematic and consistent content analysis. The most vigorous efforts to ensure internal consistency in coding responses were observed in the Beaulieu et al. (1999, p. 2) study. Independent assessments were made by multiple coders, including one coder who did not participate in any of the focus groups and was thus less subject to bias (Beaulieu et al., 1999, 2).

Surveys

Five studies utilized survey methodologies. The first two studies made comparisons between physician and patient perceptions and knowledge of preventive health care practices (Montano et al., 1999) (Ward et al., 1999). A third study looked at the patient's perception of need for radiology services (Wilson et al., 2001) and a fourth study compared patient's perceived needs for preventive health procedures with evidentiary findings (Persell, 2002). The final study compared patient participation in colorectal screening with patient participation in gender-related

cancer screening (Lemon et al., 2001).

In the first survey based study, Montano et al. (1999, pp. 1-2) compared cancer screening rates reported by physician self-reports, chart audits, and patient surveys. A random sample of 450 family physicians was selected from the membership rolls of the Washington Academy of Family Practitioners. Questionnaires were sent to physicians in order to obtain information on their beliefs and practices with regard to seven cancer control services. Physicians were first asked to explain their own screening interval policy for each of the control services. They were next asked to approximate their completion rate which was the percentage of patients of appropriate age and sex categories screened according to the physician's own stated screening interval policy.

Potential participants for the patient survey were identified by having a research assistant visit each physician office and obtain names and addresses of 350 patients (Montano et al., 1995, p. 3). Inclusion criteria were as follows: (1) The patients were between 19 and 75; (2) The patient was seen at least twice by the physician, with the first time at least 6 months prior to the survey; and (3) The patient received most of his care from the physician. A sample of the patients who returned a survey were selected for chart reviews and were sent letters requesting their consent. The total patient population data sample consisted of 11,005 patients.

Measurements for chart audits were based on occurrence of specific procedures prior to their index visit (Montano et al., 1995, p. 3). The index visit was the most recent visit to the physician, prior to the survey. Measurements for the physician self-report screening rates represented the average proportion of patients for whom the physician reported prescribing screening during the specified interval. Measurements from the patient

survey were based on using the number of patients within the screening target population as the denominator (Montano et al., 1995, p. 4). For example, all women over 50 in the physician's practice were the target population for mammography. The numerator was the actual number in the target population that received the screening.

The agreement between chart audits and patient surveys was quite high for all procedures, except chest x-rays for smokers (Montano et al., 1995, pp. 5-6). In contrast, agreement between physician's self-reported rates and patient surveys was quite low. The authors concluded that physicians overestimate the extent to which they provide several of the studied screening services. Montano et al. (1995, pp. 5-6) indicate that physician self-report has been the method most frequently used in assessing physician practice patterns and behavior because it is probably the least costly method of making this assessment. The study findings suggest that this method may have low reliability.

A second study involving comparisons between physician and patient perceptions, used a survey methodology to compare the public and general practitioner's beliefs regarding the risks of developing prostate cancer (Ward et al., 1999, pp. 1-2). Responses to a community survey were compared to responses on a postal survey sent to GPs in Australia. Both the public and GPs overestimated the risk of developing prostate cancer. However, GPs were significantly less likely than men in the general public to overestimate the risk of dying from prostate cancer. Furthermore, over one-third of the GPs very much over-estimated the lifetime morality risk as one in 20, when it is actually 1 in 65 (Ward et al. 1999, p. 2). The authors indicate that it is very important for men to understand the controversies related to prostate screening because the absolute risk of dying of prostate

cancer before the age of 75 is very low, while treatment may result in serious complications (Ward, et al., 1999, 3).

In a third study using survey methodologies, Wilson et al. (2001, p. 1) studied patient beliefs regarding perceived need for radiological services. Using a cross-sectional survey methodology, patients receiving outpatient services in predominantly rural areas of eight states were asked their opinion of how necessary radiological tests were in evaluating four common presenting complaints: respiratory problems, low back pain, knee pain, and knee swelling. Utilization rates for radiology procedures were obtained through patient self-report.

The study found that patient's perceived needs for radiological studies were associated with outpatient utilization of these services for respiratory problems and low back pain (Wilson et al., 2001, p. 1). The authors suggest that the study provides evidence supporting previous anecdotal reports indicating that patients directly or indirectly communicate their testing preferences to their physicians which subsequently influences utilization of services (Wilson et al., 2001, p. 5).

In a fourth survey based study, Persell (2002, p. 1) studied the beliefs of Americans in regard to whether or not they perceived a need for an annual physical exam, as well as an annual physical exam and laboratory tests. He also studied the impact of monetary charges on these attitudes. Using a random-digit, dialed telephone survey methodology, study participants in three American cities were questioned about specific facets of the annual physical exam and what they viewed as necessary and unnecessary.

Survey participants were specifically asked if they agreed with the following statement: "In addition to seeing my regular doctor when I am sick or for chronic

medical problems, I need an annual physical exam" (Perell, 2002, p. 1). Respondents were also given a list and asked to select items which they believed should be included in the physical exam (Persell, 2002, p.1). Six hundred of the 1,203 respondents were asked if they would still want the exam and the items they specified, if required to pay standard charges for the services.

The response rate to the survey was 89% (Persell, 2002, pp. 1-2). The mean age of respondents was 49 years old.. The results demonstrated that 66% of respondent's believed they needed a physical examination. The percentage of respondent's indicating need for the other preventive health procedures listed in the survey was not necessarily related to the scientific evidence for its inclusion in annual preventive care. Moreover, the study found that perceived needs are very much affected by costs and may be changed subject to cost . For example, the percentage of respondents indicating perceived need for fecal occult blood testing, chest radiography, mammography, and Pap smears fell considerably when asked to take costs into account. In contrast, changes in beliefs about low cost tests, such as a urinalysis were less pronounced.

Commenting on the study findings, Persell (2002, p. 2) advises clinicians to openly elicit from patients their expectations about specific tests and address them with patients. He states that while it may take extra time to explain why certain tests are not necessary, it is well worth the time in helping patients adapt to evidence based approaches. Furthermore, these discussions also provide opportunities for clinicians to advocate for preventive strategies that may be worth the cost for the patient.

The fifth and final study involving a survey methodology was conducted by Lemon et al. (2001, pp. 1-2). The authors compared the prevalence and predictors of colorectal

cancer (CRC) screening for men and women with the prevalence and predictors of mammographic screening for women and prostate specific antigen (PSA) screening for men.

Participants were randomly selected individuals over the age of 50, residing in Massachusetts (Lemon et al., 2001, pp. 1-2). The methodology involved the use of a cross-sectional random-digit-dialed telephone survey. Telephone interviewers queried a sample of 954 participants on their experience with fecal occult blood test kits, flexible sigmoidoscopy, colonoscopy, and double contrast barium enemas. In obtaining information on mammography and PSA screening, men and women were asked if they had ever received the sex appropriate test. Demographic information was also collected.

The overall results showed that 53.3% of participants currently participated in some type of CRC screening (Lemon et al., 2001, 4). Women who had a mammogram in the past year were four times as likely to be current for CRC screening than women who had not had a mammogram. Men who were current for PSA screening were seven times as likely to be current for CRC screening.

In general, within sex groups, health and lifestyle behaviors affecting patient choice about screening were similar for CRC, mammography, and PSA screening (Lemon et al., 2001, pp. 7-9). Individuals interested in preventive health, as measured by check-ups, non-smoking, and supplement use are more likely to seek screening. The authors speculate that participation in one type of screening test may facilitate participation in another. They advise that working with individuals to accept one type of screening test, may help change their attitudes about other types of screening.

Surveys present a primary and useful methodology for studying patient expectations pertaining to a variety of health care procedures and practices . The survey instruments may be designed to query participants on a broad range of issues. Relationships among many variables can be measured and appropriate correlations made. The Lemon et al. (2001) study demonstrated relationships between the individual's participation in colorectal cancer screening and participation in gender related cancer screening. It was also used to measure relationships between personal characteristics and health and lifestyle practices.

Surveys methodologies pertaining to health care may yield extremely useful information for providers, consumers, public and private administrators, and policy makers. The surveys conducted by Montano et al. (1995) and Ward et al. (1999) comparing patient and physician perceptions of preventive health practices, may yield information which is useful to patient and physician educators. Likewise, the factors affecting utilization and health care costs identified and analyzed in the Wilson et al. (2001) and Persell (2002) studies may be very useful to health administrators and policy makers. Lemon et al. (2001) also provided information on compliance with screening guidelines which may have value to providers of such services.

Depending on their structure, surveys can be used for both descriptive studies and to test hypotheses. Descriptive information can be very valuable in studies of patient expectations. However, descriptive information needs to be balanced with outcome data from hypothesis driven studies. Despite their reasonably good survey designs, none of the studies using survey methodologies were hypothesis driven. This would be the primary weakness identified in this group of studies.

Experimental-Control Group

The next study conducted by Dolan and Frisina (2002, p.1) used an experimental-control group design to study the use of a patient decision aid in helping patients to clarify beliefs and values in choosing among options for colorectal screening. The study methodology was a random controlled pilot study. Patients in the experimental group were provided with a multi criteria based decision aid for making decisions about colorectal screening. Patients in the control group participated in an educational intervention which consisted of a short (470 word) description of colorectal cancer and the five recommended screening procedures developed by an expert panel (Dolan and Frisina, 2002, pp. 2-3).

The sample population consisted of 96 patients (Dolan and Frisina, 2002, pp. 1-2). Four patients were being seen in being seen in an inner city faculty-resident teaching practice. The remainder were recruited from two suburban private practices. Inclusion criteria required that patients be of average risk for colorectal cancer which was defined as 50 years of age or older, negative family history, no history of inflammatory bowel disease, colorectal cancer, or polyps, and several other factors related to normal cognitive status and overall general health.

The theoretical basis of the decision aid used by Dolan and Frisina (2002, p. 3) was based on the analytic heirarchy process (AHP), a multi-criteria decision making method. It was designed for decisions involving integration of quantitative data with less concrete data, such as values and preferences. The AHP involves four steps: (1) Development of a decision model involving the goal of the decision and the alternatives under consideration; (2) Comparisons to determine the relative abilities of the alternatives to fill the criteria;

(3) Comparisons among the criteria to determine their relative importance in meeting the goal; and (4) Combining of information obtained in steps 2 and 3 to determine the alternative most likely to fulfill the goal of the decision.

The study tested two hypotheses (Dolan and Frisina, 2002, p. 6). The first hypothesis stated that patients in the experimental group using the decision aid would have lower decisional conflict scores than the control group. The second hypothesis stated that patients in the experimental group would be more likely to complete screening plans at the study site than those in the control group.

The two outcome measures were patient decision process and decision outcome (Dolan and Frisina, 2002, pp. 5-6). Decision process was measured using the Decision Conflict Scale. This instrument is a 16 item scale designed to measure the degree of uncertainty which an individual has regarding a specific course of action. The authors state that it has been shown to have a high degree of internal consistency. The study results indicated that patients in the experimental group had lower conflict scores on several scales measuring knowledge, clarity of values, and quality of decision process than patients in the control group.

Decision outcome was measured by the actual decision made by the patient regarding whether or not to undergo colorectal screening (Dolan and Frisina, 2002, p. 7). In contrast to the decision process, no differences were found in decision outcomes, with 52% of patients in the experimental group completing screening, and 49% of patients in the control group completing screening.

The authors concluded that a patient decision aid for decisions regarding colorectal screening improved patient the patient decision-making making process, but had no effect

on the decision implementation (Dolan and Frisina, 2002, pp. 10-11). However, they point out that while there were no significant differences between the two groups, the trend was for more patients in the experimental group to choose screening than in the control group. The authors indicate that their study confirms the need for greater study on the use of decision aids in helping patients make clinical decisions.

An experimental-control group design allows the researcher to test hypotheses. However, the study's validity is highly dependent on its design methodology. The Dolan and Frisina, (2002, p. 10) study was a pilot study and the authors acknowledged its limitations. The limitations cited included a non-representative sample; omission of a usual care control group; lack of a physician intervention; and outcome measures were limited to patient decisions made at the study site, rather than longer term changes in patient perceptions.

Interviews

Silverman et al. (2001, pp. 1-2) used an interview methodology to study how women view breast cancer; their personal risks of developing breast cancer; and how screening mammography affects that risk. The objective of the study was to help physicians and other clinicians better understand women's knowledge and beliefs about breast cancer so that they could more effectively counsel them.

The study methodology was based on a theoretical framework for effective risk communication developed by Fischhoff and others at Carnegie Mellon University (Silverman et al., 2001, p. 2). The three step "mental models methodology" Silverman et al. (2001) used in the study was as follows: (1) Summarize all available information in a way that represents how experts view the issue; (2) Learn how non-experts view the same

issue by conducting in-depth interviews with the target population in which the interviewer attempts to be as non-directive as possible; and (3) Compare the expert and non-expert views in order to identify misunderstandings and conceptual gaps that require special attention in subsequent patient communication.

Women were randomly selected from a commercially maintained sample frame (Silverman et al., 2001, p. 2). They were telephoned and asked about their age, race, and income and whether they ever had breast cancer. Those who previously had breast cancer were eliminated from the sample. Strata sampling was used to select specific age, income, and ethnic categories. Forty-one women participated in the interviews. Four age categories were used, under 40, 40-49, 50-69, and over 70. The two categories of income were \$25,000 or less and more than \$25,000 per year. Ethnic categories were white, black, and o. Participants were offered \$20 for completing the interview, as well as a personalized breast cancer risk assessment.

The interview protocol was open-ended and designed to allow respondents to fully express themselves before the interviewer introduced any new concepts (Silverman et al., 2001, p. 3). The following prompts were used to promote further communication (Silverman et al., 2001, 3): "Anything else? Can you tell me more? Anything else-don't worry about if its right? Can you explain why?" In order to reduce variability in interviewing techniques, two interviewers, one master's level and one doctoral level) conducted all the interviews (Silverman et al., 2001, 4-5). After transcribing the interview, a coding system was used for each response (Silverman et al., 2001, 4).

The results demonstrated that women viewed breast cancer as a uniformly progressive disease which was curable in the early stages, but deadly in the later stages

(Silverman et al., 2001, 1). In contrast, experts viewed false-positives as a very harmful aspect of screening, many women viewed them as an acceptable aspect of screening.

The authors expressed concern regarding two of the findings (Silverman et al., 2001, p. 8).

The first finding was related to women's decisions about screening. The public messages the women received were skewed in favor of screening, rather than urging them to balance the facts and make their own decisions. This finding concerned the authors because high screening rates are presently viewed by health plans as a quality measure, whether or not they are based on informed decision making. The second finding indicated that women attributed exaggerated importance to a variety of behavioral factors, such as smoking, diet, and attitudes, viewing them as risk indicators, even though no proven relationships with breast cancer have been found (Silverman et al., 2001, 8). This finding also concerned the authors because it suggested that women diagnosed with breast cancer may unnecessarily blame themselves for engaging in risk taking behavior or failing to have regular mammograms.

An interview methodology has the advantage of allowing the interviewer to ask pre-selected questions which may provide further explanation and elaboration than provided in a survey methodology. However, as in focus groups, the consistency in coding procedures may introduce bias. Moreover, the representativeness of the sample may also be open to question, as many women might be reluctant to discuss personal health matters with a telephone interviewer. The lack of consistency in coding responses and a non-representative sample may potentially bias the results.

Meta-analysis

The final methodology to be reviewed in studies of patient expectations consists of meta-analyses of existing literature. Two such studies will be discussed. The first meta-analysis conducted by Kravitz (1996) involved a very extensive review of the literature on patient expectations for medical care, published in England from the late 1960's through the early 1990's. The second meta-analysis conducted by Tudiver et al. (1998, pp. 1-4) was more limited in scope than the Kravitz (1996) meta-analysis. Tudiver et al. (1998) primarily focused on literature which would explain the lack of acceptance of screening guidelines by Canadian physicians.

The goal of the Kravitz (1996, pp. 1-2) meta-analysis was to develop a conceptual framework for understanding patient expectations of medical care. The strategy for literature retrieval focused on the linkage between patient expectations and patient satisfaction. The key words were "consumer satisfaction" or "patient satisfaction" (Kravitz, 1996, p. 2). Of the 294 citations found, 35 were empirical studies and became the basis of the meta-analysis.

Kravitz (1996, pp. 5-7) analyzed the data on patient expectations with respect to operational definitions, level of specificity, and content of encounters. At its most basic level, patient expectations may be defined or conceptualized as "beliefs or attitudes that interact with perceived occurrences to produce care-related evaluations" (Kravitz, 1996, p. 8). Based on his review of the literature, Kravitz proposed a taxonomy or classification system for studying patient expectations of medical care (Kravitz, 1996, p. 4). He suggested that the operational definitions of expectations within studies can be broken down into two basic categories, (1) expectations as probabilities and (2)

expectations as values. Expectations as probabilities are beliefs which the patient holds about the likelihood of future clinical occurrences (Kravitz, 1996, p. 4). They are expectancies of what is probably going to occur. Of the 35 empirical studies, five treated expectations in this manner. The meta-analysis concluded that there was insufficient evidence suggest that expectancies as beliefs or probabilities contribute to patient satisfaction.

Alternatively, expectations as values are attitudes related to events or specific phenomena (Kravitz, 1996, 4-5). Kravitz (1996, p. 5) states that expectations as values are expressions of patient perceptions of their individual wants, needs, and entitlements. Kravitz (1996) indicates that operational definitions in the literature, most often refer to these value orientations, as opposed to expectancies. Kravitz (1996) is essentially drawing a distinction between expectations based on knowledge, facts, and information (expectations as probabilities) and expectations based on affective or feeling components (expectations as values).

In regard to level of specificity of expectations, Kravitz (1996, p. 5) distinguishes between patient expectations pertaining to health care in general and those based on specific visits or encounters. He indicates that most of the studies reviewed pertain to specific medical encounters. The author suggests that while it would be reasonable to assume that general expectations of health care would be correlated with visit specific encounters, no supporting evidence was found to support this relationship.

In regard to content of encounters, Kravitz (1996, p. 5) suggests that patients have expectations of health care structures, process, and outcomes. Structure refers to physical setting. Process refers to what health providers actually do in providing care. Outcomes

refer to the end results. Kravitz states that most studies to date have focused on process of care. Very few have focused on structure or outcome.

Kravitz (1996, p. 7) also discusses measurement of timing of patient expectations. With one exception, studies of visit-specific expectations have focused on previsit expectations only. Previsit expectations have the benefit of not being biased by clinical events. However, Kravitz (1996) suggests that they may be less relevant than expectations that persist during and after the encounter.

Kravitz's (1996) meta-analysis presents limited quantifiable data, but focuses on components of patient expectations which can be studied and become part of a conceptual framework for further research. He argues that studying patient expectations benefits clinicians, policy makers, and researchers (Kravitz, 1996, p. 1). Clinicians need to communicate with their patients and elicit their expectations, particularly in the many situations in which the patient's preferences may be critical to the clinical decision-making process. Clinicians must also determine if patient expectations are reasonable and provide education when they are unreasonable. Policy makers and researchers need to understand the influence of patient expectations in the measurement of health care quality patient outcomes, service delivery, and costs of care (Kravitz, 1996, p. 1).

A second meta-analysis was conducted by Tudiver et al. (1998, p. 1). As indicated, the objective of this study was to determine why Canadian physicians were not following the screening guidelines developed by the Canadian Task Force On Periodic Health Exams (Tudiver, et al. 1998, p. 1). The authors used a literature search methodology to assist in developing a conceptual model to explain physician's level of compliance with practice guidelines. After examining the literature, the authors

concluded that conceptual frameworks to explain physician behavior with respect to acceptance of screening should encompass four components, physician characteristics, patient characteristics, social factors, and practice characteristics (Tudiver et al., 1998, p. 2).

Patient characteristics which influenced whether or not a physician suggests screening, pertained to the physician's knowledge of and perceptions of his patient's wishes (Tudiver, et al. 1998, p. 2). They included knowledge of the patient's preferences, social circumstances and support systems, and the patient's fear of and willingness to tolerate procedures. Desires to avoid patient complaints and length and quality of the patient-physician relationship were also factors.

Physician characteristics that were positively associated with adherence to screening and preventive health guidelines included physician's perceived effectiveness of the procedures; agreement with guidelines; level of continuing medical education; and perceived probability of disease (Tudiver et al., 1998, p. 2). Physician characteristics that were negatively associated with agreement with guidelines included older age, male sex, and not having completed a postgraduate residency program.

Drawing on a theory by Mittman and colleagues, three types of social influences are suggested . (Tudiver et al., 1998, p. 2). They are categorized as "interpersonal," "persuasion," and the "media" (Tudiver et al., 1998, p. 2). The first type of social influence, referred to as "interpersonal" (Tudiver et al., 1998, p. 2) encompasses academics, training, and consultations with specialists. The second type of social influence, referred to as "persuasion" (Tudiver et al., 1998, p. 2) encompasses opinion leaders, quality improvement, study groups, and rounds. The third social influence is the

“media” (Tudiver et al., 1998, p. 2), but no further elaboration of this third influence is provided.

Tudiver et al. (1998, pp. 2-3) indicate that the assumption that physicians study and incorporate new evidence into practice is not supported by the research to date. They suggest that research on the determinants of physician behavior which affect screening decisions should be broadened to include the four influences identified in their literature review. These influences pertain to patient, physician, social and practice factors.

Meta-analyses are useful methodologies in studying social science and educational issues. The Kravitz (1996) study made some attempt to quantify findings or at least provide comparisons on the pervasiveness and volume of literature on patient expectations and study outcomes, where applicable. In this sense, it is a true meta-analysis. In contrast, the Tudiver (1998) study provides support within the literature for the four component model suggested by the authors, but is not a true meta-analysis, as no quantifiable information is provided.

Conclusions: Patient Expectations of Screening & Other Preventive Medicine Practices

The reviewed studies on patient expectations of screening and related preventive health practices offer intriguing and scientifically valid designs and content for further study. The methodologies have been described in detail. The merits and challenges involved in each methodology have also been discussed. Other noteworthy components of the reviewed methodologies included the adaptation of theoretical models to the studies; comparisons between patient and physician samples; and analysis of the impact of specific patient characteristics on screening decisions. Aspects of these methodologies may be adapted to the proposed study on patient expectations of full body CT screening.

Furthermore, several of the outcomes support the rationale for further research in this area of inquiry.

Based on the reviewed studies, it would be suggested that the proposed study on patient expectations of full body CT screening utilize a theory based, survey methodology. The instrument developed for this purpose should be subjected to validity and reliability studies and provide the quantifiable data to vigorously test the study hypothesis. Comparisons of patient and physician survey responses or use of two population-specific survey instruments might yield additional useful data. Likewise, a questionnaire or other tool should also be incorporated to obtain demographic or other personal data relevant to patient or physician characteristics which might impact on the study results.

In addition to generating possible methodologies, several of the reviewed studies provided useful outcome data on facets of patient expectations specific to prostate cancer, colorectal, breast cancer, and other cancer screening. Regardless of the specific disease or purpose of the screening, the common theme in all of these preventive health activities focused on inconsistencies between scientific evidence and the expectations of patients and physicians.

Persell's (2002, pp. 1-2) study found that patients' perceived needs for annual preventive health procedures were not consistent with scientific evidence and may be influenced by cost. Ward et al. (1999, p. 2) found that both patients and physicians overestimate the risks of developing prostate cancer and its lifetime mortality, as well as the benefits of screening. Two of the Canadian studies demonstrated that both physician and patient views of screening and preventive health practices were not consistent with

the evidentiary based guidelines of the Canadian Task Force On Periodic Health Exams (Tudiver et al., 1998, p. 1) (Beaulieu, et al, 1999, pp. 1-2) (Tudiver,et al. 1998, p. 1). A study by Wilson et al. (2001, p. 5) found that patient's perceived needs for radiological services were communicated to physicians and influenced utilization of these services.

The individual and conglomerate findings from these studies support the need for a study on patient expectations of full body CT screening. Given the lack of scientific evidence on the effectiveness of full body CT screening and absence of evidentiary guidelines, clinicians and researchers need to determine the expectations of patients selecting this radiological procedure. As discussed in the purpose and rationale for the proposed study, this information would assist patient educators and physician educators in developing educational programs for patients and continuing education activities for physicians.

Informed decision making and effective physician communication would be two components of educational programming very much supported by the research on patient expectations. Several studies have demonstrated that patients require assistance in developing skills for informed decision making and in selecting among options for screening and other preventive health procedures (Clarke-Tasker, 2002, pp. 1-2) (Dolan et al., 2002, p. 3) (Becker et al., 2000, pp. 7-8) (Ward et al., 1999, pp. 1-3). However, studies also suggest that physicians may not always have the requisite knowledge or communication skills to assist patients in making these decisions (Montano et al., 1995, pp. 1-7) (Ward et al., 1999, pp. 1-4). Physician education can be a mechanism for educating doctors in the technical knowledge and communication skills required for counseling patients considering screening. The importance of understanding patient

expectations in providing counseling on screening was noted in the Silverman et al. (2001, p. 2) study.

Kravitz (1996, p. 1) elaborates on the rationale for studying patient expectations based on his meta-analysis of studies. He states that clinicians need to understand patient expectations because meeting patient expectations has been shown to enhance patient satisfaction and lead to greater adherence to therapy and better outcomes (Kravitz, 1996, p. 1). Moreover, clinicians need to communicate with their patients and elicit their expectations in the many situations in which the patient's preferences may be critical to the clinical decision-making process.

Clinicians must also determine if patient expectations are reasonable and provide education when they are unreasonable (Kravitz, 1996, 1). Welch (2001, p. 2) argues that decisions on screening should be based on accurate patient beliefs and knowledge. Welch's paper is not an empirical study and was thus not included in the previous review. However, he discusses several limitations of screening that have been strongly supported within the studies in the first section on issues in evaluating the effectiveness of screening (Welch, 2001, pp. 2-3).

These limitations primarily focus on the fact that patients may receive ambiguous results, which may require them to undergo further testing, and possibly unnecessary treatments. Welch (2001) advises that these limitations need to be incorporated into patient communication on screening, so that patients have realistic expectations of the procedure. He further states that the focus of education needs to change from persuading patients to undergo screening to informing them of screening limitations.

Need for Further Study

Informed decision-making regarding participation in full body CT screening screening is predicated upon realistic patient expectations. Clinicians cannot facilitate informed decision-making in patients without an evidence-based knowledge of the patient's expectations of the procedure. The studies reviewed in this section on patient expectation of screening and other preventive health practices physician, as well as those reviewed in the previous section on issues associated with screening effectiveness provide strong support for the need for the proposed study on patient expectations of full body CT screening. This study would pioneer a new line of inquiry with respect to full body CT screening, while also contributing to the existing knowledge base on patient expectations of other screening and preventive health procedures.

The reviewed studies on patient expectations of screening and other preventive medicine interventions provided valuable descriptive information, however, they did not test hypotheses. This was a primary weakness in the studies. The proposed study on full body CT screening will utilize a hypothesis driven survey methodology. The survey instrument will be designed to collect critical self-report information from the patient within an approximate 10-15 minute time frame. Patients will be queried regarding their expectations of the full body CT procedure, as well as asked to provide information specific to a broad range of variables which may influence their expectations.

In addition to generating possible methodologies, several of the reviewed studies provided useful outcome data concerning patient expectations related to screening for prostate cancer, colorectal cancer, breast cancer, and other medical conditions.

Regardless of the specific disease or purpose of the screening, the common theme in all of these studies focused on inconsistencies between scientific evidence and the expectations of patients and physicians. Given the lack of scientific evidence on the effectiveness of full body CT screening and absence of evidentiary guidelines, clinicians and researchers need to determine the expectations of patients selecting this radiological procedure. As discussed in the purpose and rationale for the proposed study, this information would assist physicians and patient educators in developing educational programs which help patients make informed decisions about full body CT screening.

Chapter III

METHODS

The study used a pretest-only between-subjects, descriptive survey design to study the influence of specific patient attributes on patient expectations of the health benefits of full body CT screening. The sampling method required a minimum of three nationally representative sites performing full body CT screening. The target population consisted of patients within these sites scheduled to receive full body CT screening. Each full body CT screening, included at a minimum, the chest, abdomen, and pelvis. The only criteria for inclusion required subjects to be at least 21 years old.

The Seton Hall University Institutional Review Board approved the research proposal. Ninety-four subjects were included in the study sample. At the close of the study, six geographically diverse sites had participated for all or part of the study period.

Subjects

All patients in the target population at the selected sites who met the inclusion criteria were invited to participate in the study. Through the use of either a verbal script or written correspondence, patients were informed by the sites that their office/medical facility was participating in a voluntary, university-based research study. If interested in further information, patients were directed to the researcher's solicitation letter. The sample population was comprised of those patients in the target population who voluntarily agreed to participate in the study after receiving this information.

The solicitation letter was written directly to potential participants and explained the purpose of the study and the protections safeguarding the confidentiality of their responses and identity. Consent was demonstrated by the participant voluntarily completing the hard copy survey, enclosing it in the sealed addressed envelope, and submitting it at the site or anonymously e-mailing it to the researcher (Portnoy & Watkins, 2000, p. 312). Confidentiality and other rights of patients consenting to participate were protected in accordance with IRB requirements.

Study Sites

Potential study sites were identified through the internet. The researcher personally telephoned physicians and administrators at these sites to discuss the study rationale and preliminary study procedures. Sites interested in possibly participating or receiving further information were e-mailed a letter which further elaborated the design and study procedures. They were also provided with copies of the study instruments. If the site agreed to participate after reviewing the provided documents, they were required to submit a letter to the Seton Hall University IRB authorizing their inclusion in the study. The six geographically diverse regions agreeing to participate were identified as follows: Northeast, Southeast, Midwest, Far West, Northern Pacific, and Southern Pacific. The Northern Pacific, and Southern Pacific sites were owned by the same parent company, but due to a geographic separation of approximately 200 miles, were considered two separate sites. The Far West site represented two office facilities owned by the same parent company, but due to their geographic proximity of approximately five miles, were considered one site.

Instrumentation

Validity Studies

Validity studies were performed on the two preliminary survey instruments. The first research instrument was a patient questionnaire and the second research instrument, was a patient expectation survey. A panel of twelve experts assessed the content and face validity of the preliminary survey instruments. These individuals included seven radiologists and five non-radiologists. The radiologists represented both academic and private practice settings. The non-radiologists included an academic ethicist; two radiology practice administrators; a hospital COO whose clinical background and administrative responsibilities included radiology; and an academic health care researcher.

Prior to the selection of the panel, it was determined that experts were required to meet one or more of the following criteria: (1) Ten or more years medical/technical experience performing radiological procedures and appropriate professional certification/licensing; (2) Five or more years administrative experience or operational familiarity with radiological practice operations; and (3) Recognized scholarship as radiology/health care researcher or published author/ journal editor. Of the twelve members of the panel of experts, four of the reviewers met all three criteria, eight met two of the three criteria, and one reviewer met one of the three criteria.

The panel of experts assessing content and face validity were asked to review the study instruments and provide recommendations on one or more of the following items:

(1) wording of specific items; (2) deletions or additions of specific items; and (3) style and organization of survey.

An item-by-item analysis was conducted to assess percentage of agreement among panelists. All recommended content, design, and organizational revisions were initially reviewed by the researcher. Appropriate content revisions involving the wording of specific items or deletions and additions of specific items were implemented.

The recommended design and organizational revisions primarily pertained to font size and style, order of items, and general layout. Based on recommendations from two reviewers, the patient questionnaire and patient expectation survey were combined into one revised instrument, entitled, "Patient Expectations of Full Body CT Screening Survey". The modified, integrated survey instrument was forward to the SHU Internal Review Board for revision approval.

Revised Survey Instrument

The patient questionnaire component of the revised integrated instrument was designed to collect information relevant to the independent variables, determinants of disease susceptibility. These attributes included: level of health concern, number of health concerns, other health screenings and preventive health practices, and patient knowledge. Demographic information relevant to age, gender, marital status, race/ethnicity, educational level, and annual income was also collected., as well as information on referral procedures.

The patient survey component of the revised integrated instrument was designed to collect the information relevant to the dependent variables, patient expectations. These included: reassurance of health, early diagnosis, health maintenance/prevention,

consumer empowerment, and patient satisfaction/safety. The patient expectation survey questions were formulated based on issues identified in the literature review relevant to patient expectations of full body CT screening. The survey utilized a five point Likert scale in which respondents indicated their level of agreement/disagreement (SA-Strongly Agree; A-Agree; N-Neutral; D-Disagree; and SD-Strongly Disagree) with a series of 15 statements designed to assess expectations of the benefits of full body CT screening.

Procedures

The initial four sites providing authorization letters were included in the validation studies. One of these sites withdrew prior to starting the study after the medical director who had authorized the study, left the practice. These four sites were offered the opportunity to suggest revisions in the study instruments and procedures. None of the site reviewers recommended changes in the content of the instruments, but two site reviewers requested changes in procedures.

The initial study procedure required all surveys to be completed on-site at the imaging facility. However, two sites expressed concern that completion of the surveys on-site would cause delays in scheduled procedures. In order to address this concern, hard copy and on-line options for completion of the surveys at home were added to the study procedures. The "at-home hard copy" option was submitted to the IRB and approved on October 25, 2003. The "at-home on-line" option was subsequently also submitted to the IRB and approved.

Three options were available after the initial pilot study for completion of the identical survey. These were on-site hard copy; at-home hard copy; and at-home on-line copy. Four of the six study sites elected to only use the on-site option.

Similarities in procedures among the three options were as follows: All options required the subject to complete the survey prior to receiving the full body screening procedure. Similarly, all options provided scripted information directly from the sites to the target population. Potential subjects were advised that the site was participating in a voluntary, university-based research study on patient expectations of full body CT screening, the procedure which they were scheduled to receive. The purpose of the study was to help health professionals better understand what patients expect from the procedure. These same individuals were further assured that the information which they provided would be kept anonymous and confidential. Potential subjects were directed to the researcher's solicitation letter for further information.

Differences in procedures among the three options were as follows: In the on-site hard copy procedure, designated site personnel delivered a verbal script in providing the study information to potential subjects. Patients expressing an interest in participating as research subjects, received a survey packet. The packet consisted of copies of the research instruments and a manila return envelope addressed to the primary researcher and her advisor at Seton Hall University, School of Graduate Medical Education. Patients volunteering to participate, were asked to place and seal the completed surveys in the provided envelope and submit at the imaging center.

For the at-home options, potential subjects were mailed a letter and study packet from the study sites which contained almost identical information to that provided in the on-site verbal script. The mailed correspondence additionally provided a telephone number at the site where a professional would be available to assist them, should they have any questions or concerns. The solicitation letter included with the at-home options,

was slightly modified from the one distributed with the on-site survey option. It included two additional sentences advising potential participants of a secured website where the survey could also be completed and anonymously e-mailed it to the researcher. Both solicitation letters were reviewed and approved by the IRB. The website was not included with the on-site option to help ensure that a subject would not complete a survey at the study site and again complete one at home on the web.

Two different colored return envelopes were used to differentiate surveys completed on-site from those completed at home. Address labels on both the white and manila envelopes were coded "A-F" to identify the specific site. All on-site and at-home hard copy surveys received by the researcher were coded by a number, 1-72, reflecting the order in which they were received, and a letter, identifying the study site, e.g. 32A. At-home on-line copies were e-mailed without site identifying codes and were included in the numbered sequence with an "I", after the number to indicate, internet, e.g. 33I. Four of the six study sites elected to only use the on-site option. The other two study sites provided volunteer subjects a choice of completing hard copy or on-line surveys at home approximately a week before the scheduled visit or on-site, before receiving the procedure at the imaging facility.

Pilot Study

A pilot study using the revised survey instruments was conducted. The site with largest volume of weekly studies was selected for the pilot study in order to collect this data in the shortest time possible. The first eleven completed and submitted surveys at this site constituted the pilot data. Each of these eleven pilot subjects had either selected the on-site completion option or due to the proximity of the date in which they scheduled

their appointment to the actual appointment, were never offered the at-home survey completion options. Therefore, a twelfth survey from another site (owned by the same parent company) was later included because it was the only mailed survey received, to date. Pilot results were analyzed as follows: (1) Willingness of potential subjects to participate in the study; (2) Comprehension of questions; and (3) Variability of responses.

Data Analysis Methods

Data obtained from each of the 94 submitted surveys were coded and entered on an excel spreadsheet. SAS software, version 612 was used to analyze the data. The distribution of the data was examined in order to determine which statistical methods would be most appropriate for assessing the associations between the independent variables and the dependent variables.

Independent Variables

The thirteen independent variables were the patient characteristics, enumerated as follows: (1) age; (2) gender; (3) marital status; (4) race/ethnicity; (5) educational level; (6) income; and (7) referral source; (8) self-estimation of current health status; (9) level of concern for personal health; (10) number of health concerns; (11) number of other health screening tests; (12) number of preventive health activities; and (13) patient knowledge. The survey was constructed so that each of these independent variables had a minimum of one corresponding question on the survey and several levels of response (see Appendix A for the listing of the patient characteristics {independent variables} and the codings for each of their response levels).

Dependent Variables

Fifteen patient expectation questions.

The fifteen dependent variables were the patient expectation questions (see Table I).

Table I

15 Patient Expectation Questions (Dependent Variables)

Item	Statement
1	Full body CT screening may give me peace of mind and reduce my worries about my health.
2	Knowing the results of this test may improve my overall health.
3	Regular full-body screening exams may prolong my life.
4	Finding a disease process early, may increase the chances of being cured.
5	This test will detect many, but not all diseases.
6	Effective treatments exist for almost any condition this test may find.
7	This test is available to both self-referred and physician-referred patients.
8	Full body CT screening is appropriate for healthy people, as well as people with specific diseases.
9	This test is one of the best options available today for preventive health care.
10	The comprehensive nature of CT screening makes it unlikely that I will require further testing.
11	I will want to recommend this test to my close friends and relatives.
12	The results of this screening will be discussed with me by a health care professional.
13	Additional tests may be needed to complement full body CT screening.
14	Full body CT screening may be repeated throughout a person's lifetime.
15	Scientists have studied the benefits and limitations of this procedure.

The patient expectation questions were analyzed both as discrete variables, as well as grouped into six patient expectation dimensions, each of which combined 2-3 discrete patient expectations. The six patient expectation dimensions were as follows: (1) "Reassurance" (2) "Cure" (3) "Prevention" (4) "Empowerment" (5) "Satisfaction" and (6) "Limitations" (see Table II for listing of corresponding patient expectations within each of the six dimensions).

Six patient expectation dimension

The six patient expectation dimensions were derived from current controversies identified in the scientific literature pertinent to the risks and benefits of CT screening for health care consumers. The terminology applied to each dimension represents an extrapolation of the specific controversial issue into a specific consumer expectation. (see Chapter 1 for definitions and scientific literature citations).

Table II

Six Patient Expectation Dimensions

Dimension	Corresponding Survey Questions
Reassurance	Full body CT screening may give me peace of mind and reduce my worries about my health. (1) Full body CT screening may be repeated throughout a person's lifetime. (14)
Cure	Finding a disease process early, may increase the chances of being cured. (4) Effective treatments exist for almost any condition this test may find. (6)
Prevention	Knowing the results of this test may improve my overall health. (2) Regular full body screening exams may prolong my life. (3)
Empowerment	This test is available to both self-referred and physician-referred patients. (7) Full body CT screening is appropriate for healthy people, as well as people with specific diseases. (8) The results of this screening will be discussed with me by a health care professional. (12)
Satisfaction	This test is one of the best options available today for preventive health care. (9) The comprehensive nature of CT screening makes it unlikely that I will require further testing. (10) I will want to recommend this test to my close friends and relatives. (11)
Limitations	This test will detect many, but not all diseases. (5) Additional tests may be needed to complement full body CT screening. (13) Scientists have studied the benefits and limitations of this procedure. (15)

Descriptive Statistics

The data analysis methods included both descriptive statistics and statistical testing. Descriptive statistics in the form of frequencies, means, medians, and standard deviations were constructed and used to examine the specific characteristics of the study population with respect to their (1) demographic attributes; (2) health perceptions and practices; and (3) knowledge of full body CT screening. Descriptive statistics were also used to examine trends in the scores on the Likert Scale responses with respect to the 15 patient expectation questions and the six patient expectation dimensions.

Statistical Testing

Statistical testing was used to analyze associations between the patient characteristic independent variables and the patient expectation dependent variables. The examination of the distribution of the data indicated that the data was not normally distributed. Therefore, two non-parametric tests, the Chi Square Test for Independence and the Spearman Correlation Coefficient were identified as appropriate methods for analyzing these associations. For both statistical tests, an alpha of .05 was used as the level of significance.

The chi square test for independence and two way tables were selected as the statistical method to analyze the associations between the 13 patient characteristic, independent variables and the 15 patient expectation, dependent variables. The results will be discussed in terms of their associations as 15 discrete patient expectation variables, as well as within the context of the six dimensions of patient expectations. The Spearman correlation coefficient test was selected to further analyze associations between the 13 independent variables and each of the six patient expectation dimensions.

Chapter IV

RESULTS

Study Sample

The study sample consisted of 94 subjects. Each subject was a patient at a study site who voluntarily agreed to complete a survey prior to receiving a full body CT screening procedure. Four of the six sites, Southern Pacific, Southeast, Midwest, and Northeast chose to only use on-site administration. Two of the sites, Far West and Northern Pacific chose to use both on-site and at-home administration. At these two sites, the surveys were mailed to patients' homes, prior to the designated date in which they were to receive the procedure. However, if the patient had not completed the "hard copy" or internet survey at home, they were provided with another opportunity on the day of their appointment at the imaging center.

Of the 94 submitted surveys, 82% were completed through the on-site procedure and 18% were completed through the at-home procedure. Of the surveys completed at-home, 14% were mailed as "hard copies" and 4.% were submitted through the internet. Table 3 provides survey submission data from each of the of the six study sites and internet surveys.

These percentages are estimated because in the interests of protecting the confidentiality of the study subjects, records were not kept of the number of patients who were offered the survey and refused it. Table 3 provides survey submission data from each of the of the six study sites and internet surveys.

Table III

Response Information by Study Site

Study Site	% of Total Surveys	No. of Surveys	No. of On-Site Surveys	No. of At-Home Surveys	Response Interval*
Southern Pacific	24.5%	23	23	0	11/15/03-2/4/04
Southeast	20.2%	19	19	0	12/24/03-2/17/04**
Midwest	10.6%	10	10	0	2/05/04-2/11/04
Northeast	18.1%	17	17	0	11/24/03-2/20/04**
Far West	11.7%	11	5	6	12/10/03-2/20/04
Northern Pacific	10.6%	10	3	7	12/11/03-2/28/04
Internet	4.3%	4	NA	4	11/25/03-/21/04
TOTALS	100%	94	77	17	

*Response Interval-First date postmarked-Last date postmarked

**No postmark on first survey received, date approximate

Validity Study Results

The content validity study conducted by the panel of twelve experts included an item-by-item review of the patient questionnaire and patient survey, as well as a general review of all other study documents. Fifty percent of the 12 reviewers recommended one or more changes to the content of these materials. In the review of the patient questionnaire and patient survey, the percentage of agreement in the item-by-item content validity analysis, ranged from 75%-100%. Appendix B details the item-by-item percentage of agreement among reviewers and the revisions implemented based on reviewer recommendations.

Reviewed comments relevant to the general content, format, and organization of the study instruments were as follows: (1) Include more negative items on the patient expectation survey; (2) Combine the patient questionnaire and patient expectation survey into one instrument; (3) Enhance user friendliness and presentation, i.e. font style, organization of response scales, etc.

The other study documents reviewed by the panel of experts included the patient solicitation letter; the verbal script delivered by the site personnel for on-site survey administration; and the written letter from the sites for at-home survey administration. One reviewer suggested including within the solicitation letter, a sentence stating, "If you decide not to participate, your care will in no way be affected." Appendix C is the actual revised survey and solicitation letter used in study. Appendix D presents the written and verbal scripts provided to the sites for informing patients of the study.

Pilot Study Results

Pilot results were analyzed as follows: (1) Willingness of potential subjects to participate in the study; (2) Comprehensibility of questions; and (3) Variability of responses to the patient expectation questions. An on-site pilot study was conducted for a two week period. Twelve surveys were analyzed. The site personnel reported that almost every patient offered the survey agreed to participate.

The patients were able to independently complete the surveys and did not ask any questions specific to understanding the survey items. However, several patients noted that in the item related to "marital status", the response category, "married" was missing, as it had been accidentally deleted from the earliest copies of the survey. This error was later corrected and the sites were asked to only use the corrected replacement copies.

Ten of the patient volunteers responded to all of the items. One patient completed all of the items related to the demographic, health practices, and patient knowledge segments, but the patient expectation questions were unanswered. Another patient completed all of the items related to the demographic and health practice, and patient knowledge segments, but only completed eight of the 15 patient expectation questions. Variability in the responses was somewhat limited. Out of a total of 175 possible responses, the percentage of responses within each Likert category were as follows: 29% "strongly agree; 39.5% "agree;" 14% "neutral," 4.5% "disagree," 1% "strongly disagree" and 13% of questions were unanswered. The question showing the most variability in responses was #6, "Effective treatments exist for almost any condition this test may find" (see Appendix E for pilot study results). Similar response trends to those observed in the pilot study were later observed in the comprehensive three month study results.

Descriptive Statistics

Demographic Characteristics of the Study Sample

Data on the demographic characteristics of the study sample were collected in the first section of the survey, referred to as "general information." The variables studied included gender, age, marital status, race/ethnicity, educational level, and income. Fifty-nine percent of the subjects in the study sample were male, 41% percent were female (see Figure 1). Most subjects were between 36-65 years old, with 44% between 36-50 and 51% between 51-65. The median age group was 51-65 years old (see Figure 2).

Figure 1. Percent of survey respondents within study sample represented by age (n = 93).

Figure 2. Percent of respondents within study sample represented by age ($n = 93$).

Eighty two percent were married (see Figure 3). Sixty-nine percent of incomes were in the highest response category, over \$100,000 per year, with the median income being over \$100,000 per year (Figure 4). Eighty-nine percent identified their race/ethnicity, as "White" (see Figure 5).

Figure 3. Percent of survey respondents within study sample represented by marital status ($n = 81$).

Figure 4. Percent of survey respondents within study sample represented by income (n = 88).

Figure 5. Percent of survey respondents within study sample represented by race/ethnicity (n = 94).

Educational levels were distributed somewhat more evenly than age, marital status, race/ethnicity, or income with the median educational level being "Bachelor's Degree."

Thirty-five percent of the subjects had bachelor's degrees, 26% graduate degrees, 22%

had attended some college, and another 15% were high school graduates (see Figure 6).

Figure 6. Percent of survey respondents within study sample represented by educational level ($n = 93$).

Patients in the study sample were also asked to indicate their method of referral. Sixty-five percent were self-referred and 35% were physician-referred. Of the 65% who said they were referred by a physician, approximately 54% responded that they requested the referral and 46% responded that their physician requested the referral. It is important to note that of the five states in which the study sites were located, the Southeast site was the only site located in a state which required a physician referral for the procedure.

Health Perceptions and Health Practice Characteristics

Data on the health perceptions and health practice characteristics of the study population were collected in the second section of the survey, referred to as "health information." The variables studied included the following: (1) participants' self-

estimations of their current health status; (2) their perceived levels of personal health concern in comparison to other people of similar age and health status; (3) the number and specific type of health issues which were of concern to them; (4) the number and type of other screening procedures in which they previously participated; and (5) the number and type of preventive health activities and practices in which they regularly engage. The following interesting trends were observed:

Self-estimation of current health status.

Fifty-six percent of participants self-estimated their health status as "very good." This was followed by 20% of participants reporting their health status as "excellent" and an almost equal percentage, 19%, reporting it as "good." Four percent of participants estimated their health status as "fair" or "poor" (see Figure 7). The median rating on participant's self-estimation of their current health status was 4.0, which corresponded to "very good."

Figure 7. Percent of survey respondents within study sample represented by their self-estimations of their current health status ($n = 93$).

Level of personal health concern.

Participants were asked to rate their level of concern regarding their personal health in comparison to other people of similar age and health status. Thirty-five percent reported they were “moderately concerned” (i.e. they thought about it monthly or several times a month). This was followed by 32% of participants reporting they were only “somewhat concerned” (i.e. they thought about it several times a year) and 23% reporting they were “very concerned” (i.e. they thought about it weekly or several times a week). The median rating on participants’ level of concern regarding their person health was 4.0, which corresponded to “very concerned” (see Figure 8).

Figure 8. Percent of survey respondents within study sample represented by their levels of personal health concerns (n = 94).

Number and specific types of health concerns.

The number of health concerns and specific types of health concerns reported by participants were examined. Patients reported concerns with respect to their personal and family health histories, as well as concerns regarding their weight, smoking, and current stress levels. Eleven possible response categories were listed. Sixty-one percent of participants reported having two or three health concerns. Twenty percent reported having four or more health concerns and an almost equal percentage, 19%, reported having no health concerns or one health concern. The median rating on the number of health concerns reported by participants was 3.0 which corresponded to three concerns.

The most frequently reported health issues of concern to participants were related to having family histories of cancer and family histories of other serious illnesses. The next most frequent concerns pertained to being moderately overweight, followed in descending order by "moderate stress within home or work life;" "former smoker;" "extremely overweight;" and "personal history of cancer." Other concerns included "extreme stress within personal or work life;" "current smoker" and personal histories of a serious illness, other than cancer (see Figure 9).

Figure 9. Percent of survey respondents within study sample represented by their specific health concerns (n = 93).

Number and specific types of other health screenings.

Additional data were collected on the number of other health screening procedures in which participants have engaged. Sixty-one percent of participants reported having two or three other health screenings in the time interval specified on the survey for the specific procedure. Another 20% reported having four or more health screenings and an almost equal percentage, 19%, reported having no health screenings or one health screening. The median rating on the number of health screenings reported by participants was 3.0, which corresponded to three other health screenings.

The two most frequently reported other health screening tests were blood testing (84%) and physical exams performed by primary care or OB/GYN physicians (79%) within the past 1-2 years. Eighty-four percent of women also reported having a mammogram within this same time interval. Forty-three percent of participants reported having a colonoscopy within the last five years and 32% reported having a cardiac stress test within the past 1-2 years (see Figure 10).

*Mammogram Percentage Represents 84% of women in the survey.

Figure 10. Percent of survey respondents within study sample represented by their participation in other screening procedures (n = 93).

Number and specific types of preventive health/lifestyle activities.

The final category of survey data examined on health perceptions and health practice characteristics was the number and specific type of preventive health activities in which participants' engaged. Eighty-six percent of participants reported engaging in at least one preventive health activity within the time interval indicated for that item on the survey. Of these participants, 28% reported engaging in 3 preventive health activities; another 28% reported 2 activities; and 29% reported engaging in only one preventive health activity in the specified time interval.

At the other two extremes, 7.5 % of the participants reported not engaging in any preventive health activities, in contrast to the 6.5% who reported that they engaged in four or more activities. The median rating on the number of preventive health activities

reported by participants was 2.0, corresponding to two preventive health activities. In regard to the specific types of preventive health activities in which participants engaged, 34% reported eating healthy food and an equal percentage reported they took vitamin supplements everyday or almost everyday. Another 23% reported they exercised three or more days per week (see Figure 11).

Figure 11. Percent of survey respondents within study sample represented by their participation other preventive health/lifestyle activities (n = 92).

Patient Knowledge Of Full Body CT Screening

Patient knowledge of the full body CT screening procedure was collected in the third section of the survey, referred to as "consumer information." Data was analyzed within two categories: (1) how study participants first learned about full body CT screening; and (2) the number and specific sources of information participants consulted after learning about the procedure. Twenty-nine percent of survey participants reported first learning about the procedure from friends and relatives and another 29% reported learning about it from TV/radio announcements. Twenty percent of participants reported

learning about the procedure from a physician and 10% from newspaper and magazine articles (see figure 12).

Figure 12. Percent of survey respondents within study sample represented by how they first learned about full body CT screening ($n = 78$).

Over 58% of survey participants reported consulting one or two other sources of information after learning about the procedure, while 38% did not consult any other sources. Of those survey participants who did consult other sources, the most frequent sources consulted, in descending order were the internet, popular media, and physicians (see figure 13).

Figure 13. Percent of survey respondents within study sample represented by additional sources of knowledge they used to learn about full body CT screening (n = 70).

Patient Expectations Questions & Dimensions

Fifteen Questions

Participants generally showed limited variability in their responses to the 15 patient expectation questions. Most participants "strongly agreed" or "agreed" with most items with the median score being four, on eleven of the 15 questions. The one question which did show variability was question number 6, which states that that effective treatments exist for almost any condition the test may find.

The median score was four, on eleven of the 15 questions. Three questions demonstrated median scores of five. These pertained to early diagnosis leading to cure; the test being available to both self-referred and physician-referred patients; and the results being discussed by a health care professional. The only question with a median score below 3.0, pertained to the comprehensiveness of the procedure and whether or not the patient may need to undergo further testing. Participants responses to each of the 15 patient expectations are graphically represented in Appendix J.

Six Patient Education Dimensions

The median scores on the Likert Scale responses were examined with respect to each of the six patient expectation dimensions. The median Likert Scale score was 4.0 for three of the six dimensions, labeled "reassurance", "cure", and "prevention." Upon review, the median Likert Scale score was slightly higher for the "empowerment" dimension. The median Likert Scale scores for both the "limitations" and "satisfaction" dimensions were somewhat lower, with "satisfaction" having a median score of 3.7 and "limitations" having a median score of 3.3 (see Table IV).

In summary, the data suggest that patients tended to have the highest level of agreement with survey expectation questions within the patient "empowerment" dimension and the lowest level of agreement with survey expectation questions within the "limitations" dimension.

Table IV

Distribution of Likert Scale Scores For Six Patient Expectation Dimensions

Dimension	Number	Mean	Standard Deviation	Median
Reassurance	92	4.28	.50	4.0
Cure	92	4.09	.61	4.0
Prevention	92	3.97	.84	4.0
Empower	92	4.33	.59	4.3
Satisfaction	91	3.62	.63	3.7
Limitations	92	3.43	.38	3.3

Results of Statistical Analysis

Associations Between Patient Characteristics And Patient Expectations

The associations between the patient characteristics and the patient expectations were primarily analyzed through statistical testing. The Chi Square test for independence and two way tables were used to analyze the associations between the 13 patient characteristics, the independent variables, and the 15 patient expectation questions, the dependent variables. The Spearman rank correlation coefficient test was used to analyze the associations between the 13 independent variables and each of the six patient expectation dimensions. For both statistical tests, an alpha of .05 was used as the level of significance.

The results of the Chi Square and Spearman statistical testing contributed to the analysis of the study hypothesis, "There is a significant positive association between patients' perceptions of their susceptibility to disease and their expectations of the health benefits of full body CT screening." For both statistical tests, an alpha of .05 was used as the level of significance.

Coding System

The same coding system was used for the Chi Square and Spearman statistical analyses. The fifteen patient questions (PE1-15) were scored based on the Likert Scale responses as follows: 5 = Strongly Agree; 4 = Agree; 3 = Neutral; 2 = Disagree; 1 = Strongly Disagree. The inspection of the frequencies for the responses to the 15 expectation questions showed that the full range of possible Likert scores were not always used or only a small number of respondents used the full range of possible response. Therefore, the five Likert response categories were collapsed into three

response categories which were coded as follows: category 1-strongly disagree & disagree; category 2-neutral; and category 3-agree & strongly agree. Recoding was also necessary for most of the response levels relevant to the patient characteristic independent variables (see Appendix A).

As indicated, the results of the Chi Square and Spearman statistical procedures were used to analyze the study hypothesis, "There is a significant positive association between patients' perceptions of their susceptibility to disease and their expectations of the health benefits of full body CT screening." They were also used in analyzing the associations between patient characteristics and patient expectation questions which were not integral to the study hypothesis, but may also contribute to the scientific knowledge base on patient expectations of full body CT screening and possibly other types of screening procedures (see Chapter V). Significant findings were as follows:

Chi Square Test for Independence

The data analysis using the chi square test for independence suggested that there were significant associations between several patient characteristics and patient expectations of full body CT screening. The significant characteristics were as follows: (1) Level of personal health concern; (2) Number of other health screenings; (3) Gender, and (4) Method of referral. The results of the chi square test for independence for which there were sufficient group sizes to make valid comparisons are represented in tables and graphs in Appendices G,H, and I. They are reported as follows:

Level of personal health concern.

A significant association was found between the level of concern which patients reported regarding their personal health and their expectations that knowing the results of

this test may improve their overall health, $X^2 (4, 92) = 10.073, p = .04$. This expectation is included within the "prevention" patient expectation dimension. Two way tables were constructed by cross-classifying patients by the number of health concerns they reported and their responses to each of the expectation questions.

Among the 27 patients who reported that they were "extremely concerned" or "very concerned" about their health, 89% agreed or strongly agreed that knowing the results of the test may improve their overall health; 11% were neutral; and none disagreed or strongly disagreed with the statement. Among the 31 patients who were "moderately concerned" about their health, 90% agreed or strongly agreed that knowing the results of this test may improve their overall health; almost 7% were neutral; and 3% disagreed or strongly disagreed with this statement. Among the 33 patients who were only "somewhat concerned" or "not concerned" about their health, 67% agreed or strongly agreed that knowing the results of this test may improve their overall health; 15% were neutral; and 18% disagreed or strongly disagreed with this statement.

Therefore, the data suggest that patients who were "extremely concerned", "very concerned" or "moderately concerned" about their health tended to have higher expectations that knowing the results of this test may improve their overall health when compared to patients who were only "somewhat concerned" or "not concerned."

Number of other health screenings.

A significant association was found between the number of other health screenings patients reported and patient expectations that the results of the CT screening would be discussed with them by a health professional, $X^2 (8, 90) = 17.80, p = .02$. This expectation is included within the "empowerment" patient expectation dimension. Two

way tables were constructed by cross-classifying patients by the number of other health screening tests they reported and their responses to each of the expectation questions.

Among the 30 patients who had four or more other health screenings, 100% agreed or strongly agreed that the results of their full body CT screening would be discussed with them by a health professional. Among the 25 patients who had three other health screenings, 92% agreed or strongly agreed that the results of their screenings would be discussed with them by a health professional; 8% were neutral; and none disagreed or strongly disagreed with this statement.

Among the 18 patients who had two other health screenings, 94% agreed or strongly agreed that the results of their full body CT screening would be discussed with them by a health professional; 6% were neutral; and none disagreed or strongly disagreed with this expectation. Among the 13 patients who had one other health screening, 77% agreed or strongly agreed that the results of their full body screening would be discussed with them by a health professional; 15% were neutral; and 8% disagreed or strongly disagreed with this expectation. Finally, among the 4 patients who had not reported any other health screenings, 75% agreed or strongly agreed that the results of their full body CT screenings would be discussed with them by a health professional; none were neutral; and 25% disagreed or strongly disagreed with this statement.

Therefore, the data suggest that the higher the number of other previous health screenings reported by patients, the higher their expectations that a health professional will be available to discuss the results of their full body CT screening exam. Every patient with four or more other health screenings reported expecting that the results of their full body CT screening would be discussed with them by a health professional,

followed by over 90% of patients with two or three other previous health screenings. Over 75% of patients who had only one previous health screenings agreed with this statement.

Gender.

Significant associations were observed between gender and three of the patient expectations questions. One of the three associations was within the "reassurance" dimension and the other two were within the "satisfaction" dimension. Two way tables were constructed by cross-classifying patients by their gender and their responses to each of the patient expectation questions.

Within the "reassurance" dimension, a significant association was observed between gender and patients' expectations that full body CT screening may be repeated throughout a patient's lifetime, $X^2(2, 91) = 9.77, p = .01$. Among the 37 female patients in the study sample, 97% agreed or strongly agreed that full body CT screening may be repeated throughout a patient's lifetime. Among the 54 male patients in the study sample, 80% agreed or strongly agreed that full body CT screening may be repeated throughout a patient's lifetime; 20% were neutral; and no one disagreed with the statement. Therefore, while the data suggest that a higher percentage of female patients than male patients agreed or strongly agreed that the full body CT screening may be repeated throughout a patient's lifetime, both men and women patients, generally had a high level of agreed with this statement.

Within the "satisfaction" dimension, two significant associations were observed between gender and two of the patients' expectation questions: (1) the comprehensive nature of full body CT screening makes it unlikely that patients will require further

testing, $X^2 (2, 91) = 12.08, p = .01$; (2) patients will want to recommend this test to their close friends and relatives $X^2 (2, 89) = 8.09, p = .02$. In examining the first significant association in the "satisfaction" dimension, it was observed that among the 37 female patients, 38% agreed or strongly agreed that the comprehensive nature of full body CT screening makes it unlikely that they will require further testing; 19% were neutral; and 43% disagreed or strongly disagreed with the statement. Among the 54 male patients, 9% agreed or strongly agreed that the comprehensive nature of full body CT screening makes it unlikely that they will require further testing, 41% were neutral; and 50% disagreed or strongly disagreed with the statement. Therefore, the data would suggest that female patients are more likely than male patients to be satisfied that they will not need further testing.

In examining the second association in the "satisfaction" dimension, it was observed that among the 35 female patients, 89% agreed or strongly agreed that they will want to recommend this test to their close friends and relatives; 9% were "neutral"; and 3% disagreed or strongly disagreed with this statement. Among the 54 male patients, 63% agreed or strongly agreed that they will want to recommend this test to their close friends and relatives; 35% were neutral; and 2% disagreed or strongly disagreed with this statement. Therefore, while the data suggest that a higher percentage of female patients than male patients agreed or strongly agreed that they will want to recommend full body CT screening to their close friends and relatives, over one-third of the males were neutral and almost none of the males or females disagreed or strongly disagreed with this statement.

Method of referral.

A significant association was found between the method of referral for full body CT screening and the expectation that this test is available to both self-referred and physician-referred patients, $X^2 (2, 91) = 15.1678, p = .001$. This expectation is included within the "empowerment" patient expectation dimension. Two way tables were constructed by cross-classifying patients by the method of referral they reported and their responses to each of the expectation questions. The number of patients in each of the cells was counted.

Among the 61 patients who were self-referred, 92% agreed or strongly agreed that full body CT screening is available to both self-referred and physician referred patients; 5% were neutral; and 2% disagreed or strongly disagreed with this expectation. Among the 30 patients who were physician-referred, 60% agreed or strongly agreed that full body CT screening is available to both self-referred and physician referred patients; 10% were neutral; and 30% disagreed or strongly disagreed that full body CT screening is available to both self-referred and physician referred patients. Therefore, the data suggest that patients who were self-referred had higher expectations that full body CT screening is available to both self-referred and physician referred patients than patients who were physician-referred.

Other associations.

The chi square analysis also suggested there were significant associations between marital status and ethnicity and patient expectations of full body CT screening. However, for both of these patient characteristics, the group sizes outside the predominant group represented were quite small, making the generalizability of any comparisons

questionable. For example, for ethnicity, approximately 91% of the sample reported their ethnicity as "White" while only 4 people reported it as "Asian," one person as "Hispanic" and 3 people as "other." Similarly, for marital status, 82% of the sample were married" while 6% were single and never married, 9% were divorced", and 3% were widowed.

Spearman Analysis

The data analysis using the Spearman correlation coefficient suggested that for two of the patient characteristics, (1) Self-Estimation of Current Health Status and (2) Level of Personal Health, there were significant associations with one or more of the patient expectation dimensions. All significant associations are delineated in Table V and two are additionally graphically represented in Appendix J. They were as follows:

Table V

Significant Spearman Correlation Coefficients

Patient Characteristic	Patient Expectation Dimension	Spearman r	P Value
Self-Estimation of Current Health Status			
	Empower	.30	.01
	Reassurance	.23	.03
	Prevention	.22	.04
Level of Personal Health Concern			
	Prevention	.29	.01

Self-Estimation of Current Health Status

Using the Spearman analysis, significant associations were found between patients' self-estimations of their current health status and three of the six patient expectation dimensions, namely, "empowerment" ($r = .30$, $p = .004$), "reassurance" ($r = .23$, $p = .003$), and "prevention" ($r = .22$, $p = .04$). The data from the Spearman analysis suggest that of these three significant relationships, the strongest association was between "self-estimation of current health status" and "empowerment," ($r = .30$, $p = .004$).

The Spearman analysis suggests that there is a "fair" association (Portney & Watkins, 2000, p. 494) between patients' responses when asked to self-estimate their current health status and their responses to the patient expectation questions in the "prevention" dimension. Moreover, the direction of this relationship is positive. The higher patients' "self-estimations of their current health status," the higher their expectations in regard to the questions in the "empowerment" dimension. The lower patients' self-estimation of their current health status, the lower their expectations in regard to the questions in the "empowerment" dimension. (The p value of .004 suggests that this association did not occur by chance). The r^2 or overlapping variance between "self-estimation of current health status" and "empowerment" is .09. Therefore, 9% of the variance in the "empowerment" dimension can be explained by "self-estimation of current health status" and 91% by other factors.

The associations between "self-estimation of current health status" and "reassurance" ($r = .23$, $p = .003$) and "self-estimation of current health status" and "prevention" ($r = .22$, $p = .04$) were also significant. However, the extent of these two

associations was somewhat "limited" (Portney & Watkins, 2000, p. 494), in comparison to the relationship between "self-estimation of current health status" and "empowerment." The r^2 or overlapping variance between "self-estimation of current health status" and "reassurance" is .05. Therefore, 5% of the variance in the "empowerment" dimension can be explained by "self-estimation of current health status" and 95% by other factors. The r^2 or overlapping variance between "self-estimation of current health status" and "prevention" is .048. Therefore, 4.8% of the variance in the "empowerment" dimension can be explained by "self-estimation of current health status" and 95.2% by other factors.

The direction of the relationships between "self-estimation of current health status" and "reassurance" and "prevention" were also positive. This would suggest that the higher patients' self-estimation of their current health status, the higher their expectations that full body CT will provide "reassurance" they are healthy and health "prevention."

In summary, the data suggest that patients' self-estimation of their current health status would have the strongest association with expectations that full body screening may empower them in their health care management. The second strongest association would be with patient expectations that the procedure may reassure them that they are healthy. The third and weakest association would be with patient expectations that the procedure may provide preventive health benefits.

Level of Personal Health Concern

Using the Spearman analysis, a significant association was also found between patients' "level of personal health concern" and the "prevention" patient expectation dimension, ($r = .29$, $p = .004$). The data suggest a that there is "fair" association (Portney & Watkins, 2000, p. 494) between patients' responses when asked to rate their level of personal health concern "in comparison to other people their age and similar health status" and their responses to the patient expectation questions in the "prevention" dimension.

The direction of this relationship was positive. The higher the level of personal health concern, the higher the patients' expectations in regard to the questions in the "prevention" expectation dimension. The lower the level of personal health concern, the lower the patients' expectations in regard to the questions in the "prevention" expectation dimension. The p value of .004 suggests that this association did not occur by chance. The r^2 or overlapping variance between level of personal health concern and "prevention" is .084. Therefore, 8.4% of the variance in the "prevention" dimension can be explained by the level of the patients' health concern and 92.6% by other factors.

Chapter V

DISCUSSION

The study participants were a predominantly high income, well-educated group of individuals between 35 and 65 years old. They were generally healthy and health conscious, as evidenced by their regular participation in other health screenings and preventive health/lifestyle activities. Patients' highest expectations related to consumer empowerment and lowest expectations related to the limitations of the procedure. The five patient characteristics found to have significant associations with patient expectations were level of personal health concern; number of other health screenings; patients' self-estimations of their current health status; gender; and referral method. In interpreting the study results, it is important to note that the findings reflect the self-reports of those individuals who volunteered to participate in the study and do not necessarily represent all individuals electing to receive full body CT screening.

The primary purpose of this study was to develop a scientific knowledge base on patient expectations of full body CT screening and to determine if specific characteristics of patients influence their expectations of the health benefits of the procedure. This study presents quantitative and descriptive findings which add to the existing, primarily anecdotal knowledge base on these issues. The study also tested the following hypothesis: "There is a significant association between patients' perceptions of their susceptibility to disease and their expectations of the health benefits of full body CT screening." The theoretical basis for this hypothesis was derived from Hochbaum's Health Belief Model.

Hochbaum's Health Belief Model: Thriving, Outdated, or Complementary Paradigm?

In his research on tuberculosis screening, Hochbaum found that participants' "psychological" (Hochbaum, 1956, p.20) readiness to engage in tuberculosis screening was based on the belief or expectation that they may contract or actually have the disease. Screening participants also believed that early diagnosis would have beneficial effects, such as shorter treatment and a better prognosis (Hochbaum, 1956, p. 7). In addition to the "psychological" readiness created by these beliefs, Hochbaum (1956, pp. 7) found that specific "situational" (Hochbaum, 1956, p. 7) factors, such as access to services and the ability to afford the services also influenced the decision to seek tuberculin screening.

Hochbaum's Health Belief Model (Hochbaum, 1956, p.1; Hochbaum, et al., p. 305, 1992) was an outgrowth of this research. Within this model, "perceived susceptibility" to disease and the ability to pay were two of the factors that explained participants' decisions to seek screening and expect health benefits. Although it is almost fifty years since its initial development, the model which Hochbaum proposed in the 1950's continues to provide a rigorous theoretical framework to explain patient participation in and expectations of the health benefits of targeted screening programs for diseases like tuberculosis. The model was more recently used in a study to explain participation in prostate cancer screening (Tasker, 2002, p. 2).

To some extent, this model may also help to explain patient participation in and expectations of the health benefits of full body CT screening, as well as the association between specific patient characteristics and patient expectations of the procedure. Several of the study findings strongly support the resiliency of the Health Belief Model and its applicability to this new screening technology. However, other findings would indicate

that more contemporary explanations are needed to complement this model.

Resiliency And Applicability of Health Belief Model

Two of the five significant positive associations found in the study between patient characteristics and patient expectations of the health benefits of full body CT screening strongly support the explanatory power of the Health Belief Model. One of these positive associations was between how frequently patients thought about their health and their expectations of the benefits of full body CT screening. The other positive association was between the number of other screening procedures in which patients had participated and their expectations of the benefits of full body CT screening.

The Health Belief Model may have applicability to these findings. The model would suggest that patients who more frequently think about their health, may feel more susceptible to disease and have higher expectations that the procedure will provide preventive health benefits. Similarly, the model would also suggest that patients who participate in more health screenings may also feel more susceptible to disease and have higher expectations that full body CT screening will empower them to better manage their health care, than patients who participate in fewer health screenings.

Frequent thought or concern about one's health and past participation in other screening procedures may be characteristics related to patients' perceived susceptibility to disease. As such, these characteristics may explain the "psychological readiness" of these participants to engage in full body CT screening and their higher expectations of the preventive health and consumer empowerment benefits of the procedure.

The model's inclusion of the "situational" component with respect to

accessibility of services is also supported in the present study. The study participants had the financial resources to access a high cost medical procedure which is generally not covered by insurance (Pennachio, 2002, p. 1). All of the study sites were located in urban and suburban cosmopolitan centers. Therefore, study participants either lived close enough to locally access these services or had the financial resources to travel and gain access. Moreover, five of the six study sites were located in states that did not require a physician referral, further increasing patient accessibility to the full body CT screening services.

Alternative Findings & Explanations

Conversely, three of the five significant associations found in the study between patient characteristics and patient expectations of the health benefits of full body CT screening are not explained or are only partially explained by the Health Belief Model. These were patients' self-estimations of their current health status; gender; and referral method. For example, a positive association was found between patients' self-estimations of their current health status and their expectations of the health benefits of full body CT screening. However, based on the Health Belief Model, a negative association, rather than a positive association would have been expected between these variables. Therefore, this association is not explained by the Health Belief Model.

Patients who considered themselves to be in better health would have been expected to feel less susceptible to disease and thus, have lower expectations of the health benefits of the procedure. Likewise, patients who considered themselves to be in poorer health would have been expected to feel more susceptible to disease and have higher expectations of the health benefits of the procedure. Therefore, while many study

participants thought a great deal about their health and engaged in other preventive screening procedures, their self-reports indicate that they still generally perceived themselves to be a healthy population. They may have self-referred for the procedure in the hopes of reaching higher levels of wellness, rather than in response to disease. This possibility is further supported by anecdotal evidence in the literature (Stanley, 2001, p. 990) (Rogers, 2002, p. 2) (Brandt-Zawadski, 2002a, p. 2).

The positive association between gender and patient expectations is only partially explained by the Health Belief Model. Gender may be a determinant of disease susceptibility in that studies have shown that women may feel more susceptible to disease as measured by their higher participation in preventive health activities and greater medical compliance (Courtenay, et al., 2002, p. 226). This may explain why female participants had higher expectations than male participants that they would be satisfied with the procedure and thus, reassured that they were healthy. However, the higher number of men in the study sample makes this assumption somewhat questionable. One explanatory factor may be men's higher income levels and correspondingly greater ability to assume the costs of the procedure. However, no significant associations were found between income levels and the expectations of the participants in the study sample.

Similar to gender, the association between referral method and patients' expectations is only partially explained by the Health Belief Model. Referral method may be a determinant of patient's perceptions of their susceptibility to disease in that patients who self-refer may feel more susceptible to disease. However, in interpreting this finding, it must be noted that 85% of the participants in the study sample were either self-referred or requested the referral from their physician. Therefore, it would be expected that self-

referred patients would be more likely to agree that full body CT screening may be obtained through both self-referral and physician referral.

Interestingly, two patient characteristics consistent with the Health Belief Model, namely number of health concerns and number of preventive health activities were not significantly associated with patient expectations of the health benefits of full body CT screening. The model would have suggested that patients with more health concerns would feel more susceptible to disease and would have higher expectations of the health benefits of full body CT screening than patients with fewer health concerns. Similarly, it would also have been expected that patients who participated in more preventive health activities would have felt more susceptible to disease and would have higher expectations of the health benefits of full body CT screening. Both of these expected findings were not supported by the study data.

Furthermore, it is somewhat surprising that the number of other health screenings in which patients participated had a significant association with patient expectations, while the number of preventive health activities in which they participated did not have any significant associations with patient expectations. Perhaps, individuals who feel susceptible to disease are more likely to participate in other health screenings, rather than healthy lifestyle activities. This may be explained by the fact that health screenings are more passive and time-limited than preventive health lifestyle activities. In contrast, lifestyle activities, such as healthy eating and physical fitness, may require greater motivation and sustained commitment.

Need For Complimentary Models & New Paradigms

In summary, the Health Belief Model provided a conceptual framework from which to develop the study hypothesis and to explain some of the study findings. It represented the first attempt to apply a theoretical model to a study on patient expectations of full body CT screening. Two of the five significant associations between patient characteristics and patient expectations, namely level of personal health concern and participation in other health screenings, support the model's utility in explaining patient expectations of the health benefits of full body CT screening. However, three other significant associations, namely patients' self-estimations of current health status; gender; and referral method are not explained or are only partially explained by this model. Moreover, two associations which may have been expected to be explained by this model, were not found to be significant.

The Health Belief Model provides a theoretical model which partially explains patient expectations of the health benefits of full body CT screening, but does not fully explain patient expectations of the health benefits of the procedure. Thus, other factors in addition to perceived susceptibility to disease and access to services must be considered and integrated in developing the scientific knowledge base on this issue in order to formulate a newer paradigm to explain the findings.

The Contemporary Health Screening Paradigm

Hochbaum's Health Belief Model may continue to explain many of the reasons why individuals engage in targeted health care screenings and their expectations of its health benefits. However, it does not fully address the reasons why individuals engage in full body CT screening or their expectations of its benefits. The study findings

support much of the anecdotal literature indicating that the rationale for participating in the procedure and the expectations of its health benefits may in part be explained by two very contemporary consumer needs, 1) empowerment in health care management and 2) comprehensive wellness.

Empowerment In Health Care Management

Patients volunteering to participate in the study generally had high expectations regarding the perceived benefits of full body CT screening, as evidenced by the fact that the preponderance of their responses to the patient expectation questions were within the agree/strongly agree categories. However, the comparison of median response scores on the six patient expectation dimensions, indicated that patients' highest levels of agreement corresponded to questions in the empowerment dimension. The saliency of consumer empowerment in the promotion and growth of self-referral for newer imaging procedures has been repeatedly mentioned in the cited literature on the new consumerism in medicine (Harris, 2001, p.10) (Rogers, 2002, pp.1-2) (Brandt-Zawadski, 2002a, pp. 1 - 3) (Brandt-Zawadski, 2002c, pp. 2-3) (Illes, et al., 2003, pp. 347-350). These study findings suggest that patients may perceive participation in full body CT screening as an opportunity for greater control over the management of their health care.

The demographic data provided by the self-reports of study volunteers provide evidence that the individuals self-referring for the procedure generally have the financial resources to pay for this aspired level of control. However, while the ability to purchase out-of pocket medical services may enhance empowerment and choice for the affluent, this ability may further widen the disparities in the health care options available to those who cannot afford such services. These issues are not specific to full body CT screening

and may be leading to a two-tiered system of health care delivery. Similar dilemmas are posed by cosmetic enhancements, experimental treatments, medical specialist and out-of-network referrals, and aspects of alternative and complementary medicine. These dilemmas and the issues they pose within health care policy are more extensively discussed in Chapter II.

This study is not intended to make policy recommendations because such policy decisions may be premature without additional clinical evidence. Until researchers and practitioners accumulate the clinical evidence on the efficacy of the procedure, it is very difficult to determine if access to this procedure should be extended to those who currently cannot afford it or if those who can afford it should be denied access due to its possible risks.

Comprehensive Whole Body Wellness

The rationale for seeking screening and the expectations of its benefits may be expanding from individuals perceiving themselves as susceptible to specific diseases and wanting reassurance that they are free of this disease to a need to feel invulnerable and protected from an array of disease states and health conditions. Several authors have discussed the quest for immortality and longer life span which have motivated the baby boomers (Brandt-Zawadski, 2002a, pp. 1-3) and young urban professionals (Harris, 2001, pp. 1-2) to seek full body CT screening (Roger, 2002, pp.1-2) (Brandt-Zawadski, 2002a, pp. 1-3).

This expanded concept of wellness, may explain why three-quarters of the survey participants reported being in excellent or very good health, but nonetheless wanted to undergo the full body CT screening procedure. Less than 5% of participants estimated

their health status as fair or poor. Moreover, very few participants reported personal health histories of cancer or other serious illnesses, although many did report family histories of serious illness.

The study findings on the health concerns and health practice characteristics of the survey participants, support the anecdotal reports and opinions expressed by many of the radiology experts within the literature. They indicate that most individuals self-referring for the procedure are healthy and asymptomatic (Stanley, 2001, p. 990) (Rogers, 2002, p. 2). The study data also support the results of the Lemon et al. study (2001, pp. 7-9) which found that individuals who participate in one type of health screening procedure are more likely to participate in other types of screening procedures and preventive health activities.

Most importantly, the study data affirm many of the cautions and concerns expressed within the literature about administering full body CT screening, as well as many targeted CT screenings to a basically healthy population, while the scientific data on the risks and benefits of these procedures are limited and inconclusive (Obuchinski, et al., 2001, pp. 2-11) (Siegel, 2001, pp. 1521-1523) (Black, 2002, pp. 1-3) (Stanley, 2001, pp. 989-992) (Herman, et al., 2002, pp.8-11).

In summary, the study findings support the anecdotal literature which use the concepts of consumer empowerment and the desire for comprehensive wellness to explain why individuals seek the procedure and the health benefits they expect to attain from it. The findings also support the need for patient and physician education on the risks and benefits of the procedure.

Need for Patient Education And Decision-making Skills

The empowerment of the health care consumer and the quest for wellness require patients to have information regarding the procedures they are considering, as well as the skills to effectively make decisions about their health care management. It is essential that physician and patient education incorporate balanced approaches. Patients considering full body CT screening need to be cognizant of the potential benefits, as well as the responsibilities and risks inherent in their freedom to make decisions through self-referral. Likewise, physician and patient education needs to incorporate an evidenced-based approach in providing information on the extent to which the procedure may or may not promote the comprehensive level of wellness which consumers expect to achieve.

Most study participants learned about full body CT screening in very conventional ways (e.g. friends, relatives, and TV and radio advertisements). Only one-fifth of participants reported learning about it from a physician. Over half of the study sample additionally reported consulting other sources of information prior to receiving the procedure. The most frequent source of information was the internet, followed by the popular media, followed by physicians.

The specific sources of information and depth of accurate information required for informed decision-making about participation in full body CT screening may have been inadequate for many study participants. This may explain why in the comparison of median scores on the six patient expectation dimensions, patients tended to have the

lowest level of agreement with questions related to the risks and limitations of the procedure.

The patient survey used in the study focused on patient expectations of the procedure, rather than knowledge of the procedure. However, in reporting their expectations, patients revealed a cluster of perceptions, attitudes, and beliefs. Such data may add to the scientific knowledge base by suggesting consumer education needs. Graphic representations of patient responses for each of 15 survey questions are provided in Appendix J.

These data and the related study findings may assist in developing curricula to train physicians and health professionals regarding specific patient expectations of full body CT screening. The data may also assist in developing patient education programs. By knowing what patients expect from the procedure, patient educators can present appropriate information and advice which may enable patients to make effective decisions about whether or not they want to participate in this type of screening.

In addition to knowledge and information, patients also require training in effective decision-making skills. Decisions regarding participation in health screening programs often involve tradeoffs between risks and benefits (Dolan & Frisina 2002, p. 1). Decision aids have been developed to help patients in making decisions about participation in targeted screening programs. Dolan & Frisina (2002, pp. 3-6) developed a model to assist patients in decisions regarding whether or not they wanted to participate in colorectal cancer screening. Their model and other existing models may also be applicable to decisions involving participation in full body CT screening.

Limitations of the Study

Differences Between the Study Sites & Non-Study Sites

This study represented one of the first systematic attempts to obtain direct self-report information from patients about to receive full body CT screening. Obtaining access to the study sites and subsequently the study population proved to be a formidable task. Most of the imaging centers contacted either refused to participate in the study or never responded to the researcher's electronic or telephone inquiries. In order to obtain a geographically representative sample of study participants, efforts were made to include several diverse regions as study sites. While the geographic diversity strengthened the representativeness of the study sample, it also further limited the specific sites which could be included in the study.

The physicians and administrators who consented to participate in the study within these diverse regions demonstrated a great deal of support for the research. Their openness to participate in the research study and contribute to the scientific knowledge base was atypical. This difference in philosophy regarding scientific research may reflect other differences in the administrative and clinical operations of the participating sites from many non-participating sites. These differences may have had an influence on patients' perceptions of the procedure and consequently their responses to the survey items. As such, they are confounding variables. This possible bias must be considered in generalizing the study results to patients receiving the procedure at non-participating sites.

Differences Within the Six Participating Sites

In addition to the noted differences between the participating sites and non-participating sites, there may also have been differences in the administrative and clinical operations among the six sites that consented to participate in the study. These differences may have also introduced confounding variables. For example, there may have been differences in the amount and type of information which each of the participating sites provided to patients before they received the procedure.

Differences in the amount and type of information provided by the sites may to some extent explain why question # 6 showed the greatest variability in participant responses. It stated, "Effective treatments exist for almost any condition this test may find." It is possible that patients' responses to this particular item were sometimes based on information which they received from site personnel in response to questions which they asked they about their individual health concerns.

A review was conducted of the imaging center websites, as well as other materials supplied by several of the sites, such as promotional brochures and consent forms. Anecdotal information was also collected in telephone conversations with imaging center physicians, administrators, and office staff. However, in order to maintain the primary focus of the study on patient characteristics and patient perceptions, differences in what patients were told about the procedure by site personnel and the written materials provided to them by the sites were not included among the primary variables studied.

While this omission may have introduced some level of bias and should be noted in interpreting the findings, the bias may have been quite limited due to the inclusion of Section III in the survey. This section, titled "consumer information" queried

patients on how they learned about the procedure and the sources of information which they consulted. While the study site itself was not one of the specific options on the survey, "physician," "health professional," and a space for "other" were included. These response options provided opportunities for patients to have included physicians, health professionals and other personnel employed by the sites among the sources of information they consulted. Interestingly, no significant associations were found between any of the categories of information sources and patient expectations and only three respondents indicated in the optional space provided that reading material from the sites was used as a source of information. This would additionally suggest that if bias were introduced by the omission of the site information variable, it was probably quite limited.

Patient Volunteers May Represent A Biased Sample

Although the demographic findings on the study participants showed a high level of consistency with anecdotal reports, the possibility exists that patients who volunteered to participate in the study may not be representative of the larger population of individuals receiving the full body CT procedure. Individuals volunteering to participate may introduce confounding variables which may potentially bias the study. This potential limitation was noted in the section discussing the interpretation of the study findings.

Chapter VI

CONCLUSIONS

The Health Belief Model was used as the theoretical basis for this study.

While still a useful model in explaining patient participation and expectations of targeted screening programs, the model only partially explains patients' expectations of full body CT screening. The study findings have suggested that health care consumers may no longer be seeking screening based primarily on their perceptions of susceptibility to specific diseases. They may view full body screening and similar imaging modalities as opportunities to more globally and comprehensively control the health states of their bodies.

A paradigm shift may be occurring in which consumer empowerment and the desire for comprehensive wellness may be a complementary model to explain patient participation in and expectations of full body CT screening and newer imaging technologies. This study has substantiated the need for education on the risks and benefits of full body screening, so that patients may engage in informed decision making before providing informed consent.

The study also very strongly validates the need for further study on the clinical aspects of full body CT screening. Physician educators and patient educators require a valid scientific knowledge base if they are to effectively train other physicians and educate patients. This knowledge base currently does not exist and in part accounts for why this study was primarily descriptive. There are presently no conclusive clinical or scientific criteria for scoring the surveys. However, the responses of the patients

to the survey items have provided some of the first scientific data on patient perceptions and expectations of full body CT screening.

The descriptive data on patient characteristics may also enable physician educators to better understand which individuals may be most likely to self-refer for this procedure, as well as how their individual characteristics may be associated with specific expectations of the procedure. This information could also be incorporated into patient education and patient counseling and facilitate a more individualized approach.

The present study may provide a basis for future studies. It suggests the need for additional research on patient expectations and perceptions of full body CT screening, as well as patient satisfaction with the procedure. These studies may need to incorporate methodologies and sample sizes beyond the scope of this study.

Full body CT screening is one among several newer radiological screening procedures which are increasingly being directly marketed to the public; regularly appear within popular literature; and have been the subject of television newscasts and talk shows. If health care consumers are to have the empowerment to self-refer for these procedures, it is essential for physicians and patient educators to continue to expand their knowledge base on patient expectations of these procedures. The following additional studies are suggested:

(1) Comparison of Patient Education Approaches Used By Different Study Sites

The present study did not examine differences in the manner in which specific sites addressed patient decision making, patient advisement, and reporting of results to patients. However, differences in how these patient educational needs were addressed within the different imaging facilities, may have influenced patient expectations. It would

be very valuable to study these differences in approaches to patient education. Such comparisons may help to identify if specific educational approaches are more effective in promoting realistic patient expectations. If so, other facilities and patient education programs may want to incorporate those approaches found to be most effective.

(2) Comparison of Pre and Post Procedure Patient Perceptions

The present study used a pretest only design because the intent was to primarily examine what patients expected from the procedure before they actually received it. This methodology was selected because a posttest only methodology may have been biased by the actual clinical event (Kravitz, p. 7). However, future studies comparing pretest and posttest results within a specified time period after the procedure may provide valuable information. A pretest/ posttest methodology would provide a measure of the extent to which the procedure actually met or did not meet patient expectations and may also serve as a measure of patient satisfaction with the procedure.

Furthermore, the methodologies and findings used within the present study on full body CT screening may also be used to study patient expectations related to other radiological screening procedures. These procedures may include mammography, virtual colonoscopy cardiac calcium scoring, bone densitometry, pelvic ultrasound, and targeted CT screenings, such as lung cancer screening. Studies on patient expectations of screening related to any of these modalities would also contribute to the existing knowledge base and facilitate the development of the patient education needed to foster informed decision making concerning the procedure.

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Appendix A

Patient Characteristics (Independent Variables) With Codings For Statistical Testing		
Patient Characteristic (Independent Variables)	Code	Category
(1) Age	1	Under 21
	2	21-35
	3	36-50
	4	51-65
	5	66-80
	6	over 80
(2) Gender	0	Male
	1	Female
(3) Marital Status	1	Married
	2	Single, Never Married
	3	Separated
	4	Divorced
	5	Widowed
(4) Ethnicity	1	African-American
	2	Asian
	3	Hispanic
	4	Native American
	5	White

6 Other		
Characteristics (Independent Variables) With Codings For Statistical Testing		
Patient Characteristic (Independent Variables)	Code	Category
(5) Educational Level	1	High School
	2	Attended College, Did Not Graduate
	3	Bachelors Degree
	4	Graduate Degree
(6) Income	1	Under 30,000
	2	30,000-50,000
	3	51,000-75,00
	4	76,000-100,000
	5	Over 100,000
(7) Referral Source	0	Self-referred
	1	Physician-referred
If Self-Referred, only	0	I requested the referral
	1	My physician suggested the referral

Characteristics (Independent Variables) With Codings For Statistical Testing

Patient Characteristic (Independent Variables)	Code	Category
(8) Health Status	2	Not Concerned, Somewhat Concerned
	3	Moderately Concerned
	4	Very Concerned, Extremely Concerned
(9) Level of Personal Health Concern	2	Fair, Poor
	3	Average
	4	Good, Excellent
(10) Number of Health Concerns	1	0-1
	3	2-3
	4	4 or more
(11) Number of Other Health Screenings	0	none
	1	1
	2	2
	3	3

Characteristics (Independent Variables) With Codings For Statistical Testing

Patient Characteristic (Independent Variables)	Code	Category
(12) Number of Preventive Health Activities	0	none
	1	1
	2	2
	3	3
	4	4 or more
(13) How Patient Learned of CT Screening	1	Physician
	2	Other Health Professional
	3	Friend or Relative
	4	Newspaper/Magazine article
	5	TV/ Radio Advertisement
	6	Written Advertisement
	7	Internet
	8	Other
Number of Sources of Knowledge	0	None
	1	1
	2	2
	3	3
	4	4 or more

Characteristics (Independent Variables) With Codings For Statistical Testing

Patient Characteristic

(Independent Variables)	Code	Category
Specific Source of Knowledge	1	none
	2	Popular Media,
	3	Internet
	4	Internet
	5	Professional Journals
	6	Physicians(s)
	7	Other Health Professional(s)
	8	Other

Appendix B

Validity Study On Original Survey Instrument

12 RatersI. GENERAL INFORMATION:

Age-91% agreement-Eliminate Overlapping Categories

- ☐ Under 21 years old
☐ 21-35 years old
☐ 35-50 years old
☐ 50-65 years old
☐ 65-80 years old
☐ over 80 years old

Referral Source: Please check whichever applies-100% agreement

- ☐ Self-Referred
☐ Physician-Referred/Physician Prescription
 If you responded physician-referred, please check one:
☐ I requested the referral/prescription from my physician
☐ My physician suggested the referral/prescription

Sex-91% agreement-Change to Gender

- ☐ Male ☐ Female Marital Status-100% agreement
☐ Single, Never Married
☐ Married
☐ Separated
☐ Divorced
☐ Widowed

Race/Ethnicity-75% agreement-Alphabetize, Use NIH Terminology, Use White &

Non-White Hispanic

- ☐ White
☐ African-American
☐ Hispanic
☐ Native American
☐ Asian
☐ Other

Annual Income-91% agreement-Eliminate Overlapping Categories

- ☐ Under 30,000
☐ 30,000-50,000
☐ 50,000-75,000
☐ 75,000-100,000
☐ Over 100,000

Highest Level of Education Attained-91% agreement-Eliminate Vocational School**Category**

- ☐ High School
☐ High School/ Vocational School Graduate
☐ Attended College, Did Not Graduate
☐ Bachelors Degree
☐ Graduate Degree

II. HEALTH INFORMATION:**Self-Estimation of Current Health Status: 100% agreement**

Based on how you feel and what you know, how would you describe your current health status:

- ☐ Excellent
☐ Good
☐ Average
☐ Fair
☐ Poor

Concern Regarding Personal Health: 91% agreement-Eliminate Overlapping Categories

In comparison with other people your age and similar health status, how would you rate your level of concern regarding your personal health?

- ☐ Extremely concerned (Think about it daily or several times a day)
☐ Very concerned (Think about it weekly or several times a week)
☐ Moderately concerned (Think about it monthly or several times a month)
☐ Somewhat concerned (Think about it several times a year)
☐ Not concerned

Specific Health Concerns: (Please check all that apply) 91% agreement-For smoking-

Quantify number of packs and number of years

- ☐ Personal History of Cancer
- ☐ Family History of Cancer
- ☐ Personal History of Other Serious Illness, Specify _____
- ☐ Family History of Other Serious Illness, Specify _____
- ☐ Current Smoker
- ☐ Former Smoker
- ☐ Moderately Overweight (10-30 lbs. above ideal weight)
- ☐ Extremely Overweight (30 or more lbs. above ideal weight)
- ☐ Experiencing moderate stress within personal or work life
- ☐ Experiencing extreme stress within personal or work life
- ☐ Other, Specify _____

Other Screening Tests (Please check all procedures which you have had during the specified time period) 91% agreement-Include PSA screening

- ☐ Physical Exam (Past 1-2 years)
- ☐ Blood Testing (Past 1-2 years)
- ☐ Cardiac Stress Testing (Past 1-2 years)
- ☐ Mammogram (Past 1-2 years)
- ☐ Colonoscopy (Past 5 years)
- ☐ Other, Specify _____

III. CONSUMER INFORMATION

How did you first hear about of this procedure? 91% agreement-Include Internet

- ☐ Physician
- ☐ Other Health Professional, Specify _____
- ☐ Friend or Relative
- ☐ Newspaper/Magazine article
- ☐ TV/ Radio Advertisement
- ☐ Written Advertisement
- ☐ Other, Specify _____

After first hearing about this procedure, did you obtain any additional information?

☒ 100%

☒ agreement-Include PSA screening

☐ No

☐ Yes

If Yes, please check one or more of the sources of information listed below:

☐ Popular Media, i.e. newspaper, magazine article, TV/Radio Programs

☐ Internet

☐ Patient/Consumer Education Lectures or Community Events

☐ Professional Journals

☐ Physician(s)

☐ Other Health Professional(s), Specify _____

☐ Other, Specify _____

PATIENT EXPECTATION SURVEY ... FULL BODY CT SCREENING

Please indicate your level of agreement with the following statements, by circling the most appropriate choice, using the scale listed below:

SA = Strongly Agree; A = Agree; N=Neutral; D=Disagree; SD= Strongly Disagree

1. This procedure may give me peace of mind and reduce my worries about my health.
100% agreement

SA A N D SD

2. Knowing the results of this test may improve my overall health. 100% agreement

SA A N D SD

3. Regular full-body screening exams may prolong my life. 100% agreement

SA A N D SD

4. Finding a disease process early, may increase the chances of being cured. 100% agreement
SA A N D SD
5. Almost all diseases will be detected by this test. 91% agreement
SA A N D SD
6. Effective treatments exist for almost any condition this test may find. 100% agreement
100% agreement
SA A N D SD
7. This test is available to both self-referred and physician-referred patients. 100% agreement
100% agreement
SA A N D SD
8. Full body CT screening is appropriate for healthy people, as well as people with specific diseases. 100% agreement
SA A N D SD
9. This test is one of the best options available today for preventive health care. 100% agreement
SA A N D SD
10. The comprehensive nature of CT screening makes it unlikely that I will require further testing.
100% agreement
SA A N D SD
11. I will want to recommend this test to my close friends and relatives. 100% agreement
SA A N D SD
12. The results of this screening will be discussed with me by a health care professional.
100% agreement
SA A N D SD

13. Additional tests may be needed to complement full body CT screening. 100% agreement

SA A N D SD

14. Full body CT screening may be repeated throughout a person's lifetime. 100% agreement

SA A N D SD

15. Scientists have studied the benefits and limitations of this procedure. 100% agreement

SA A N D SD

Appendix C

Revised Patient Expectation Survey

(After Validity Study)

To Patients Interested In Patient Expectation Study:

I am a doctoral student in the Health Sciences Program at Seton Hall University School of Graduate Medical Education, located in South Orange, New Jersey.

I am currently doing research on patient expectations of full-body CT screening, the procedure which you are about to receive. The information you provide may help physicians, physician educators, and patient educators to better understand what patients anticipate and expect from this procedure.

Your cooperation in completing the attached Patient Expectation Survey would be greatly appreciated. It will take approximately 15-20 minutes to complete the form.

The Patient Expectation Survey consists of a series of statements regarding your expectations of full body CT screening. You will be asked to indicate your level of agreement or disagreement with 15 statements related to the procedure. You will also be asked to provide some general information about yourself; your perception of your current health status; and how you have learned about this procedure. When you are finished, kindly place and seal the Patient Expectation Survey in the provided confidential envelope and submit at the imaging facility. A secured, web-based format of this same survey may also be accessed, completed, and anonymously e-mailed to me at http://gradmeded.shu.edu/survey_ckolber. To access the page, you will also need the following: Account Name: guest and Password: survey2003.

Participation in this study is completely voluntary. If you decide not to participate, your care will in no way be affected.

Your responses will be completely anonymous, as names and any other identifying information are not required. Confidentiality will be strictly maintained. When the sealed forms are received by the researcher, they will be secured in locked file cabinets. Your doctor and other personnel at the site in which you are receiving

the full body CT screening will not have access to your completed forms. The only information provided to them will be group data which will have no information which may identify the individual participants.

{This project has been reviewed and approved by the Seton Hall University Institutional Review Board for Human Subjects Research. The IRB believes that the research procedures adequately safeguard the subject's privacy, welfare, civil liberties, and rights. The Chairperson of the IRB may be reached at (973) 275-2977 or 313-6314.}

Thank you for taking the time to consider participating in this study.

Sincerely,

A handwritten signature in cursive script, appearing to read "Carole Kolber".

Carole Kolber, M.Ed.

PATIENT EXPECTATIONS OF FULL BODY CT SCREENING SURVEY

Please place an X before the most appropriate response to the questions listed below:

I. GENERAL INFORMATION:

1. Age

☐ Under 21 ☐ 21-35 ☐ 36-50 ☐ 51-65 ☐ 66-80 ☐ over 81

2. Gender

☐ Male ☐ Female

3. Marital Status

☐ Married ☐ Single, Never Married ☐ Separated ☐ Divorced
☐ Widowed

4. Race/Ethnicity

☐ African-American ☐ Asian ☐ Hispanic ☐ Native American ☐ White
☐ Other

5. Highest Level of Education Attained

☐ High School ☐ Attended College, Did Not Graduate
☐ Bachelors Degree ☐ Graduate Degree

6. Annual Income

☐ Under 30,000 ☐ 30,000-50,00 ☐ 51,000-75,00 ☐ 76,000-100,000
☐ Over 100,000

7. Referral Source: Please place an X before whichever applies:

A) ☐ Self-referred-I did not obtain a physician prescription.

B) ☐ Physician-referred-I did obtain a physician prescription

C) If you responded Physician-referred, Please place an X before whichever applies:

☐ I requested the referral/prescription from my physician

☐ My physician suggested the referral/prescription

II. HEALTH INFORMATION:

1. Self-Estimation of Current Health Status:

Based on how you feel and what you know, how would you describe your current health status:

☐ Excellent ☐ Good ☐ Average ☐ Fair ☐ Poor

2. Concern Regarding Personal Health:

In comparison with other people your age and similar health status, how would you rate your level of concern regarding your personal health?

☐ Extremely concerned (Think about it daily or several times a day)

☐ Very concerned (Think about it weekly or several times a week)

☐ Moderately concerned (Think about it monthly or several times a month)

☐ Somewhat concerned (Think about it several times a year)

☐ Not concerned

3. Specific Health Concerns: (Please place an X before all that apply)

☐ Personal History of Cancer ☐ Family History of Cancer

☐ Personal History of Other Serious Illness, Specify _____

☐ Family History of Other Serious Illness, Specify _____

☐ Current Smoker ☐ Packs per day ☐ Number of years smoked

☐ Former Smoker ☐ Packs per day ☐ Number of years smoked

☐ Moderately Overweight (10-30 lbs. above ideal weight)

☐ Extremely Overweight (30 or more lbs. above ideal weight)

☐ Experiencing moderate stress within personal or work life

☐ Experiencing extreme stress within personal or work life

☐ Other, Specify _____

4. Other Procedures (Please place an X before all procedures which you have had during the specified time period).

☐ Blood Testing (Past 1-2 years)

☐ Cardiac Stress Testing (Past 1-2 years)

☐ Colonoscopy (Past 5 years)

☐ Mammogram (Past 1-2 years)

☐ Physical Exam/Visit to Primary Care Physician or OB/GYN (Past 1-2 years)

☐ Other (Specify) _____

5. Preventive Health/Lifestyle Activities (Please place an X before all activities in which you regularly engage).

- ☐ Healthy Eating (Everyday or most days)
☐ Physical Fitness/Exercise (3 or more times per week)
☐ Stress Reduction Activities e.g. meditation, yoga (2 or more times per week)
☐ Vitamin Supplements (Everyday or most days)
☐ Other (Specify) _____ Number of days per week

III. CONSUMER INFORMATION:

How did you first hear about of this procedure?

- ☐ Physician
☐ Other Health Professional, Specify _____

☐ Friend or Relative

☐ Newspaper/Magazine article
☐ TV/ Radio Advertisement
☐ Written Advertisement
☐ Internet
☐ Other, Specify _____

After first hearing about this procedure, did you obtain any additional information?

- ☐ No
☐ Yes, please place an X before one or more of the sources of information listed below:

- ☐ Popular Media, i.e. newspaper, magazine article, TV/Radio Programs
☐ Internet
☐ Patient/Consumer Education Lectures or Community Events
☐ Professional Journals
☐ Physicians(s)

☐ Other Health Professional(s), Specify _____
☐ Other, Specify _____
-

IV. PATIENT EXPECTATIONS

Please indicate your level of agreement with the following statements regarding full body CT screening, by placing an X before the most appropriate choice, using the scale listed below:

SA = Strongly Agree; A = Agree; N=Neutral; D=Disagree; SD= Strongly Disagree

1. Full body CT screening may give me peace of mind and reduce my worries about my health.
____SA ____A ____N ____D ____SD
2. Knowing the results of this test may improve my overall health.
____SA ____A ____N ____D ____SD
3. Regular full-body screening exams may prolong my life.
____SA ____A ____N ____D ____SD
4. Finding a disease process early, may increase the chances of being cured.
____SA ____A ____N ____D ____SD
5. This test will detect many, but not all diseases .
____SA ____A ____N ____D ____SD
6. Effective treatments exist for almost any condition this test may find.
____SA ____A ____N ____D ____SD
7. This test is available to both self-referred and physician-referred patients.
____SA ____A ____N ____D ____SD
8. Full body CT screening is appropriate for healthy people, as well as people with specific diseases.
____SA ____A ____N ____D ____SD

9. This test is one of the best options available today for preventive health care.

___SA ___A ___N ___D ___SD

10. The comprehensive nature of CT screening makes it unlikely that I will require further testing.

___SA ___A ___N ___D ___SD

11. I will want to recommend this test to my close friends and relatives.

___SA ___A ___N ___D ___SD

11. The results of this screening will be discussed with me by a health care professional.

___SA ___A ___N ___D ___SD

12. Additional tests may be needed to complement full body CT screening.

___SA ___A ___N ___D ___SD

13. Full body CT screening may be repeated throughout a person's lifetime.

___SA ___A ___N ___D ___SD

15. Scientists have studied the benefits and limitations of this procedure.

___SA ___A ___N ___D ___SD

Thank you for completing this survey.

Appendix D

Written Letter & Verbal Script Used By Study Sites

LETTER TO PATIENT FROM PARTICIPATING STUDY SITE: (Placed on site letterhead). Forwarded To Patient's Home By Facility Prior To Patient Receiving Full Body CT Screening. (To mailed be if sufficient time permits before appointment or otherwise faxed).

Dear Patient:

This office/medical facility is participating in a voluntary university research study on patient expectations of full-body CT screening, the procedure which you are scheduled to receive at our office.

Completing this voluntary survey may help health professionals to better understand what patients expect from this procedure.

All information is anonymous and confidential.

If you would like to consider participating, further information is provided in a cover letter attached to the survey from the university researcher. You may complete this form on the confidential, secured Seton Hall University website, (web address) or if sufficient time allowed prior to your appointment, a hard copy has been included in this correspondence. (Please see researcher's instructions in her letter).

Should you decide to participate in the study and have any questions or concerns at any time, please call us at _____ and a professional in our facility will be available to assist you.

Thank you for taking the time to learn about this study.

Sincerely,

(Site Designee/Position)

VERBAL EXPLANATION TO PATIENT AT STUDY SITE:**SCRIPT-Delivered by Site Designee Before Patient Receives Full Body CT****Screen**

- This office/medical facility is participating in a voluntary university research study on patient expectations of full-body CT screening, the procedure which you are about to receive.
- Completing this voluntary survey may help health professionals to better understand what patients expect from this procedure.
- All information is anonymous and confidential.
- If you are interested in participating, further information is provided in this letter. (Site designee points to cover letter).

Appendix E

Pilot Study Data

id	pe1	pe2	pe3	pe4	pe5	pe6	pe7	pe8	pe9	pe10	pe11	pe12	pe13	pe14	pe15
1C	DNA	DNA	DNA	DNA	DNA	DNA	DNA	DNA	DNA	DNA	DNA	DNA	DNA	DNA	DNA
2C	4	2	2	4	4	3	4	4	DNA	DNA	DNA	DNA	DNA	DNA	DNA
3C	4	4	5	5	4	4	4	4	4	2	5	4	4	4	3
4C	5	5	5	5	4	5	5	5	5	5	5	5	2	4	4
5B	4	4	2	5	4	2	4	4	3	2	3	4	4	3	4
6C	4	1	3	5	4	3	5	5	5	1	DNA	5	5	5	4
7C	4	4	3	4	3	2	4	4	4	3	3	4	5	5	4
8C	4	4	4	5	4	3	5	4	4	4	3	5	4	4	4
9C	4	4	4	4	5	3	5	5	4	3	4	4	3	5	4
10C	5	5	5	5	4	4	5	4	4	2	4	4	3	4	3
11C	5	5	5	5	5	5	5	5	5	3	3	5	5	5	5
12C	5	4	5	4	3	4	4	4	4	2	3	3	3	3	4
5	4	3	5	7	2	2	6	4	3	1	2	4	3	4	1
4	7	6	2	4	7	3	5	7	6	1	2	5	3	4	7
3	0	0	2	0	2	4	0	0	1	3	5	1	3	3	2
2	0	1	2	0	0	2	0	0	0	3	0	0	1	0	0
1	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0
*DNA	1	1	1	1	1	1	1	1	2	2	3	2	2	2	2

5 28%

4 39%

3 14%

2 5%

1 1%

DNA 13%

100%

Appendix F
Significant Chi Square Associations

Table 1

Significant Chi Square Association Between Personal Health Concern and Patient Expectation, #2, "Knowing the results of this test may improve my overall health", (X^2 (2, 91) = 10.07, $p = .04$).

Likert Response	Level of Concern						Total Number
	Number	Percent	Number	Percent	Number	Percent	
	Somewhat or not Concerned	Somewhat or not Concerned	Moderately Concerned	Moderately Concerned	Extremely Concerned	Extremely Concerned	
Disagree & Strongly Disagree	6	18%	1	3%	0	0%	7
Neutral	5	15%	2	7%	3	11%	10
Agree & Strongly Agree	22	67%	28	90%	24	89%	74
TOTAL	33		31		27		91

Table 2

Significant Chi Square Association Between Number of Other Health Screenings and Patient Expectation, #12, "The results of this screening will be discussed with me by a health care professional," ($X^2 (8, 90) = 17.80, p = .02$).

Likert Response	Number of Health Screenings									
	0	Percent of 0's	1	Percent of 1's	2	Percent of 2's	3	Percent of 3's	4	Percent of 4's
Disagree/ Strongly Disagree	1	25%	1	8%	0	0.0%	0	0.0%	0	0.0%
Neutral	0	0	2	15%	1	6%	2	8%	0	0.0%
Agree/ Strongly Agree	3	75%	10	77%	17	94%	23	92%	3 0	100%
TOTAL	4		13		18		25		3 0	

Table 3

Significant Chi Square Association Between Gender and Patient Expectation, #10, "The comprehensive nature of CT screening makes it unlikely I will require further testing" ($\chi^2 (2, 91) = 12.08, p = .01$).

Likert Response	Number of Males	Percent of Males	Number of Females	Percent of Females	Total Number
Disagree & Strongly Disagree	27	50%	16	43%	43
Neutral	22	41%	7	19%	29
Agree & Strongly Agree	5	9%	14	38%	19
TOTAL	54	100%	37	100%	91

Table 4

Significant Chi Square Association Between Gender and Patient Expectation, #11, "I will want to recommend this test to my close friends and relatives, ($\chi^2 (2, 89) = 8.09, p = .02$).

Likert Response	Number of Males	Percent of Males	Number of Females	Percent of Females	Total Number
Disagree & Strongly Disagree	1	2%	1	3%	2
Neutral	19	35%	3	9.5%	22
Agree & Strongly Agree	34	63%	31	88.5%	65
TOTAL	54	100%	35	100%	89

Table 5

Significant Chi Square Association Between Gender and Patient Expectation, #14, Full body CT screening may be repeated throughout a person's lifetime, ($X^2 (2, 91) = 9.79, p = .01$).

Likert Response	Number of Males	Percent of Males	Number of Females	Percent of Females	Total Number
Disagree & Strongly Disagree	0	0.0%	1	3%	1
Neutral	11	20%	0	0.0%	11
Agree & Strongly Agree	43	80%	36	97%	79
TOTAL	54	100%	37	100%	91

Table 6

Significant Chi Square Association Between Referral Source and Patient Expectation, 7, "This test is available to both self-referred and physician-referred patients," ($X^2 (2, 91) = 15.17, p = .001$).

Likert Response	Number of Self- Referred	Percent of Self- Referred	Number of Physician Referred	Percent of Physician Referred-	Total Number
Disagree & Strongly Disagree	2	3%	9	30%	11
Neutral	3	5%	3	10%	6
Agree & Strongly Agree	56	92%	18	60%	74
TOTAL	61	100%	30	100%	91

Appendix G

Bar Graph Representations of Significant Chi Square Associations

Figure 1. Significant Chi Square Association Between Level of Personal Health Concern and Patient Expectation, #2, "Knowing the results of this test may improve my overall health," $X^2 (4, 91) = 10.07, p = .04$.

Figure 2. Significant Chi Square Association Between Number of Other Health Screenings and Patient Expectation, #12, "The results of this screening will be discussed with me by a health care professional," $X^2 (8, 90) = 17.80, p = .02$.

Figure 3. Significant Chi Square Association Between Gender and Patient Expectation, #10, "The comprehensive nature of CT screening makes it unlikely I will require further testing," $X^2 (2, 91) = 12.08, p = .01$.

Figure 4. Significant Chi Square Association Between Gender and Patient Expectation, #11, "I will want to recommend this test to my close friends and relatives, $X^2 (2, 89) = 8.09, p = .02$.

Figure 5. Significant Chi Square Association Between Gender and Patient Expectation, #14, Full body CT screening may be repeated throughout a person's lifetime, $X^2 (2, 91) = 9.79, p = .01$.

Figure 6. Significant Chi Square Association Between Referral Source and Patient Expectation, #7, "This test is available to both self-referred and physician-referred patients," $X^2 (2, 91) = 15.17, p = .001$.

Appendix H

Pie Graph Representations of Significant Chi Square Associations

Figure 1. Significant Chi Square Association Between Personal Health Concern and Patient Expectation, #2, "Knowing the results of this test may improve my overall health," ($X^2(4, 91) = 10.07, p = .04$).

Responses to Patient Expectation, #2, among patients who were somewhat concerned or not concerned about their health (n=33).

Responses to Patient Expectation, #2, among patients who were moderately concerned about their health (n=31).

Responses to Patient Expectation, #2, among patients who were very concerned or extremely concerned about their health (n=27).

Figure 2. Significant Chi Square Association Between Number of Other Health Screenings and Patient Expectation, #12, "The results of this screening will be discussed with me by a health care professional," $X^2(8, 90) = 17.80, p = .02$.

Responses to Patient Expectation, #12, among patients who had not participated in any other health screenings (n=4).

Responses to Patient Expectation, #12, among patients who had participated in one other health screenings (n=13).

Responses to Patient Expectation, #12, among patients who had participated in two other health screenings (n=18).

Responses to Patient Expectation, #12, among patients who had participated in three other health screenings (n=25).

Responses to Patient Expectation, #12, among patients who had participated in four other health screenings (n=30).

Figure 3. Significant Chi Square Association Between Gender and Patient Expectation, #10, "The comprehensive nature of CT screening makes it unlikely I will require further testing" ($X^2 (2, 91) = 12.08, p = .01$).

Responses to Patient Expectation, #10, among male patients (n=54).

Responses to Patient Expectation, #10, among female patients (n=37).

Figure 4. Significant Chi Square Association Between Gender and Patient Expectation, #11, "I will want to recommend this test to my close friends and relatives, (X^2 (2, 89) = 8.09, $p = .02$).

Responses to Patient Expectation, #11, among male patients (n=54).

Responses to Patient Expectation, #11, among female patients (n=35).

Figure 5. Significant Chi Square Association Between Gender and Patient Expectation, #14, Full body CT screening may be repeated throughout a person's lifetime, (X^2 (2, 91) = 9.79, p = .01).

Responses to Patient Expectation, #11, among male patients (n=54).

Responses to Patient Expectation, #14, among male patients (n=54).

Responses to Patient Expectation, #14, among female patients (n=37).

Figure 6. Significant Chi Square Association Between Referral Source and Patient Expectation, 7, "This test is available to both self-referred and physician-referred patients," ($X^2 (2, 91) = 15.17, p = .001$).

Responses to Patient Expectation, #7, among self-referred patients (n=30).

Responses to Patient Expectation, #7, among physician-referred patients (n=61).

Appendix I

Graphic Representations of Significant Spearman Correlation Coefficients

Figure 1. Association between self-estimations of current health reported by respondents and mean patient expectation scores on questions within the empowerment dimension, ($r = .30, p = .004$).

Figure 2. Association between the level of personal health concern reported by respondents and mean patient expectation scores on questions within the prevention dimension, ($r = .29, p = .004$).

Appendix J

Responses To 15 Patient Expectation Questions

Figure 1. Patient Expectation #1: Full body CT screening may give me peace of mind and reduce my worries about my health (n=92).

Figure 2. Patient Expectation #2: Knowing the results of this test may improve my overall health (n=91).

Figure 3. Patient Expectation #3: Regular full-body screening exams may prolong my life (n=92).

Figure 4. Patient Expectation #4: Finding a disease process early, may increase the chances of being cured (n=92).

Figure 5. Patient Expectation #5: This test will detect many, but not all diseases (n=92).

Figure 6. Patient Expectation #6: Effective treatments exist for almost any condition this test may find (n=92).

Figure 7. Patient Expectation #7: This test is available to both self-referred and physician-referred patients (n=91).

Figure 8. Patient Expectation #8: Full body CT screening is appropriate for healthy people, as well as people with specific diseases (n=92).

Figure 9. Patient Expectation #9: This test is one of the best options available today for preventive health care (n=91).

Figure 10. Patient Expectation #10: The comprehensive nature of CT screening makes it unlikely that I will require further testing (n=91).

Figure 11. Patient Expectation #11: I will want to recommend this test to my close friends and relatives (n=89).

Figure 12. Patient Expectation #12: The results of this screening will be discussed with me by a health care professional (n=91).

Figure 13. Patient Expectation #13: Additional tests may be needed to complement full body CT screening (n=91).

Figure 14. Patient Expectation #14: Full body CT screening may be repeated throughout a person's lifetime (n=92).

Figure 15. Patient Expectation #15: Scientists have studied the benefits and limitations of this procedure (n=90).

September 25, 2003

Carole Kolber
20 Adams Street
Morganville, NJ 07751

Dear Ms Kolber:

The Seton Hall University Institutional Review Board has reviewed and approved as submitted your research proposal entitled "Patient Expectations of Full body CT Screening". Enclosed for your records are the signed Request for Approval form and the stamped original Consent Forms. Make copies only of this stamped Consent Forms.

The Institutional Review Board approval of your research is valid for a one-year period from the date of this letter. During this time, any changes to the research protocol must be reviewed and approved by the IRB prior to their implementation.

According to federal regulations, continuing review of already approved research is mandated to take place at least 12 months after this initial approval. You will receive communication from the IRB Office for this several months before the anniversary date of your initial approval.

Your protocol has been reviewed and approved under expedited review. The IRB reserves the right at any time to request full review of the study.

Thank you for your cooperation.

Sincerely,

Elaine Walker, Ph.D.
Chairperson
Institutional Review Board

Cc: Genevieve Pinto-Zipp, Ph.D.

Giuliana Mazzoni, Ph.D.
Director
Seton Hall University
Institutional Review Board
President's Hall-3rd Floor
400 South Orange Avenue
South Orange, New Jersey 07079

Dear Dr. Mazzoni:

We have reviewed the materials submitted by Carole Kolber, M.Ed., a doctoral candidate in the Seton Hall University Graduate School of Medical Education Health Science Program relevant to the research study, "Patient Expectations of Full Body CT Screening."

We would like to authorize participation (Name of Facility) as a study site.

Sincerely,

(Position Title(s))