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Medication compliance among breast cancer patients on long-term adjuvant chemotherapy

Jackson, Tena M.

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MEDICATION COMPLIANCE AMONG
BREAST CANCER PATIENTS
ON LONG-TERM ADJUVANT CHEMOTHERAPY

TENA M. JACKSON ©

A THESIS SUBMITTED TO THE FACULTY OF ARTS
IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE
DEGREE OF MASTER OF ARTS

DEPARTMENT OF PSYCHOLOGY
LAKEHEAD UNIVERSITY
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DECEMBER, 1991
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ABSTRACT

Treatment compliance refers to performing behaviours which follow a course of treatment that has been agreed upon by the patient and the health care professional. Noncompliance can result in prolongation of current health problems, may lead to more extensive treatments, may compromise the effectiveness of treatment and may increase the chance of recurrence. The present pilot study, carried out at the Thunder Bay Regional Cancer Centre, assessed the compliance of 20 female breast cancer patients taking Tamoxifen, an oral medication considered to have prophylactic benefits. Measures were taken on desirability of control (Burger & Cooper, 1979), health locus of control (Wallston, Wallston & Devellis, 1978), mood states (the Profile of Mood States, Cella et al., 1987), quality of life (Functional Living Index - Cancer, Schipper et al., 1984), and the patients' perceptions of the Cancer Centre, their relationship with their oncologist, and their own likely rate of compliance. Further, half of the subjects were asked to complete a daily diary of their medication taking. Each patients' physician was asked to provide information on diagnosis, present status, physical functioning rating and likely compliance rate. Subjects were seen four times over a six-week period. At these meetings, the investigator counted the number of pills (Tamoxifen) remaining in the bottle and asked the subject to complete the quality of life measure. Subjects were not told this was a study of compliance.

It was hypothesized that:

1. patients scoring lower on the quality of life measure would be more likely to be compliant than those whose quality of life was high.
2. patients who displayed an internal locus of control, who scored high on desirability of control, and whose relationship with their oncologist
allowed for this internal/high desire control would be more compliant
than similar patients whose relationship did not allow for this control.
3. patients showing signs of mood disturbance would be less compliant
to the medication regimen.
4. patients regarding the Centre highly would be more compliant.
5. patients on the regimen for a longer period of time would be less
compliant than those just beginning the regimen.
6. patients' predictions about their own rate of compliance would
accurately reflect actual compliance, while oncologists' predictions would
not be accurate and would overestimate actual compliance rates.
7. patients who kept a daily medication diary would be more compliant
than those not using a diary.

The hypotheses were not supported by the data with the exception that
oncologists' predictions of compliance were not related to actual
compliance. However, age was significantly related to compliance in that
older women were more likely to be compliant to the medication
regimen. Also, it appears that oncologists base their estimations of
compliance on the length of time which has elapsed since the patient first
began treatment - a factor showing no relationship to actual compliance
rate. Several tentative, albeit statistically nonsignificant, relationships
provide compelling suggestions for future research. Also, implications for
the care of cancer patients are discussed.
DEDICATION

I would like to dedicate this thesis to my Mum, Beulah Davis, and my husband, Ken Jackson. These two wonderful people have encouraged me and have listened to my ranting and rambling. Their love and support and acceptance are the most precious gifts I could ever receive.

I also dedicate this work to my Dad, Norwood Davis. My father's life ended because of lung cancer in 1984 but his love and my memories of him continue to offer me a great deal of comfort when times are hard.
ACKNOWLEDGEMENTS

I want to take this opportunity to express my sincere gratitude and appreciation to Dr. Scott Sellick and Dr. Margaret Sellick for their encouragement, support and valued advice throughout the process of this study. I feel very fortunate in having had two such talented and caring supervisors.

I would also like to thank the oncologists who took the time to provide me with the medical information I sought, specifically Dr. H. S. Dhaliwal, Dr. H. Rayner, Dr. L. Pratt and Dr. D. Vergidis. A special thank you goes to the breast cancer patients who participated in this study. I wish you all a long life and the best of health.
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Medication Compliance Among
Breast Cancer Patients
On Long-Term Adjuvant Chemotherapy

With our increasing medical knowledge and pharmaceutical advances, medication regimens are becoming a part of life for many individuals. Compliance to these regimens may be the factor which turns the tide away from illness and toward health, with the added benefit of saving health care dollars. If we are able to identify predictors of noncompliance, we will be able to intervene and deal with the problem before it adversely affects the patient. This is as true in the care of people with cancer as it is in other types of illness; cancer now being a chronic illness and not necessarily the "death sentence" it once was.

Interest in the care of future cancer patients provides even more incentive for maximizing compliance. Many cancer patients participate in clinical trials designed to determine the best treatment for a particular disease. Noncompliance could have a serious effect on the interpretation of the results of that research. Given and Given (1989) state that "the results of well designed randomized clinical trials for therapeutic approaches ... may be in question without knowledge about patients' compliance levels with the clinical protocol" (p. 98). Identifying
the incidence of noncompliance in this population (i.e. cancer patients) and some of the factors associated with it would allow us to predict which patients are more likely to be noncompliant and the extent to which it may be a problem to consider in specific clinical trials.

In general, compliance is a term used to refer to health behaviour, on the part of a patient, that follows medical advice. It can be a controversial term to use since, to many people, it suggests passive obedience. For this reason, other terms with less negative connotations have been suggested, such as adherence, cooperation, collaboration, and therapeutic alliance (Feist & Brannon, 1988; Barofsky, 1978). However, compliance and adherence are still the most widely recognized and accepted labels to describe a person’s willingness to follow recommended health practices, and will be used interchangeably here.

Although the specific and operational definition of compliance and noncompliance varies across studies, for the purposes of this work noncompliance is considered to be failing to adhere to a course of treatment which has been negotiated by the patient and the health care professional. In this way, modifying the treatment in consultation with the physician would not be considered noncompliance, but rather a renegotiation of a contract.

In the days prior to the Renaissance, compliance was not an issue
because treatments such as bloodletting, leeching, and trephining were administered (often by force), rather than being prescribed (Davidson, 1982). Today however, we recognize the right of the individual to know the treatment options available to him/her and to make conscious, informed choices involving this treatment. The patient is in a unique situation with health care professionals in that he/she must trust but also doubt and must accept but also question (Fitzpatrick, Hinton, Newman, Scambler, & Thompson, 1984). This raises the possibility that patients will not comply with a recommended treatment regimen and, given that the success of any intervention depends upon the recipient's willingness and ability to comply or adhere to the recommended course of action, noncompliance can be a very serious problem.

Noncompliance to prescribed medical treatments can result in more serious illness and/or the prolongation of current health problems and thus, in the need for more extensive treatment (Gatchel, Baum & Krantz, 1989; Food and Drug Administration, 1980). Not complying often necessitates more appointments and increases the likelihood of long-term terminal care. In addition, if it is not recognized as noncompliance by the physician, it can even result in a more powerful, different, and/or perhaps even inappropriate, treatment being prescribed. Masur (1981) reports the case of a 25 year old male being followed for essential
hypertension who was prescribed antihypertensive agents. Eight weeks after the start of therapy, the patient's blood pressure was still well above normal and the physician prescribed more powerful drugs, not knowing that the reason for the patient's lack of improvement was that the patient did not comply with the regimen.

Noncompliance not only jeopardizes the rehabilitation and recovery of patients, but results in a heavy burden to the tax-payer. The American Food and Drug Administration (1980) has estimated that nonadherence costs $400 to $800 million dollars annually.

**Types of Compliance**

Perhaps the most basic form of noncompliance is not appearing for a scheduled appointment with a health care provider. It has been estimated that 25 - 50 % of persons fail to appear for a scheduled appointment (Dunbar & Stunkard, 1979). Sackett and Snow (1979) reported that compliance is higher when patients initiate the contact (at an overall compliance rate of 75%) than when the physician initiates the contact (at an overall compliance rate of 50%).

Noncompliance is also manifested when medication is prescribed. Patients may simply fail to fill the prescription, they may fill the prescription and then not take the medication, they may take too little or too much of it, they may not follow the frequency or dose instructions, or
they may stop taking the medication early (Buckalew & Sallis, 1986; Dunbar & Stunkard, 1979). It is this form of compliance which has received the most research, since noncompliance with a medical regimen can have an immediate, and sometimes dramatic effect on one’s life. In general, compliance to medical treatment is estimated at approximately 50% (Stone, 1979).

Thirdly, and it would appear that this happens quite often, patients may fail to make recommended lifestyle changes. Dunbar and Stunkard (1979) estimate that, in general, 20 - 80% of participants drop out of lifestyle change programmes. Sackett and Snow (1979) report that noncompliance to dietary regimens approaches 70%; and Dishman (1982) estimates that 50% of participants in exercise programmes drop out during the first six months.

Factors Affecting Compliance

Compliance estimates range considerably, depending upon the nature of the physical illness, its threat to life, the adverse nature of the interventions, the possible loss of self-esteem due to being ill and perhaps not being able to do the things you once did so easily, and, in some jurisdictions, the financial burden to the individual undergoing treatment. It can also vary depending on how one defines compliance (e.g. as keeping appointments, taking all prescribed medication, etc.)
and on who judges whether a particular act or omission is to be considered compliance or noncompliance. For example, a carefully thought out decision on the part of the patient not to undergo certain procedures may be considered noncompliance by a physician while others (including the patient) view it as simply one of the patient's basic rights. Falvo (1985) stressed that when people are faced with illness, they may experience fear, anxiety and other reactions that will affect their behaviour and "what the health professional may at times perceive as noncompliance may actually be that patient's attempt to gain some control over his or her own destiny" (p. xiii). Obviously, compliance is a very complex issue involving several factors.

The many factors possibly associated with compliance can be divided into three general categories. These categories include patients' personal characteristics, the nature of the physician-patient relationship and illness characteristics.

Patients' Personal Characteristics

Studies have attempted to find personal characteristics which may be related to compliance. Characteristics such as age, sex, race, religion, educational level, and social class do not appear to reliably predict compliance when considered in isolation (Davidson, 1982). However, considering four or more characteristics together can give an
indication of the probability of compliance (Masur, 1981).

A factor commonly identified with the patient’s ability to comply with a prescribed regimen is remembering and understanding the physician’s advice. Ley (1979) found that one can expect patients to remember about two-thirds of the instructions they are given, if they are asked immediately following the office visit. It appears that the more information the patient is given, the more he/she forgets (Ley, 1979). Dunbar (1980) reports that presenting details of the regimen both in writing and verbally; tailoring the instructions to the patient; emphasizing the 'how to' component of the regimen rather than the 'why'; and assessing the patient's comprehension and skill by asking him/her to describe what he/she is going to do when he/she gets home will all help the patient to understand and remember what he/she is to do.

Cultural beliefs and attitudes are other personal characteristics that relate to compliance. People living within a culture that does not have faith in modern medical procedures are unlikely to comply with medical recommendations (Nyazema, 1984). Further, it appears that patients are more likely to comply with such recommendations if their physician demonstrates some understanding and respect for their cultural practices and beliefs (Ruiz & Ruiz, 1983).

Another personal characteristic that seems to be related to
compliance is social support. People who have close interpersonal relationships are more likely to follow medical advice than those whose lives are isolated from others. Their family members and friends can encourage or remind them to comply with the therapeutic regimen and can even give them added reason to follow the regimen and become well again (e.g. when a mother reports fighting illness because her child needs her). Sherwood (1983) found that compliance by haemodialysis patients increased when family members were involved and showed an understanding of the disease, the medication regimen, and the emotional effects of illness. Interestingly, Sherwood (1983) also found that there is an ideal level of family involvement midway between family members being emotionally distant and being emotionally overinvolved.

Quality of Life is another patient variable which may impact on compliance. Quality of Life measures, particularly in cancer care, assess such things as freedom from pain, sociability, "impact" of the illness and satisfaction. It can be said that quality of life "reflects a composite of factors that individuals view as important to the reality of functional living" (Schipper, Clinch, McMurray & Levitt, 1984, p. 473). Those patients scoring lower on such measures are reporting more illness symptoms and more general dysfunction than their counterparts with higher quality of life scores. While research evaluating a possible relationship between
quality of life and compliance has not been done, common sense suggests that those people who are not experiencing active illness symptoms may be less likely to comply with medication regimens. Many of us have had the experience of strictly following an antibiotic regimen while feeling ill, but then forgetting to take the medication more and more after beginning to recover. Perhaps the same thing happens with other medication regimens.

Personality traits are another aspect of patient characteristics which have been studied. For a time, there was a search for the 'compliant personality' (Bloom, 1988). Research in this area has been equivocal. Some research has reported a link between noncompliance and personality factors such as authoritarianism, neuroticism, and impulsivity (Davis, 1968; Jacobs, 1972; Fitzpatrick et al., 1984) while other researchers state that strong evidence to back up the claim of a relationship between personality and compliance does not exist (DiMatteo & DiNicola, 1982; Feist & Brannon, 1988).

One particular personal characteristic which has received a lot of attention in the area of compliance is locus of control. Locus of control is concerned with what we believe determines the events in our lives. It may be internal (i.e. we believe events are determined by our own behaviour) or external (i.e. we believe events are determined by chance
or powerful others). Again, the conclusions about the impact of locus of control on compliance are varied. DiMatteo and DiNicola (1982) and Feist and Brannon (1988) state that the two are not related, while other researchers provide evidence that they are.

Blotcky, Cohen, Conatser and Kloovich (1985) compared adolescents who refused cancer treatment with consenting adolescents. The refusers tended to have a more external locus of control than the adolescents who consented to treatment. In other words, they felt their health was not something over which they had control. In a similar study, Jamison, Lewis and Burish (1986) found that adolescents with an external locus of control tended not to cooperate or comply with treatment.

Poll and Kaplan De-Nour (1980) studied locus of control in respect to adjustment to chronic haemodialysis and compliance with the required diet for these patients. They found that those with an internal locus of control tended to adjust and adapt better than those with an external locus of control. Further, 'internals' complied with the diet more than 'externals'. This issue then does seem to have some influence on compliance and so study evaluating the link between the two should continue.

How much control one desires is another issue to consider.
Perhaps some patients want to be actively involved in their treatment and when this involvement is not allowed, they fail to comply in an attempt to have control in some manner (Falvo, 1985). This issue has not been examined in relation to compliance. However, Blanchard, Labrecque, Ruckdeschel and Blanchard (1988) reported that 69% of patients prefer to participate in therapeutic decisions-making (i.e. they desire control). Blanchard et al. (1988) also report that 25% of patients prefer an authoritarian relationship with physicians in which the physician takes charge and tells the patient what to do, rather than a participatory or negotiative relationship. Thus, there is obviously a difference in how much people wish to be directly involved in their health care and this difference may impact on compliance. Desirability of control then appears to be closely linked to patient-physician relationship - the next set of factors to be discussed.

**Patient-Physician Relationship**

The lack of a definitive link between compliance and personal characteristics has led some researchers to believe that perhaps compliance should be thought of as being a comment on a relationship (e.g. physician-patient, therapist-client, clinic-public) rather than a description of a person. Practitioner-patient interaction variables do appear to play a role in patient compliance. Patients who experience a
delay in getting an appointment with a physician and those who wait in a waiting room for an hour or more are more likely to be noncompliant (Feist & Brannon, 1988).

On the other hand, patients tend to be more compliant if they view their physician as friendly, nonauthoritarian, interested in the patient's welfare, and if they are satisfied with the relationship they have with their physicians (Gastorf & Galanos, 1983; Fitzpatrick et al., 1984). In addition, Gilbar (1989) reported that the less confidence a patient has in her physician, the more likely that patient is to refuse chemotherapy.

Further, compliance has been found to decrease when physicians are seen as authoritarian or directive (Gastorf & Galanos, 1983). Turk, Salovey and Litt (1986) report that fostering a sense of active participation is critical to forming a working relationship between patient and physician. They go on to suggest that this lays the groundwork for compliance. However, Blanchard et al.'s (1988) work reveals that not everyone wants this type of relationship. What happens to compliance when patients do not get the type of relationship they want?

Kincey, Bradshaw and Ley (1975) report that patients who feel disappointed or dissatisfied when leaving a clinic are more likely not to follow advice or take prescriptions as required. In describing situations in which the patient was dissatisfied with the communication with the
physician, Fitzpatrick et al. (1984) concluded that the physician had perceived their responsibility as being the treatment of the disease rather than the treatment of the person and "in some sense, they must have felt their responsibilities at an end when they had solved the diagnostic puzzle and announced their solution. However, for the patient, treatment had yet to begin and until they could see the connection between the worries which brought them to the doctor and the advice given, they were unlikely to follow instructions" (p. 96). This points out the need for more study on the impact of the patient-physician relationship on compliance.

**Illness Characteristics**

Disease characteristics are a third group of factors which can have an impact on compliance. Severity of the illness is often thought to be important, and common sense suggests that people with severe, perhaps life-threatening illnesses would be more likely to be compliant. This however is not necessarily the case. In fact, it appears that a physician's objective opinion of the severity of a disease is not related to compliance, but the patient's perception of disease severity is important (Hulka, 1979; Becker & Maiman, 1980). Patients who perceive themselves as susceptible to an illness seem to be more compliant.

Severity of side effects is another illness characteristic which is
widely assumed to be related to compliance. It would be easy to
assume that compliance to a non-toxic drug would be higher than
compliance to a drug with many unpleasant side effects. This issue
could be especially important in considering compliance in cancer
patients because the treatments often have such distressing and long-
lasting side effects (e.g. hair loss). Lee (1983) and Smith, Rosen,
Trueworthy and Lowman (1979) do report that unpleasant side effects of
drugs was the most compelling reason for noncompliance in cancer
patients. On the other hand, Masur (1981) reports that unpleasant side
effects are not a major reason for noncompliance to medical treatment.
Indeed, some people may even interpret toxicity of drugs as evidence
that the treatment is working and therefore may welcome the side effects.
Side effects and compliance may still be related, but more research is
needed to determine how important they figure in a patient's
noncompliance.

Research has revealed that the longer a person must remain in
treatment, the more likely it is that the person will be noncompliant
(Haynes, 1976). Berger, Braverman, Sohn and Morrow (1988) found that
cancer patients exhibited 100% compliance to therapy at two months and
that this reduced to 82% compliance at six months and 75% compliance
at one year. Closely related to the issue of duration of treatment is the
complexity of the treatment. It appears that the number of daily doses required is not definitely related to compliance but if patients are required to take a variety of medications, noncompliance will increase as variety of medications increases (Hulka, Cassel, Kupper & Burdette, 1976).

**Measuring Compliance**

Compliance can be measured in several ways. The most obvious of these is patient self-report. If patients are reporting past behaviour, this report may not be accurate because most patients wish to be thought of positively and can not be expected to willingly portray themselves negatively by admitting to noncompliance (Sheiner et al., 1974). Asking questions in such a manner as to anticipate and be permissive of reports of failure to comply may offset this trend somewhat (Sackett & Haynes, 1976). It appears however that patients will be truthful and quite accurate if asked to predict to what degree they will comply with a given treatment regimen (Dunbar & Stunkard, 1979).

A second method of assessing compliance is by physicians' estimates. Although this method might appear to be useful, research has shown that health care providers tend to overestimate compliance. Roth and Caron (1978) assessed compliance in peptic ulcer patients by antacid bottle count, patient self-report and physicians' estimates. They found that physicians' estimates of compliance were significantly better
than chance, and were more accurate that the patients' self-report, but were nevertheless quite low in accuracy. Further, physicians' accuracy did not improve as they gained familiarity with the patient.

Another method that has been used to assess compliance is clinical outcome - if the patient's condition improves, it can be assumed that he/she was compliant. There are serious problems associated with using this method. The outcome of a treatment regimen is dependent on many factors, only one of which is compliance. The medication must be the appropriate one and must be prescribed at an adequate dosage level and it must be a treatment to which the patient is biologically responsive. If the prescribed treatment is relatively ineffective, compliance and improvement will be unrelated. Further, improvement may occur as a result of factors other than medical care and patients may take several medications with varying degrees of compliance, making it difficult, if not impossible, to determine which medication might have been related to the improvement (Bloom, 1988).

Compliance can also be measured by pill counts or medication measurement. This is a commonly used method given that it is easily, quickly and inexpensively carried out. On the one hand, this is effective because medication that is still in the bottle has clearly not been taken by anyone. However, it can become problematic when the medication is
gone. This medication may or may not have been taken according to the prescription (e.g. in terms of frequency). It may have been discarded rather than being taken. It may even have been taken by someone other than the person for whom it was intended. These possibilities must all be considered.

Medication monitors are sometimes used to assess compliance. These are devices which measure when medications are removed from containers. Masur (1981) reported an interesting use of such a device. The pills to be taken were packaged in a stack and alongside the stack was a strip of radiation sensitive film. On top of the stack was a radiation emitting chemical (a small uranium source) and a spring that kept pressure on the stack. Removing pills at regular intervals left a pattern of equally dark spots on the film. Forgetting to take a pill for a long period of time resulted in a very dark spot on the film. Removing several pills at once resulted in an absence of spots. An obvious problem with this method is the cost associated with the development and use of such monitors.

A sixth method of measuring compliance is by direct chemical analysis of urine or blood serum to detect the presence of the medication or a tracer that was added to the medication. These chemical tests are the most accurate methods for measuring compliance that are currently
available (Bloom, 1988) and yet they are not without problems. They are inconvenient and, in the case of blood tests, invasive. Not all medications can be traced or tested and some are absorbed by the body too quickly, others too slowly. Not all lab procedures are perfectly reliable and many are time-consuming and costly. Levels of tracers can be influenced by changes in body metabolism, diet or weight and finally, many tests can not distinguish between a medication taken regularly and one taken irregularly but just before the blood or urine sample is collected.

Compliance and Cancer

Hoagland, Morrow, Bennett and Carnrike (1983) surveyed oncologists about the extent of and reasons for cancer patient noncompliance. Ten potential compliance problem areas were identified and the majority of oncologists reported having some problem with nine out of ten of these areas. The noncompliance behaviour which was seen to be a problem by the greatest number of oncologists was that of the cancer patient who accepts treatment and then fails to complete the entire protocol. The main reasons given by oncologists for patient noncompliance were psychological problems such as denial and fear, but treatment side effects were also seen as contributing to noncompliance.
Authors differ in their estimations of compliance among cancer patients and the degree to which they believe compliance is even an issue in the treatment of cancer. Gerber and Nehemkis (1986) explain that while "noncompliance colors every aspect of dialysis treatment . . . the opposite is true of advanced cancer patients in whom the incidence of noncompliance to their likewise demanding treatment program is negligible" (p.73). Barofsky (1984), in reviewing investigations looking at noncompliance among cancer patients, concluded that the relative lack of such studies, and the perception that noncompliance is of minimal concern among oncologists, is due in part to the fact that most treatments are provider rather than self administered. The studies which are available however, reveal that cancer patients are noncompliant and are, in fact, as noncompliant as patients with other diseases.

Smith et al. (1979) studied prednisone compliance in children and adolescents with cancer during three phases of therapy. Compliance was evaluated through random urine 17-ketogenic steroid assay. The authors found that 33% of all patients were not complying. Analysis of patients by age group revealed that 59% of adolescents were not complying with their prednisone therapy. Given the advances which have been made in treating childhood cancers, noncompliance in this group can have especially tragic consequences, particularly if a child's
lifespan is shortened.

In looking at adults, Wellisch et al. (1983) reported that in their study, when asked directly about their compliance, 26% of cancer patients indicated they had not adhered to treatment as directed. Noncompliance was explained to the patients as "failing to follow and/or refusing prescribed treatment routing (e.g. drugs, chemotherapy, etc.)" p. 12. Details regarding the reasons for noncompliance were not provided.

In another study, Barofsky and Sugarbaker (1979) approached patients to participate in sarcoma clinical trials. Of those who agreed to participate, 16.5% were noncompliant in that they did not complete the treatment as prescribed. These patients cited the aversive aspects of treatment such as amputation and chemotherapy side effects as the major reason for noncompliance.

Similarly, side effects of treatment was given as the reason for noncompliance for the majority (71%) of the noncompliers in Wilcox et al.'s (1982) study. They defined noncompliance as discontinuing adjuvant chemotherapy and reported an overall rate of noncompliance of 27% among breast cancer patients.

Treatment-related complications or side effects and noncompliance were not correlated in a study conducted by Berger et al. (1988). They studied compliance in patients with locally advanced breast
cancer. Compliance was defined as completing the chemotherapy protocol as prescribed, and treatment took place at a large municipal hospital. They found that 25% of the patients were not compliant according to this criteria. Duration of treatment and initial delay in seeking treatment were the factors most closely related to noncompliance in this study.

As further evidence of the important effect of both duration of treatment and side effects on compliance, Lee (1983) studied breast cancer patients who accepted post mastectomy adjuvant chemotherapy. She found that 77% of the patients stayed on the treatment for at least six months, and that compliance declined over time, with 50% of patients staying on the treatment for 12 months or more. Side effects of treatment as well as "personal and psychosocial factors" were given as reasons for discontinuing treatment. Examples of personal and psychosocial factors were not provided.

In a very recent article, Lebovits et al. (1990) studied the prevalence of noncompliance with self-administered chemotherapy. These authors measured compliance via patient report during repeated interviews over a six month period. Dosage noncompliance was defined as the patient ingesting 90% or less of the total prescribed dosage of medication. There was also a behavioural definition in which
noncompliance was judged to have occurred if the patient, at any one of the visits, reported ingesting 90% or less, or 110% or more, of the prescribed medication. They found that 43% of patients met these criteria for noncompliance. Thus, it appears obvious that compliance is a very serious concern in treating cancer patients and one which requires further research into the best ways to measure it and the best ways to maximize it.

Proposed Research Question

To summarize, compliance in cancer care is an area which has received relatively little study to date. Given the prevalence of cancer and the seriousness of this chronic illness, it is imperative that we understand the issue and take steps to deal with noncompliance before it jeopardizes a patient’s health.

Many factors have been discussed which may be related to the compliance of cancer patients. Obviously, these can not all be addressed within the scope of this one pilot study. Thus, certain variables have been chosen for examination to provide a starting base for the study of these variables in compliance (i.e. desirability of control and quality of life) or because results have been somewhat equivocal and need to be clarified. Finally, a very simple intervention will be made with half the subjects to evaluate its impact on compliance.
This pilot study will look at assessing compliance in breast cancer patients receiving the drug Tamoxifen. Compliance will be operationally defined according to medication ingestion. Patients who ingest 90-100% of their medication will be judged to be highly compliant. Patients ingesting 75-89% of their medication will be considered moderately compliant and patients ingesting 60-74% of their medication will be considered to be exhibiting low levels of compliance. Patients ingesting less than 60% of the medication will be considered noncompliant. It is expected that some patients may appear to have taken more than 100% of the prescribed medication. In these cases, the observed percentage will be converted to a comparable percentage below 100. For example, if a subject appeared to have ingested 125%, the difference from the expected percentage is 25; thus, the converted score would be 75%.

**Hypothoses**

It would be infinitely simpler if the variables involved in this study existed in their own right and were not affected by the other variables. This however is completely unrealistic since nothing remains unaffected by what happens around it. Davidson (1982) and Masur (1981) report that many variables do not affect compliance when considered alone, but several considered together can give us an accurate prediction of compliance behaviour. Thus, the hypotheses for this study are
complicated and involve many interactions.

1. It is predicted that patients scoring lower on the quality of life measure (FLIC) will be more likely to be compliant. Those patients who show a higher quality of life will be experiencing fewer 'illness symptoms' (e.g. nausea) and so will be more likely to forget to take their medication or to feel that it is not necessary to strictly adhere to the regimen. Further, as a patient's quality of life changes throughout the course of the study, so will their compliance change. In other words, a patient scoring high on the FLIC one week, but low on the FLIC at the next meeting will exhibit less compliance the first week (when feeling good) than when feeling low.

2. People who display an internal locus of control, who score high on Desirability of Control, and whose primary health care providers have negotiated a relationship with them that allows for this control (or active participation) on the part of the patient, will be compliant. This participatory relationship will be characterized by the physician making an effort to include patients in their own treatment decision-making. Also, people who attribute control to chance or powerful others (i.e. display an external locus of control), who have little desire for control and who are in directive relationships with health care providers will be compliant. Directive relationships will be characterized by the physician making
treatment decisions and telling the patient what must be done.

On the other hand, patients with a high internal locus of control, who desire control but who are in directive relationships with practitioners will not be compliant. Similarly, patients displaying a high external locus of control, with little desire for control, who are in participatory relationships with health care providers will be somewhat overwhelmed by having too much control, and thus will be noncompliant.

3. It is anticipated that patients showing signs of depression (as assessed by the POMS) will be less compliant to the medication regimen. Included in the symptoms of depression are difficulty concentrating and problems with memory. Thus, a patient may not remember whether he/she took his/her medication and this may result in the patient being labelled noncompliant.

4. Perception of the centre will affect compliance in that patients who regard the centre highly or who do not experience long waits are expected to be compliant. Studies have shown that the less faith a patient has in modern medical procedures and the longer a patient must wait, either for an appointment or in a waiting room, the less compliant the patient will be (Nyazema, 1984; Feist & Brannon, 1988).

5. The longer a patient has been on the medication regimen, the less compliant they will be. Berger et al. (1988) found that compliance
decreased as the duration of treatment increased.

6. It is anticipated that patients' predictions about their rate of compliance will accurately reflect the degree of compliance they actually do exhibit. This result has been demonstrated in other research (e.g. Dunbar & Stunkard, 1979) and it is expected that it will be replicated here. Further, it is predicted that health care providers will not be very accurate in their predictions and will probably overestimate the rate of compliance exhibited by the patients (Roth & Caron, 1978).

7. Patients who keep a diary of their medication taking are expected to be more compliant than those patients not using a diary. The act of self-monitoring one's behaviour will increase awareness of the behaviour and thus will increase the probability of complying to the treatment regimen (e.g. Haynes, 1976; Bellack, 1976).
Method

Subjects

Subjects were 20 female breast cancer patients taking Tamoxifen, a medication which is commonly used for the adjuvant treatment of breast cancer. They were recruited on a strictly voluntary basis from the Thunder Bay Regional Cancer Centre. Initially, 68 potential subjects were contacted by phone, 40 of whom declined, leaving 28 who agreed to participate. Of the 40 decliners, 11 (28%) explained they did not have transportation readily available to come to the clinic four times. Another 11 (28%) indicated that they were going on an extended vacation for the remainder of the winter. Ten potential subjects (25%) gave no reason for non-participation. The remaining 8 women reported that they were too busy or too ill to participate.

Of the 28 women who agreed to participate, four then cancelled. Only data from subjects who were in fact prescribed Tamoxifen were included in the study. This restriction required the exclusion of two subjects who had discontinued Tamoxifen therapy with the knowledge of and/or at the suggestion of their attending oncologist. Data from another two subjects were excluded from the study because the subjects did not bring their medication to any of the meetings.

The data were collected over a five month period (January 1991 to
May 1991) at the Thunder Bay Regional Cancer Centre.

Materials

1) The Multidimensional Health Locus of Control (MHLC) Scales (see Appendix A) were developed to measure people's beliefs that their health is determined either by their own behaviour (i.e. health control is internal e.g. if I take the right actions, I can stay healthy), or by chance (e.g. my good health is largely a matter of good fortune), or by powerful others (e.g. having regular contact with my physician is the best way for me to avoid illness).

Two equivalent forms, each consisting of 18 items (6 items representing each of the three aspects of health control) are available for use. Alpha reliabilities ranged from .673 to .767 (Wallston, Wallston & DeVellis, 1978). Construct validity of the measure was demonstrated by comparing it to scales developed by Levenson (1974) to measure generalized locus of control beliefs (Wallston, Wallston & DeVellis, 1978). Each MHLC scale correlated significantly with its theoretical counterpart among these scales.

Health status of patients was correlated with MHLC scales to provide an indication of predictive validity (Wallston, Wallston & DeVellis, 1978). These correlations were positive with Internal Health Locus of Control ($r = .403, p < .001$), negative with Chance Health Locus of
Control ($r = -0.275, p < .01$), and not correlated with Powerful Others Health Locus of Control ($r = 0.055$).

2) The Desirability of Control (DC) Scale (see Appendix B) consists of 20 items which measure individual differences in the desire one has for control over the events in one's life (Burger & Cooper, 1979). This scale has internal consistency of .80 and test-retest reliability of .75. Discriminant validity has been demonstrated by comparing the DC Scale with measures of locus of control (Burger & Cooper, 1979). A low negative correlation ($r = -0.19$) between these two scales suggests that they do indeed measure different constructs. Construct validation studies (Langer, 1975) found that subjects scoring high on Desirability of Control possessed a belief of personal control over chance outcomes. Further, Hiroto and Seligman (1975) found that people who have a high desire for control over the events in their lives may respond to uncontrollable, unpredictable aversive stimuli with learned helplessness. Breast cancer may be considered such an aversive stimuli and so this scale was used to assess how much control each subject desired.

3) The Profile of Mood States (POMS) is an 11 item adjective rating form that assesses present mood state (see Appendix C). The 65 item original scale is often experienced as repetitive and burdensome by physically ill patients, so a short form consisting of 11 items was
developed from the Total Mood Disturbance Score (TMDS) provided by the POMS (Cella et al., 1987). This form has been used to evaluate general distress in cancer patients and it correlates significantly with the long form ($r = .93, p < .001$). Further, it demonstrates high internal consistency ($r = .91$). To demonstrate the validity of this measure, scores of pancreatic cancer patients and gastric cancer patients were compared (Cella et al., 1987). It is known that POMS TMDS scores of pancreatic cancer patients are significantly higher than those scores of gastric cancer patients. As expected, this same tendency is evidenced in scores obtained on this 11 item scale.

In addition to the 11 adjectives, a visual analog scale developed by Dr. Scott Sellick and the author was provided with the POMS. Subjects were asked to use this scale to rate their overall enjoyment of life during the past week. One end of a 100 mm line was anchored with 'no enjoyment' while the other end was anchored with 'excellent'.

4) The Functional Living Index - Cancer (FLIC) consists of 22 items which measure the quality of life in cancer patients, including physical well being and ability, emotional state, sociability and family situation (see Appendix D). Validation of the scale was conducted in Canada using 837 patients over a three year period. Construct validity was established through factor analyzing the questionnaire (Schipper et
al. 1984). Significant correlations between the FLIC and other similar measures (e.g. the General Health Questionnaire) provide evidence of concurrent validity and suggest that the FLIC may be used as a quality of life measure and as a screening tool to identify specific dysfunction (Schipper et al., 1984).

5) The Difficulty Scale is a simple likert-type scale derived by Dr. Scott Sellick and the author to evaluate patients' predictions of potential noncompliance. The scale ranged from 0 (no problems) to 3 (many problems). Subjects were asked to indicate which number best represented the degree of difficulty they expected to encounter in following the medication regimen (see Appendix E).

6) The Patients’ Impressions of TBRCC Scale was constructed by Dr. Scott Sellick and the author to evaluate patients’ experiences at and satisfaction with the Thunder Bay Regional Cancer Centre (TBRCC) and its physicians and nurses (see Appendix F). It consists of 12 statements to which the subject gives a rating of agreement or disagreement on a likert-type scale ranging from -3 (strongly disagree) to 3 (strongly agree). Included in these 12 statements were two statements which were intended to evaluate whether the patient-oncologist relationship was primarily participatory (i.e. the physician attempts to include the patient in decision-making [Part B # 2]) or directive (i.e. the physician makes
treatment decisions and tells the patient what must be done [Part B # 6]). A visual analog scale was also provided on which the subject indicated overall satisfaction with the TBRCC by placing a mark along a 100 mm line anchored with extremely dissatisfied at one end and extremely satisfied at the other end.

In addition to the questionnaires and scales, there was a patient information sheet which was completed by the medical oncologist (see Appendix G). This sheet was used to obtain information about Diagnosis and Present Status (i.e. free of disease, recurrence or metastatic disease). Also, the oncologist was asked to estimate each patient’s compliance on a 100 mm visual analog scale and to rate the patient using the ECOG (Eastern Cooperative Oncology Group) Scale. The ECOG Scale is widely used to assess patients’ level of physical functioning. The scale ranges from zero to four, with lower numbers indicating higher functioning (see Appendix H).

**Procedure**

Potential subjects were initially contacted by phone call. The study was briefly described (see Appendix I) and participation was requested. If the subject agreed to participate, an initial meeting with the investigator was arranged and the investigator asked the subject to bring all
prescribed medication to the meeting. Interestingly, few patients questioned the logic of this request. Perhaps in their experiences with the Cancer Centre, they had been asked to do many things which did not seem logical to them and so they were not surprised by the request. For those who did question, it was explained that though it seemed strange, it was simply a standard procedure the investigator had to follow. Patients accepted this explanation. Only one subject disclosed that she realized her pills were being counted, and this subject willingly and readily brought her medication to the meetings. The investigator neither confirmed nor denied her suspicions.

At the initial meeting, participants were asked to sign an informed consent form (see Appendix J). As can be noted, the subject was not told that the study dealt with medication compliance and that their pills were being counted. The author recognizes that this raises a serious ethical question about the nature of the informed consent. However, it was important not to influence the results of this study and it was felt that subjects might strive to be more compliant than usual if they knew the nature of the investigation. Thus the somewhat difficult decision was made to keep this information from the subjects. The challenge then was to find the best way to provide the subject with enough information to make a decision to participate without revealing the nature of the
study. To this end, input was sought from the medical staff at the Thunder Bay Regional Cancer Centre, from the Ethics Committee of the Thunder Bay Medical Society and from the Ethics Committee of Lakehead University. The informed consent form in Appendix J represents the results of that quest.

At the initial meeting, subjects were also asked to complete the Difficulty Scale, the MHLC, the DC, the POMS, the FLIC, and the Patients' Impressions of TBRCC Scale. Prescription medication was recorded and Tamoxifen tablets were counted without the subjects' knowledge.

Subjects were randomly assigned to one of two experimental conditions by choosing pieces of paper from a bowl immediately prior to the initial meeting. Half the pieces of paper had a "one" written on them while the other half had a "two" written on them. This method assured that subjects had an equal chance of being assigned to either group.

One group (n=11) was given a diary at the initial meeting in which to keep track of when they had taken any prescription medication and how much they had taken (see Appendix K). After a two week period, the subjects again met with the experimenter, exchanged the completed diary for a new one, completed the FLIC and had their pills counted by the investigator surreptitiously. The investigator left the subject to
complete the questionnaires, explaining that she had to have the
secretary record the medication. At that time the Tamoxifen tablets were
counted using a standard pharmacy tray. The tablets were not directly
handled, but were poured onto the tray and moved with a pharmacy
knife. These meetings continued at two week intervals for six weeks (an
initial meeting and three study meetings with each subject).

The other group (n=11) was not asked to complete a medication
diary, but was still asked to meet with the investigator at two week
intervals. It was explained to them that their continued adjustment was of
interest and so they were to meet with the investigator three more times
to complete more questionnaires (i.e. the FLIC). At these meetings, their-pills were surreptitiously counted by the investigator. Both groups spent
the same amount of time with the investigator and received the same
amount of investigator attention.

Following the initial meeting, the patient information sheet was sent
to the medical oncologist to obtain information on diagnosis, present
status, ECOG rating and the oncologist's prediction of the patient's
compliance (see Appendix G).
Results

Demographic Information

This sample consisted of women who had been diagnosed with breast cancer. The ages ranged from 47 - 69 years with a mean age of 60.55 years (sd = 7.097). Length of time since the patient was first prescribed Tamoxifen ranged from 2 - 83 months with a mean of 19.55 months (sd = 19.734).

It is interesting to note that 85% (n=17) of the subjects were considered to be free of disease, while 15% (n=3) had a recurrence of cancer or metastatic disease. Similarly, patients’ physical functioning was high. ECOG ratings showed that 75% (n=15) were considered fully active, 20% (n=4) were restricted only in physically strenuous activity and only 5% (n=1) were unable to carry out any work activities.

Pill Count

For each subject, medication compliance was determined by pill count. The regimen for each patient required that she take one tablet once a day. Tamoxifen tablets were surreptitiously counted by the investigator at each meeting and this amount was converted to a percentage. The count taken at the initial meeting served as a baseline. At the next meeting, the number of pills missing was divided by the number of pills which should have been taken to obtain the percentage
ingested. In the event that the percentage exceeded 100%, it was converted to below 100% so that the observations used for analysis could range from 0 - 100% (e.g. if it appeared that a subject ingested 125% of the medication it was expected she would take according to her prescription, this was converted to 75% - the difference between the observation and 100 in both of these cases being 25.) If it appeared the patient had taken more than 199% of the medication, her compliance at that observation was recorded as zero. These percentages were then summed and divided by the number of meetings to obtain the average compliance rate.

Only 50% (n=10) of the subjects brought the medication to all meetings with the investigator. Another 25% (n=5) forgot to bring the medication to the initial meeting but did bring it to the other meetings. In these cases, the first time they brought the medication served as the baseline and the average pill count was derived from two observations. Two other subjects (10%) forgot to bring the medication to one of the study meetings. Their average pill count was derived from the two counts the investigator was able to obtain. The remaining three subjects (15%) forgot the medication twice. For these subjects, the pill data consisted of only a baseline and one observation which was used as their mean as well. The data for these subjects is obviously not as
complete as would be desired but it was not discarded from the analysis since failing to bring medication when requested can itself be considered an act of noncompliance. These results however point out the limitations of pill counting as a measure of compliance, which will be discussed more later in this work.

When subjects did not give the medication to the investigator at the beginning of the session, the investigator asked if she had remembered to bring it. If she had not, the investigator simply asked her to try to remember to bring it to the next meeting.

Mean compliance ranged from 85.263% (sd = 30.668) at Time 2 to 90.32% (sd = 21.106) at Time 1 (see Table 1). Overall, compliance was moderate, with a mean of 87.6% (sd = 21.849), and 15 subjects were considered to be highly compliant (see Table 2). However, even though compliance was generally high, 20% of subjects (n=4) were considered to be noncompliant - a relatively large proportion. Further, individual subject’s compliance at individual meetings ran the entire possible range of 0 - 100% On several occasions compliance was 100%, but on two occasions, the count (of two different subjects) indicated that they had taken 200% and 300% of their expected medication, leaving a percentage of 0.
### Table 1
#### Mean Medication Compliance Over Time

<table>
<thead>
<tr>
<th>Time</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (n = 19)*</td>
<td>90.32</td>
<td>21.106</td>
</tr>
<tr>
<td>2 (n = 19)*</td>
<td>85.263</td>
<td>30.668</td>
</tr>
<tr>
<td>3 (n = 16)*</td>
<td>86.000</td>
<td>27.232</td>
</tr>
<tr>
<td>Total (n = 20)*</td>
<td>87.600</td>
<td>21.849</td>
</tr>
</tbody>
</table>

* Instances in which subjects forgot to bring the medication were not included in the calculation of the mean and standard deviation.

### Table 2
#### Categorized Compliance

<table>
<thead>
<tr>
<th>Compliance</th>
<th># of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Compliance</td>
<td>15</td>
</tr>
<tr>
<td>(ingesting 90 - 100%)</td>
<td></td>
</tr>
<tr>
<td>Moderate Compliance</td>
<td>1</td>
</tr>
<tr>
<td>(ingesting 75 - 89%)</td>
<td></td>
</tr>
<tr>
<td>Low Compliance</td>
<td>0</td>
</tr>
<tr>
<td>(ingesting 60 - 74%)</td>
<td></td>
</tr>
<tr>
<td>Noncompliant</td>
<td>4</td>
</tr>
<tr>
<td>(ingesting &lt; 60%)</td>
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</tr>
</tbody>
</table>
Subject Prediction of Compliance

Subjects' evaluations of how much difficulty they would have in following the medication regimen ranged from 0 (no problems) to 3 (some problems). Most subjects anticipated no problems following the regimen, with 80% (n=16) falling into this category. Another 10% (n=2) anticipated few problems and 10% (n=2) anticipated some problems.

Oncologist Prediction of Compliance

The visual analog scale on which the oncologists gave their predictions of patient compliance was broken into seven equal parts for ease of analysis. A rating of 1 indicated very low compliance and a rating of 7 indicated very high compliance. The mean prediction of compliance was 6.0 (sd = 1.338). Several patients (35%, n=7) were considered to be very compliant (receiving a rating of 7). Another 50% (n=10) received a rating of 6, while 10% (n=2) received a rating of 5 and only 5% (n=1) were considered noncompliant by the oncologists (receiving a rating of 1). Four oncologists were involved in giving compliance ratings for patients. The mean prediction given by a particular oncologist ranged from 4.8 - 6.5 (see Appendix L). It would have been interesting to analyze for differences according to the attending oncologist, however the sample size was too small for such analysis. Further, it would be interesting in future to have compliance
ratings for each patient by more than one oncologist or physician, as a check on the reliability of this measure.

**Multidimensional Health Locus of Control**

The Multidimensional Health Locus of Control Scales (MHLC) yield scores on three separate scales: Internal Health Locus of Control Scale (IHLC), Chance Health Locus of Control Scale (CHLC) and Powerful Others Health Locus of Control Scale (PHLC). The normative sample consisted of 115 subjects (51% females) approached by a research assistant in a metropolitan airport. The mean age of the sample was 42 years.

**Internal Health Locus of Control.**

Scores on IHLC ranged from 8 - 28 with a mean of 20.150 (sd = 4.591). Only three patients scored highest on this measure of locus of control, indicating that they believed they had control over their own health. Wallston and Wallston (1978) reported that the normative sample of 115 people yielded a mean of 25.104 (sd = 4.891). A significant difference was found between our sample and the normative mean (z = 4.415, p < .01), indicating that the sample subjects did not report as strong a belief in personal control over health matters as the normative subjects did (see Table 3).
Table 3
Comparison of Sample and Normative Data Scores for Variables

<table>
<thead>
<tr>
<th></th>
<th>Sample</th>
<th>Norms</th>
<th>Z-Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHLC</td>
<td>Mean</td>
<td>20.150</td>
<td>25.104</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>(4.591)</td>
<td>(4.891)</td>
</tr>
<tr>
<td>CHLC</td>
<td>Mean</td>
<td>18.300</td>
<td>15.574</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>(6.650)</td>
<td>(5.751)</td>
</tr>
<tr>
<td>PHLC</td>
<td>Mean</td>
<td>25.300</td>
<td>19.991</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>(6.350)</td>
<td>(5.221)</td>
</tr>
<tr>
<td>DC</td>
<td>Mean</td>
<td>88.150</td>
<td>97.3</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>(13.739)</td>
<td>(11.64)</td>
</tr>
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<td>POMS</td>
<td>Mean</td>
<td>4.368</td>
<td>10.43</td>
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<tr>
<td></td>
<td>SD</td>
<td>(5.861)</td>
<td>(8.87 )</td>
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</table>

IHLC = Internal Health Locus of Control
CHLC = Chance Health Locus of Control
PHLC = Powerful Others Health Locus of Control
DC = Desirability of Control
POMS = Profile of Mood States

**Chance Health Locus of Control.**

The CHLC scores ranged from 7 to 30 with a mean of 18.300 (sd = 6.650). Only one patient in this sample reported a definite chance health locus of control. The normative data reported by Wallston and Wallston (1978) yielded a mean of 15.574 (sd = 5.751). A significant
difference was found between the sample and the normative mean (z = -2.067, p < .05), indicating that the sample subjects reported a stronger belief that health matters are controlled by chance or luck (see Table 3).

**Powerful Others Health Locus of Control.**

Subjects' scores on the PHLC scale ranged from 11 - 36 with a mean of 25.300 (sd = 6.35). In this sample, 16 patients reported a belief in the control of powerful others over health matters. The normative mean, as reported by Wallston and Wallston (1978) was 19.991 (sd = 5.221). A significant difference was found between the sample and the normative mean (z = -4.432, p< .01), indicating that the sample subjects did indeed report a stronger belief in the control of powerful others over their health (see Table 3).

**Desirability of Control**

Subjects' scores on the Desirability of Control Scale (DC) ranged from 63 - 111 with a mean of 88.150 (sd = 13.739). Scores were divided into high Desirability of Control and low Desirability of Control using the median (84) as a cutoff point. By this criteria, 11 patients were low on Desirability of Control and 9 were high on this measure. The normative data of 453 college students reported by Burger and Cooper (1979) yielded a mean of 97.3 (sd = 11.64). A z-test indicated that the sample subjects desired significantly less control over the events in their lives.
than did the normative subjects ($z = 3.427, p < .01$) (see Table 3).

Profile of Mood States

The Profile of Mood States (POMS) scores ranged from 0 - 19 (n=19). POMS scale data from one subject was excluded from the analysis because of failure to respond to more than 10% of the adjectives. The mean score on the POMS was 4.368 (sd = 5.861). Cella et al. (1987) reported that the mean of the normative sample of 619 cancer patients was 10.43 (sd = 8.87). A significant difference was found between the sample and the normative mean ($z = 2.979, p < .01$), indicating that the sample subjects experienced less mood disturbance than the normative subjects (see Table 3).

The visual analog scale asking about overall enjoyment of life during the past week was broken into 7 equal parts for ease of analysis, where 1 represented no enjoyment and 7 represented excellent enjoyment. For those who completed this scale, the mean score was 5.467 (sd = 1.356). Five subjects (25%) did not complete this scale and so it was not used for any further analysis. It appeared that some subjects had difficulty understanding the concept of the visual analog scale for there were several questions about it and with the exception of one subject’s POMS, it was the only scale not fully completed by subjects.
Functional Living Index - Cancer

Each subject completed the Functional Living Index - Cancer (FLIC) four times over the course of the study. Scores on the FLIC could range from 22 - 154 with higher scores indicating higher quality of life. Schipper et al. (1984) reported mean scores ranging from 106 - 143 with some subjects tested in Winnipeg and others in Edmonton. Mean total scores for this sample remained stable over time, ranging from a low of 131.950 (sd = 13.165) at Time 1 to a high of 134.650 (sd = 14.394) at Time 3 (see Table 4). Paired t-tests conducted on the data confirmed that none of the differences in mean FLIC scores was significant (see Appendix M). The overall mean FLIC score was 133.363 (sd = 13.274).

A recent study conducted at the same Cancer Centre yielded an overall mean FLIC score of 111.413 (Straw, Sellick & Sellick, 1990). It is worth noting that this mean is lower than that of the present study. The sample in the Straw, Sellick and Sellick (1990) study consisted of patients who had just begun toxic chemotherapy, while the subjects in the present study were generally well. This fact alone could account for the difference in mean FLIC scores between these samples.

Patients' Impressions of TBRCC

The 100 mm visual analog scale was divided into seven equal
Table 4  
Mean FLIC Scores

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<th>Mean</th>
<th>Standard Deviation</th>
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<tr>
<td>Time 1</td>
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<td>13.165</td>
</tr>
<tr>
<td>Time 2</td>
<td>133.750</td>
<td>12.657</td>
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<tr>
<td>Time 3</td>
<td>134.650</td>
<td>14.394</td>
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<tr>
<td>Time 4</td>
<td>133.100</td>
<td>17.752</td>
</tr>
<tr>
<td>Total</td>
<td>133.363</td>
<td>13.274</td>
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</table>

parts for ease of analysis, with lower numbers indicating low overall satisfaction with the cancer centre. Scores ranged from 5 - 7 with a mean of 6.850 (sd = .489). It is interesting to note that 90% (n = 18) of the subjects reported very high satisfaction with the centre (indicated by a rating of 7).

Ten statements on the Patients’ Impressions Scale dealt with impressions of and satisfaction with the centre. Scores could range from 10 - 70, with higher scores indicating more positive impressions. For this sample, scores ranged from 64 - 70 with a mean of 68.10 (sd = 2.024). Eight subjects (40%) received 70 - the highest possible score on this scale.
The remaining two statements on the Patients' Impressions Scale evaluated the general nature of the physician-patient relationship (participatory or directive). There was a full range of responses (i.e. 1-7) on both these questions. For the participatory question (i.e. the physicians encouraged me to participate in the decision about what treatment would be best for me), the mean score was 6.10 (sd = 1.832). For the directive question (i.e. the physicians decided what treatment would be best for me and expected me to follow their advice), the mean score was 5.300 (sd = 2.364).

These two questions were correlated to determine whether they adequately discriminated between these two methods of interacting. The results suggested that those who indicated that their patient-physician relationship was participatory did not endorse the statement suggesting that the physician was directive in his/her dealings with them. However, this result did not reach statistical significance (r = -.3232, p = .165). In taking a closer look at the data, it was found that only 40% (n = 8) of the subjects' relationships with physicians fit neatly into one type of relationship or the other. Six subjects (30%) indicated that they were in a participatory relationship with the physicians at the centre (evidenced by a high score on the participatory question and a low score on the directive question), while two subjects (10%) indicated that they were in a
directive relationship with the physicians. The remaining 60% 
(n = 12) endorsed both statements as representative of their patient 
physician relationship (n = 9), or endorsed one and were unsure about 
the other (n = 3). This is evidence for the fact that the relationship 
between patient and physician is a complex one. It is possible that the 
physician’s manner is participatory at some points and directive at other 
points -- making the general nature of his/her practice difficult to 
determine.

Diary Versus Non-Diary

T-tests were conducted to determine whether the group 
completing the medication diary differed from the control group on any of 
the variables. None of these tests yielded significant results (see Table 
5), indicating that notwithstanding the effects of completing the diary, the 
two groups were not different.

Relationships Among Independent Variables

Correlations.

Correlations were calculated between all independent variables to 
identify any significant relationships (see Table 6).

Age did not correlate significantly with any of the variables in 
question. This indicates that knowing a patient’s age will not help one to 
predict with any certainty what her score will be on the other variables.
### Table 5

**T-tests of Group (Diary vs Non-Diary) by Independent Variables.**

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<thead>
<tr>
<th>Variable</th>
<th>T-test</th>
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<tr>
<td>Age</td>
<td>t = -1.58, p = .133</td>
</tr>
<tr>
<td>Months Since First Treatment</td>
<td>t = .70, p = .499</td>
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<tr>
<td>Present Status</td>
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<tr>
<td>ECOG Rating</td>
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<tr>
<td>Patient Compliance Prediction</td>
<td>t = .20, p = .845</td>
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<tr>
<td>Oncologist Compliance Prediction</td>
<td>t = -.33, p = .747</td>
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<tr>
<td>Internal Health Locus of Control</td>
<td>t = .83, p = .420</td>
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<tr>
<td>Chance Health Locus of Control</td>
<td>t = -.11, p = .915</td>
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<tr>
<td>Powerful Others Health Locus of Control</td>
<td>t = -.82, p = .422</td>
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<tr>
<td>Desirability of Control</td>
<td>t = -.49, p = .634</td>
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<tr>
<td>Profile of Mood States</td>
<td>t = -.16, p = .873</td>
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<tr>
<td>Functional Living Index - Cancer</td>
<td>t = 3.51, p = .148</td>
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<tr>
<td>Participatory</td>
<td>t = 1.85, p = .081</td>
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<tr>
<td>Directive</td>
<td>t = -1.28, p = .218</td>
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<tr>
<td>Patients' Impressions</td>
<td>t = .25, p = .807</td>
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<tr>
<td>Patients' Satisfaction</td>
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</table>

* = the non-diary group all gave a rating of 7 for this question. Since there was no variance for this group, a t-test could not be performed.
Table 6

Correlations of Independent Variables

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<th>ECOG</th>
<th>PTCPM</th>
<th>OCMP</th>
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<th>POMS</th>
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</table>

* = statistically significant, p < .05
** = statistically significant, p < .01
*** = statistically significant, p < .001
Patients' prediction of compliance (or anticipated difficulty with the regimen) did not correlate significantly with any of the other independent variables. Of particular interest, patients' predictions of their compliance and oncologists' predictions of patients' compliance did not appear to be related ($r = .1797, p = .448$).

There was a tentative, although nonsignificant, relationship between patients' predictions of compliance and a directive patient-physician relationship ($r = -.3999, p = .081$). The negative correlation may appear to suggest that lower predictions of compliance and directive relationships are somewhat related but the wording of the difficulty scale was such that higher scores would indicate a greater likelihood of non-compliance. Thus, these results indicate that there is a nonsignificant tendency for those patients who report a strongly directive patient-physician relationship to predict higher levels of compliance. On the other hand, patients' predictions of their compliance and participatory patient-physician relationships do not appear to be related ($r = .0175, p = .942$).

Months since first treatment was most strongly correlated with oncologists' prediction of compliance ($r = -.7098, p < .001$). It appears that the longer it had been since the patient was first prescribed Tamoxifen, the lower the oncologists' prediction of compliance was. This
is especially interesting since patients' predictions of their own compliance were not significantly related to months since first treatment ($r = -.3463, p = .135$). It would seem that oncologists may be basing their estimation of patients' likely compliance rate on a factor that patients themselves do not feel is important.

There was a significant correlation between Internal Health Locus of Control (IHLC) and months since first treatment ($r = .4969, p < .05$). Those subjects who reported an internal locus of control also tended to have been on Tamoxifen for a longer period of time. Perhaps having the opportunity to become more involved in one's treatment by taking Tamoxifen increases the belief one has in one's own control over health matters. Or perhaps those patients high in IHLC are more likely to stay on the regimen for an extended period of time.

Given the significant positive correlation between IHLC and months since first treatment, a negative correlation might be expected between months since first treatment and the other locus of control scales (Chance and Powerful Others) which tap into external locus of control. These correlations are negative but the relationships do not reach statistical significance ($r = -.3262, p = .160$ [Chance] and $r = -.2874, p = .219$ [Powerful Others]).

Chance Health Locus of Control (CHLC) correlated significantly
with ECOG rating \( (r = -0.6761, p < .01) \) indicating that those who attribute control in health matters to chance factors tend to show higher levels of physical functioning. This is an interesting result which is somewhat puzzling at first glance. However, the source of the relationship will become more clear when the results of the t-tests for present status are presented.

The CHLC and PHLC scales were significantly correlated \( (r = .4751, p < .05) \) as would be expected since they both represent measures of external locus of control.

As has already been noted, a negative correlation would be expected between the participatory and directive relationship questions to confirm that these questions are evaluating distinct contrasting styles of interacting. Although a negative correlation is found between these two questions, the relationship does not reach statistical significance \( (r = -0.3232, p = .165) \). Perhaps with more questions to evaluate the patient-physician relationship and more subjects, a clearer result will be found.

There was a tentative, though not statistically significant relationship between ECOG rating and directive patient-physician relationships \( (r = .3975, p = .083) \). There does not appear to be any relationship between ECOG rating and participatory relationships \( (r = -0.0302, p = .900) \).
Patients reporting a higher quality of life on the FLIC tended to report a participatory relationship with physicians \((r = .6135, p < .01)\). This is a fascinating finding. It may be that patients whose quality of life is high and who are not actively ill are more likely to take an active part in their relationship with their oncologist. It may also be that physicians feel more comfortable acting in a participatory manner with patients whose quality of life is high. On the other hand, those who had a directive relationship with physicians did not report a significantly lower quality of life, though there was a nonsignificant tendency in that direction \((r = - .4028, p = .078)\). This (FLIC and participatory) was the only statistically significant correlation involving either the participatory or the directive variables. As has already been mentioned, some relationships do approach significance. Therefore, rather than concluding that patient-physician interaction is not related to these variables, it is suggested that better measures of the interaction be developed so that more information can be gleaned.

Neither the Profile of Mood States nor the Desirability of Control Scale correlated significantly with any of the other independent variables (see Table 6). In terms of Desirability of Control, the strongest suggestion of a relationship involves that measure and quality of life \((r = .3829, p = .096)\).
Neither the Patients' Impressions Scale nor the Patients' Satisfaction Visual Analog Scale correlated significantly with any of the other variables. Scores on both these variables were very high, with little variance. In addition to the fact that highly satisfied patients with favourable impressions of the Cancer Centre might be more likely to participate in a study such as this, patients may not have been comfortable expressing even slightly negative opinions. Perhaps more work could be done to develop more subtle items.

**T-Tests of Present Status.**

T-tests were conducted to determine whether disease-free patients differed from patients with a recurrence or metastatic disease on any of the variables (see Table 7).

The t-test of present status by age yielded significant results \( t = 3.27, p < .05 \). This indicates that two present status groups significantly differed on this variable.

These two groups also differed on CHLC \( t = 2.15, p < .05 \). Given that we know that CHLC was significantly correlated with ECOG rating, we can infer that those patients who are free of disease and are thus likely to be high on physical functioning, tend to attribute control in health matters to chance factors.

Finally, the t-test comparing the present status groups on
Table 7

<table>
<thead>
<tr>
<th>Variable</th>
<th>T-Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>* $t = 3.27$, $p &lt; .05$</td>
</tr>
<tr>
<td>Months Since First Treatment</td>
<td>$t = -1.67$, $p = .112$</td>
</tr>
<tr>
<td>ECOG Rating</td>
<td>* $t = 2.02$, $p = .059$</td>
</tr>
<tr>
<td>Patient Compliance Prediction</td>
<td>$t = -1.02$, $p = .387$</td>
</tr>
<tr>
<td>Oncologist Compliance Prediction</td>
<td>$t = 2.15$, $p &lt; .05$</td>
</tr>
<tr>
<td>Internal Health Locus of Control</td>
<td></td>
</tr>
<tr>
<td>Chance Health Locus of Control</td>
<td></td>
</tr>
<tr>
<td>Powerful Others Health Locus of Control</td>
<td></td>
</tr>
<tr>
<td>Locus of Control</td>
<td>$t = .76$, $p = .519$</td>
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<tr>
<td>Desirability of Control</td>
<td>$t = .32$, $p = .777$</td>
</tr>
<tr>
<td>Profile of Mood States</td>
<td>$t = .98$, $p = .342$</td>
</tr>
<tr>
<td>Functional Living Index - Cancer</td>
<td>$t = .18$, $p = .864$</td>
</tr>
<tr>
<td>Participatory Directive</td>
<td>$t = .11$, $p = .922$</td>
</tr>
<tr>
<td>Patients' Impressions</td>
<td>$t = -.95$, $p = .412$</td>
</tr>
<tr>
<td>Patients' Satisfaction</td>
<td>!</td>
</tr>
</tbody>
</table>

* = statistically significant

! = All members of the recurrence/metastatic group gave the same rating on these variables. Since there was no variance for this group, a t-test could not be performed.
oncologist compliance ratings revealed a difference that approaches significance ($t = 2.02, p = .059$). Perhaps with a larger sample, especially a larger group of recurrence/metastatic patients, the results would be more definitive.

**Pill Count Relationships**

The mean pill count for the non-diary group was 90.0 (sd = 22.853, n = 9), while for the diary group it was 85.636 (sd = 21.906, n = 11). It is important to note that the two groups are unequal in size. This is because the two subjects whose data had to be excluded because of not bringing the medication to the meetings were both originally assigned to the non-diary group. A t-test conducted on these groups revealed that the means are not significantly different ($t = .43, p = .671$).

In spite of this non-significant result, the data was examined more closely. In particular, two interesting observations were examined. First, six of the observations making up the data indicated that more than 150% of the medication was ingested (i.e. if according to the prescription it was expected that the patient would take 10 tablets, at least 15 would be "missing" at the next meeting). This could have had the effect of distorting one or both of the means. However, the six observations were equally distributed among the two groups, eliminating
this as the cause of a difference between the groups.

Secondly, subjects sometimes forgot to bring the medication to the meetings with the investigator. It appeared that this phenomenon occurred more often among subjects in the non-diary group than among those in the diary group. A chi-square test revealed however that this did not happen significantly more often in the non-diary group ($\chi^2 = 1.014, p > .05$). Interestingly, when data for the two subjects who did not bring the pills to any of the meetings with the investigator were entered into the equation, the chi-square was significant and the non-diary group then appeared to be less compliant in bringing medication to the meetings ($\chi^2 = 6.471, p < .02$).

After investigation of the possible effects of group, correlations were calculated between the average pill count and all other independent measures to identify any significant relationships (see Table 8).

Only one correlation proved to be statistically significant. This was between compliance and age ($r = .5042, p < .05$). Older women tended to be more compliant than younger women. This may be related to socialization issues - perhaps older women were taught more than their younger counterparts to view physicians as powerful and all-knowing. Or it may be that older women see themselves as more vulnerable and thus are more likely to comply with physician's recommendations.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>$r = .5042, p &lt; .05 *$</td>
</tr>
<tr>
<td>Months Since First Treatment</td>
<td>$r = .1956, p = .409$</td>
</tr>
<tr>
<td>Patient Compliance Prediction</td>
<td>$r = -.0022, p = .993$</td>
</tr>
<tr>
<td>Oncologist Compliance Prediction</td>
<td>$r = .0576, p = .809$</td>
</tr>
<tr>
<td>Internal Health Locus of Control</td>
<td>$r = -.1394, p = .558$</td>
</tr>
<tr>
<td>Chance Health Locus of Control</td>
<td>$r = -.0350, p = .884$</td>
</tr>
<tr>
<td>Powerful Others Health Locus of Control</td>
<td>$r = -.2009, p = .396$</td>
</tr>
<tr>
<td>Patients' Impressions</td>
<td>$r = .1557, p = .512$</td>
</tr>
<tr>
<td>Patients' Satisfaction</td>
<td>$r = -.1733, p = .465$</td>
</tr>
<tr>
<td>Participatory</td>
<td>$r = -.0358, p = .881$</td>
</tr>
<tr>
<td>Directive</td>
<td>$r = -.1280, p = .591$</td>
</tr>
<tr>
<td>Functional Living Index - Cancer (FLIC)</td>
<td>$r = .1878, p = .428$</td>
</tr>
<tr>
<td>Desirability of Control</td>
<td>$r = .2751, p = .240$</td>
</tr>
<tr>
<td>Profile of Mood States</td>
<td>$r = .0016, p = .995$</td>
</tr>
<tr>
<td>ECOG Rating</td>
<td>$r = -.3652, p = .113$</td>
</tr>
</tbody>
</table>

* = statistically significant
Patients' prediction of compliance and pill count yielded a correlation of -.0022, p = .993. It appears that the degree to which one expects to comply with the regimen and actual compliance are not related.

Oncologists' prediction of compliance was also not significantly related to actual pill count (r = .0576, p = .809). In other words, the degree to which the patient follows the medication regimen and the degree to which the physician expects the patient will follow the regimen are not necessarily the same.

Compliance was not significantly related to either participatory or directive patient-physician relationships (r = -.0358, p = .881 and r = -.1280, p = .591, respectively). This may be due to the questions used to measure these relationship variables. A more comprehensive measure of patient-physician relationship may reveal more about the impact of this important interaction on compliance.

Compliance was also not significantly related to scores on the Patients' Impressions Scale or the Patients' Satisfaction Scale (r = .1557, p = .512 and r = -.1733, p = .465, respectively). Again however, scores on these variables were very high with little variance. Better scales and a larger sample size may yield clearer results.

Finally, compliance was not found to be related to any of the other
variables of POMS, IHLC, CHLC, PHLC, or FLIC (see Table 8).

**Regression Analyses**

When all the variables (pill count, age, group, patient compliance prediction, oncologist compliance prediction, months since first treatment, IHLC, CHLC, PHLC, patients' impressions, patients' satisfaction, directive relationship, participatory relationship, FLIC, DC, POMS, present status and ECOG rating) were entered for a stepwise multiple regression analysis with pill count as the dependent variable, age was the only variable entered into the equation \(F(1,18) = 6.13, p < .05\), explaining 25.42% of the variance. This indicates that patient's age was the single best predictor of compliance in our study (see Appendix N).

Another stepwise multiple regression analysis (with the same variables entered as above) was performed to determine what variables, if any, predicted oncologists' compliance prediction. Months since first treatment emerged as the single best predictor of oncologists' compliance prediction, explaining 50.38% of the variance \(F(1,180) = 18.28, p < .001\) (see Appendix O).

**Locus of Control, Desirability of Control and Relationship**

It was hypothesized that locus of control, desirability of control and patient-physician relationship would interact and affect compliance. This
hypothesis could not be evaluated however because of the small cell size (see Table 9). For example, only one subject reported an internal locus of control, a high desire for control and a participatory patient-physician relationship. Similarly, only 1 subject reported an internal locus of control, a high desire for control and a directive patient-physician relationship. A further study using a larger sample size may be better able to answer the question of the effect of this interaction on compliance.

Table 9
Cell Size for Interaction of Locus of Control, Desirability of Control and Patient-Physician Relationship

<table>
<thead>
<tr>
<th></th>
<th>Participatory</th>
<th></th>
<th>Directive</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low DC</td>
<td>High DC</td>
<td>Low DC</td>
<td>High DC</td>
</tr>
<tr>
<td>IHLC</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>CHLC</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>PHLC</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Compliance to Study

In general, subjects were highly compliant in completing the
experimental tasks assigned to them. Considering both the pill count observations and the questionnaire data, there was a total of 4980 data points (249 for each subject). Out of this entire pool, 4956 scores or observations (99.5%) were collected. For the pill count data alone, 65 out of a possible 80 observations were collected (81.25%).
Discussion

Compliance to medication regimens could very well be the factor which turns the tide away from illness and toward health for many individuals. With our increasing medical knowledge and the fact that cancer is now considered a chronic illness and not necessarily a "death sentence", this is as true in the care of cancer patients as it is in other types of illness. In addition, compliance can reduce the need for more extensive treatment and thus can save health care dollars.

This study assessed one aspect of the issue of compliance in breast cancer patients. It provided some interesting results, and though the small sample size renders the results tentative, it has some implications for future research in this area.

Diary versus Non-Diary

The findings of this study did not support the hypothesis of increased compliance in those patients who kept a medication diary over those without such a diary. However, it is important to note that those patients in the non-diary group ‘forgot’ to bring the medication to the meetings with the investigator significantly more often than did those in the diary group. In fact, the data from two members of the non-diary group had to be excluded from analysis because these subjects failed to bring the medication to any of the meetings. Thus, although rate of
compliance according to pill count did not significantly differ across the groups, subjects completing the diary appeared to be more compliant in bringing the medication to the meetings.

The medication diary then may have helped to remind subjects that they had been asked to bring the medication to the meetings (a new request that one might say had been temporarily added to the regimen), though it may not have helped subjects to remember to take their medication on a daily basis. Perhaps the diary would have been beneficial when the patient was first beginning the regimen to help her to incorporate it into her everyday life. Further, the regimen in this case is quite simple - it requires only that the patient take one pill once a day. Perhaps a diary would be more helpful in more complex regimens.

The medication diary also may have inadvertently informed patients as to the purpose of the study. If so, subjects may have been more careful to comply with the investigator's requests because they believed that this was being monitored. It would be interesting to conduct a study in which the subjects were told the true purpose and that their pills would be counted. This would provide clearer evidence of the impact of such knowledge and would remove this variable from potentially confounding the differences between the Diary and Non-diary groups. Perhaps we would find that in this case, patients are able to get
past self-presentation needs and that concealing the purpose of the study is unnecessary. It is also possible that we would find exactly the opposite. This would still provide important knowledge for it would lend empirical support to a difficult ethical decision.

It may also be that the subjects in the sample do not benefit from the medication diary because they are, as a group, more compliant than the general population. Compliance in this case refers to accepting and following the advice of a physician. Perhaps those patients who are more likely to agree to follow a medication regimen are also more likely to agree to participate in a study such as this.

Further, someone having trouble with the medication regimen might not be likely to participate in a study such as this because she may feel that she has enough to deal with in coping with and adapting to the regimen. She may also not want her problems with the regimen brought to light for fear she will be judged negatively. Unfortunately, it is one of the inherent difficulties in research such as this that those who agree to participate may not be those who could benefit most from the study.

In addition, the lack of a significant difference between the groups may be at least partly attributable to the measure of compliance which was used. Pill counting has its own limitations, one of which is that
though the pills may not be in the bottle you see before you, that does not necessarily mean the patient has ingested them. On six occasions (out of 60 possible post-baseline observations), the pill count indicated that more than 150% of the medication was ingested. At one point it appeared that a patient had consumed three times the prescribed dosage. Though this may have been the case, the missing medication may also have been transferred to another bottle. Still, these extremely noncompliant counts could have masked a true difference between the groups.

Finally, the lack of a significant difference between the groups may be due to the small sample size. Perhaps studying more people would bring differences to light.

Patients' and Oncologists' Predictions of Compliance

It was hypothesized that patients' predictions about their rate of compliance would accurately reflect their actual compliance while oncologists' predictions would not be as accurate.

This hypothesis was only partly supported. As expected, it was found that oncologists' predictions of compliance did not predict the actual compliance which was exhibited. Many studies have demonstrated that physicians overestimate the degree of compliance exhibited by patients (e.g. Roth & Caron, 1978). In this case however it
seems that oncologists' predictions of compliance slightly underestimate actual compliance. Perhaps knowledge of the extent of noncompliance has prompted physicians to be more conservative in their estimates. Further, it may be that the intense relationship between an oncologist and his/her patient has allowed the patient and physician to develop a deeper relationship than is likely between a patient and a general practitioner. Though oncologists are admittedly not accurate in their estimations of patient compliance, the particular relationship which can develop between a patient and an oncologist might have reduced the likelihood of the oncologists' overestimating compliance.

Contrary to the hypothesis, patients' predictions of compliance are not related to actual pill count. It is possible that we did not ask the correct question; that in our efforts to assess anticipation of compliance without 'suggesting' the 'correct' answer to the patient, we presented a rather vague question. Subjects may have interpreted the question differently than intended. Perhaps rather than looking to the future and anticipating problems which may arise, they looked to the past and evaluated what problems they may have had following previous treatments. If this is what happened, it would not be surprising that patients' ratings were not related to compliance. In addition to the possibility of forgetting past incidents of noncompliance, Sheiner et al.
(1974) reported that patients commenting on past behaviour may not admit to noncompliance because they do not wish to portray themselves negatively.

More work needs to be done to discover an appropriate way of assessing the anticipation of patients' own degree of compliance. It may be that the ratings would be more accurate and successful if the investigator is completely open and let patients know that it is future compliance the investigator is concerned with. Otherwise the investigator is faced with the difficult task of developing a question whose answer predicts compliance without influencing the response by telling the subject directly that we are interested in how closely they adhere to the regimen.

**Duration of Treatment**

It has been found that compliance decreases as duration of treatment increases (Berger et al., 1988). This does not appear to be so in this study. Those who have been on the medication for an extended period of time are just as likely to comply as those who have just begun Tamoxifen therapy.

Again the complexity of the regimen may be a factor here. Taking one tablet once a day is an easy task to fit into one's schedule. Perhaps if the task was more complicated or difficult to perform, or was time
consuming, compliance would wane over time. Further, the regimen in this case does not require long term lifestyle changes. It is known that adherence to recommended lifestyle changes (e.g. dietary regimens) is low (Sackett & Snow, 1979; Dunbar & Stunkard, 1979). If the regimen of interest required such a change in lifestyle, perhaps a decline in compliance over time would be more likely.

Profile of Mood States

It was hypothesized that those patients showing signs of mood disturbance (as assessed by the POMS) would be less compliant to the medication regimen. This hypothesis was not supported, but the reason for this is evident. The sample as a whole reported very little mood disturbance. In fact, the sample reported significantly less mood disturbance than the normative sample of cancer patients. If mood disturbance was evident, it may alter compliance but since it does not appear to be a factor for this group of subjects, it can hardly be expected to affect their compliance.

Perception of and Satisfaction with the Cancer Centre

Patients who feel disappointed or dissatisfied when leaving a clinic have been found to be less likely to follow advice or take prescriptions as required (Bradshaw & Ley, 1975). In light of this, it was expected that those subjects reporting positive impressions of the Cancer Centre
and/or reporting overall satisfaction with the Centre would be compliant. This hypothesis was not supported by the results. As has already been discussed however, scores on these variables were quite high with little variance. Better measures of these variables need to be developed before conclusions can be drawn.

Quality of Life

It was expected that patients reporting a higher quality of life (and thus fewer illness symptoms) would be more likely to forget to take their medication or to feel that it is not necessary to strictly adhere to the regimen. Further, it was hypothesized that as quality of life fluctuated over the course of the study, so too would compliance fluctuate.

Contrary to these hypotheses, score on the FLIC did not predict the compliance of these women. However, scores were generally quite high, with a mean of 133.363. This indicates that as a group, these women felt that the quality of their lives was quite good. Since this sample did not include people who felt the quality of their lives was low, we cannot expect to find differences based on low versus high quality of life.

Further, scores on the FLIC remained consistently high over the course of the study. Obviously, the lack of change in quality of life removes the possibility of a change in compliance based on a fluctuation
Several subjects commented that they felt some of the questions on the FLIC did not apply to them since it had been some time since their original diagnosis and treatment (e.g. questions concerning nausea). Perhaps for those women who have just been diagnosed, compliance would be more closely linked with quality of life measured by the FLIC. That certain questions were not applicable to this sample also emphasizes the importance of designing quality of life measures for different times across the lifespan of an illness.

Locus of Control, Desirability of Control and Relationship

People who reported an internal locus of control and who had a high desire for control were expected to be more compliant if their relationships with their oncologists allowed for this internal/high desire control, than similar patients whose relationships with their oncologists did not allow for such control. Similarly, patients reporting an external locus of control and little desire for control were expected to be more compliant if their relationships with their oncologists were directive, than similar patients whose relationships with their oncologists allowed patients considerable control.

Unfortunately, there were insufficient numbers of subjects in this study to adequately evaluate this complicated hypothesis. However,
some comments can be made on the individual components of the hypothesis.

**Locus of Control**

None of the three scales of locus of control (internal, chance and powerful others) were significantly related to compliance. However, this should not necessarily be taken to mean that such a link does not exist. Most patients in this sample attributed control in health matters to Powerful Others.

Mahon, Sellick and Sellick (1991) reported similar results. Several of their subjects reported a Powerful Others Health Locus of Control. Further, they found that in anticipation of Cancer Centre follow-up appointments, those patients who believed powerful others controlled their health experienced lower levels of stress and dreaded the visit less than those attributing control to other factors. Considering that the physician may be the "Powerful Other", thinking this way could lead to reduced stress and dread because the visit would mean being monitored by the person who has the power and the ability to make and keep them well. It may be that those patients who have been or are seriously ill are more likely to attribute control to a "Powerful Other". A study conducted with a larger sample size may yield sufficient numbers for each type of locus of control to illustrate what, if any, effect this variable has.
Desirability of Control

Since following a prescribed medication regimen can be interpreted as a way the individual can take some control over her health, it would have been expected that increased desirability of control would lead to increased compliance. This hypothesis was only tentatively supported. However, desirability of control for these subjects was generally low and the mean was significantly lower than the normative mean. The low desirability of control demonstrated in this study is consisted with the results of Mahon, Sellick and Sellick (1991) who found low desirability of control in a sample of cancer patients with a mean age of 60.6 years. It is known that desirability of control decreases with age (Sarafino, 1990) and so a lower desirability of control in the present sample whose mean age is 60.3 years compared to a sample of college students (Burger & Cooper, 1979) is not remarkable. Perhaps younger subjects' compliance would show a greater variance according to desirability of control.

Patient-Physician Relationship

The questions asked in this study to determine the nature of the patient-physician relationship did not seem to adequately discriminate whether the relationship was generally participatory or directive. This provides evidence for the fact that the relationship between patient and
physician is a complex one. It is possible that the physician's manner is participatory sometimes and directive at other times -- making the general nature of his/her practice difficult to determine. The nature of his/her practice may vary in accordance with what the physician discerns to be what the patient is in need of (e.g. given the stage of the illness or the patient's emotional state) as much as it varies in accordance to what the physician needs to offer.

More work needs to be done to develop a scale which adequately evaluates the intricacies of the patient-physician relationship.

Limitations and Suggestions for Future Research

While the greatest limitation of this study may be its small sample size, the results do provide us with some clearer ideas on what questions to ask in an extension of this research.

Although no specific hypothesis was formulated in regard to patients' age, it was found that patients' age was significantly related to compliance in that older women were more compliant than younger women. This may be a very important finding and may provide indications for clinical application. It may be that older women perceive themselves as more vulnerable to a recurrence and thus are more likely to comply with the regimen. Conversely, younger women may perceive themselves as less vulnerable either because of the feeling of invincibility
which often accompanies youth or because to take the drug would be to admit the possibility of further illness and perhaps death. This reality may be so painful to deal with that young women cope by denying its existence and not complying with the medication regimen. In either case, these results should be further investigated to find out the true nature of the difference. In the meantime, physicians should be encouraged to pay special attention to the needs of younger patients as a group who is at risk of noncompliance. Spending some extra time with these patients and educating them as to the specifics of their disease may be able to reduce their need for denial as a coping mechanism.

Suggestions for clinical application can also be gleaned from the results in that oncologists' tended to base their predictions about patients' compliance rates on the length of time which had passed since the patient first began Tamoxifen therapy. Not only are oncologists' predictions not reflective of actual compliance rates - duration of treatment is also not related to compliance rates. If oncologists were provided with this information, they may be able to change the assumptions they make about patient compliance and then may be able to judge the likely rate of adherence more accurately.

A significant relationship was found between quality of life and participatory patient-physician relationships in that patients who were
experiencing fewer illness symptoms tended to report having a participatory relationship with their oncologist. It may be that patients whose quality of life is high demand a more active part in the relationship, or that physicians feel more relaxed and more comfortable acting in a participatory manner with patients who are not actively ill, or a combination of these effects. More research needs to be conducted to expand upon these results and to discover the explanation for this relationship.

Also, better questions need to be developed which evaluate the nature of the patient-physician relationship. Using interviews may be one way of evaluating the relationship - both patient and physician could be approached to provide data on their interaction with each other. Only with a better way of determining the nature of the patient-physician interaction can we find out how the relationship affects compliance and how to best achieve a "match" between patient and physician that will maximize compliance.

It is possible that the present status of the subjects influenced the data and contributed to the negative results which were found. Eighty-five percent of the sample was disease-free, leaving only 15% who were actively waging a battle with cancer while data collection was taking place. It may be that patients who are experiencing a recurrence or
metastatic disease are less likely to comply with the regimen because they became ill again even after taking the drug. They may feel they have been let down by the medical advice and doubt its utility. Comparing larger equivalently sized group of disease-free and recurrence/metastatic disease patients would provide more information on the impact of this variable.

A question needs to be developed which will clearly ask for a prediction of future compliance. Directly asking the patients is one solution. Otherwise it would need to be worded so that it does not influence the answer by suggesting the "appropriate" response. This may sound like a simple task but to many people even suggesting problems or memory difficulties can bring on defensiveness. Thus, the question must be accepting of human frailties as well as neutral.

It would be interesting to study two distinctive groups -- one which has just been diagnosed and one that was diagnosed some time ago. This would allow us to better evaluate the effects of duration of treatment and the effects of quality of life and its fluctuations on compliance. A further investigation might also compare anticipated compliance among newly diagnosed patients and healthy people. Dr L. Degner working with the World Health Organization (1991) has been studying a similar issue and reports that patients generally do not behave as they had anticipated
they would.

The influence of locus of control and desirability of control on compliance should be further explored to determine whether these variables interact to affect compliance.

Finally, in the future the use of pill count as a measure of compliance should be supplemented with biological measures such as blood or urine analysis. This was not possible in this study because of lack of funding and the limitations of the local facilities and equipment. Though neither of these methods is without its problems, if they were used together one could have more confidence that the measure one is getting is accurate.
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Appendix A

Multidimensional Health Locus of Control Scales
Form A

This is a questionnaire designed to determine the way in which different people view certain important health-related issues. Each item is a belief statement with which you may agree or disagree. Each statement can be rated on a scale which ranges from strongly disagree (1) to strongly agree (6). For each item we would like you to record the number that represents the extent to which you disagree or agree with the statement. The more strongly you agree with a statement, then the higher will be the number you record. The more strongly you disagree with a statement, then the lower the number you record. Please make sure that you answer every item and that you record only one number per item. This is a measure of your personal beliefs; obviously, there are no right or wrong answers.

Please answer these items carefully, but do not spend too much time on any one item. As much as you can, try to respond to each item independently. When making your choice, do not be influenced by your previous choices. It is important that you respond according to your actual beliefs and not according to how you feel you should believe or how you think we want you to believe.
NAME: ________________________________  
DATE: ________________________________  

1 = Strongly disagree  
2 = Moderately disagree  
3 = Slightly disagree  
4 = Slightly agree  
5 = Moderately agree  
6 = Strongly agree  

--- 1. If I get sick, it is my own behaviour which determines how soon I get well again.  
--- 2. No matter what I do, if I am going to get sick, I will get sick.  
--- 3. Having regular contact with my physician is the best way for me to avoid illness.  
--- 4. Most things that affect my health happen to me by accident.  
--- 5. Whenever I don't feel well, I should consult a medically trained professional.  
--- 6. I am in control of my health.  
--- 7. My family has a lot to do with my becoming sick or staying healthy.  
--- 8. When I get sick, I am to blame.  
--- 9. Luck plays a big part in determining how soon I will recover from an illness.  
--- 11. My good health is largely a matter of good fortune.  
--- 12. The main thing which affects my health is what I myself do.  
--- 13. If I take care of myself, I can avoid illness.  
--- 14. When I recover from an illness, it's usually because other people (for example, doctors, nurses, family, friends) have been taking care of me.  
--- 15. No matter what I do, I'm likely to get sick.  
--- 16. If it's meant to be, I will stay healthy.  
--- 17. If I take the right actions, I can stay healthy.  
--- 18. Regarding my health, I can only do what my doctor tells me to do.
Appendix B

Desirability of Control Scale
BELOW YOU WILL FIND A SERIES OF STATEMENTS. PLEASE READ EACH STATEMENT CAREFULLY AND RESPOND TO IT BY EXPRESSING THE EXTENT TO WHICH YOU BELIEVE THE STATEMENT APPLIES TO YOU. FOR ALL ITEMS A RESPONSE FROM 1 TO 7 IS REQUIRED. CIRCLE THE NUMBER THAT BEST REFLECTS YOUR BELIEF WHEN THE SCALE IS DEFINED AS FOLLOWS:

1 = The statement *doesn't apply* to me at all.
2 = The statement *usually doesn't apply* to me.
3 = *Most often,* the statement does not apply.
4 = I am *unsure* about whether or not the statement applies to me, or it applies to me about *half the time.*
5 = The statement *applies more often than not.*
6 = The statement *usually applies* to me.
7 = The statement *always applies* to me.

I prefer a job where I have a lot of control over what I do and when I do it. ...... 1 2 3 4 5 6 7

I enjoy political participation because I want to have as much of a say in running government as possible. ...... 1 2 3 4 5 6 7

I try to avoid situations where someone else tells me what to do. ...... 1 2 3 4 5 6 7

I would prefer to be a leader rather than a follower. ...... 1 2 3 4 5 6 7

I enjoy being able to influence the actions of others. ...... 1 2 3 4 5 6 7

I am careful to check everything on an automobile before I leave for a long trip. ...... 1 2 3 4 5 6 7

Others usually know what is best for me. ...... 1 2 3 4 5 6 7

enjoy making my own decisions. ...... 1 2 3 4 5 6 7

enjoy having control over my own destiny. ...... 1 2 3 4 5 6 7

would rather someone else take over the leadership when I'm involved in a group project.
I consider myself to be generally more capable of handling situations than others are.

I'd rather run my own business and make my own mistakes than listen to someone else's orders.

I like to get a good idea of what a job is all about before I begin.

When I see a problem, I prefer to do something about it rather than sit by and let it continue.

When it comes to orders, I would rather give them than receive them.

I wish I could push many of life's daily decisions off on someone else.

When driving, I try to avoid putting myself in a situation where I could be hurt by someone else's mistake.

I prefer to avoid situations where someone else has to tell me what it is I should be doing.

There are many situations in which I would prefer only one choice rather than having to make a decision.

I like to wait and see if someone else is going to solve a problem so that I don't have to be bothered with it.
Appendix C

Profile of Mood States
PLEASE RATE YOUR **OVERALL ENJOYMENT OF LIFE** DURING THE PAST WEEK.

no enjoyment | | | | | excellent

BELOW IS A LIST OF WORDS THAT DESCRIBE FEELINGS PEOPLE HAVE. CIRCLE A NUMBER BESIDE EACH WORD TO DESCRIBE **HOW YOU ARE FEELING RIGHT NOW**.

<table>
<thead>
<tr>
<th>Not at all</th>
<th>A Little</th>
<th>Moderately</th>
<th>Quite a Bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Discouraged</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Sad</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Bewildered</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Miserable</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Gloomy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Weary</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>On Edge</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Muddled</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Uneasy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Unhappy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
Appendix D

Functional Living Index - Cancer
PLEASE TAKE A FEW MINUTES AND RESPOND TO EACH OF THE FOLLOWING QUESTIONS. THERE ARE NO RIGHT OR WRONG ANSWERS. SIMPLY CIRCLE THE NUMBER (1 - 7) THAT MOST ACCURATELY REFLECTS YOUR SITUATION.

1. Most people experience some feelings of depression at times. How often do you have these feelings?

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
---|---|---|---|---|---|---|---|
   | never | continually |

2. How well are you coping with your everyday stress?

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
---|---|---|---|---|---|---|---|
   | well | not well |

3. How much time do you spend thinking about your illness?

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
---|---|---|---|---|---|---|---|
   | constantly | never |

4. Rate your ability to maintain your usual recreation or leisure activities.

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
---|---|---|---|---|---|---|---|
   | able | unable |

5. Has nausea affected your daily functioning?

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
---|---|---|---|---|---|---|---|
   | not at all | a great deal |

6. How well do you feel today?

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
---|---|---|---|---|---|---|---|
   | extremely poor | extremely well |

Do you feel well enough to make a meal or do minor household repairs today?

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
---|---|---|---|---|---|---|---|
   | very able | not able |

Rate the degree to which you cancer has imposed a hardship on those closest to you in the past two weeks.

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
---|---|---|---|---|---|---|---|
   | tremendous hardship |

Rate how often you feel discouraged about your life.

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
---|---|---|---|---|---|---|---|
   | says |
10. Rate your satisfaction with your work and your jobs around the house in the past month.

1 2 3 4 5 6 7
very dissatisfied very satisfied

11. How uncomfortable do you feel today

1 2 3 4 5 6 7
not at all very uncomfortable

12. Rate, in your opinion, how disruptive your cancer has been to those closest to you in the past two weeks.

1 2 3 4 5 6 7
totally disruptive no disruption

13. How much is pain or discomfort interfering with your daily life?

1 2 3 4 5 6 7
not at all a great deal

14. Rate the degree to which your cancer has imposed a hardship on you, personally, in the past two weeks.

2 3 4 5 6 7
remarkable hardship no hardship

15. How much of your usual household tasks are you able to complete?

2 3 4 5 6 7
none

16. Rate how willing you were to see and spend time with those closest to you in the past two weeks.

2 3 4 5 6 7
willing very willing

17. How much nausea have you had in the past two weeks?

2 3 4 5 6 7
a great deal
18. Rate the degree by which you are frightened by the future.
1   2   3   4   5   6   7
constantly terrified

19. Rate how willing you were to see and spend time with friends in the past two weeks.
1   2   3   4   5   6   7
unwilling

20. How much of your pain or discomfort over the past two weeks was related to your cancer?
1   2   3   4   5   6   7
none

21. Rate your confidence in your prescribed course of treatment?
1   2   3   4   5   6   7
no confidence

22. How well do you appear today?
1   2   3   4   5   6   7
extremely poor

This questionnaire is known as the--
Functional Living Index: Cancer (FLIC-C)
and has been developed by Dr. Schipper of the--
Manitoba Cancer Treatment & Research Foundation
Appendix E

Difficulty Scale

People often report difficulty taking their medication (e.g. forgetting to take their pills). Using the following scale, please rate the degree to which you think that you may have difficulty taking (remembering to take) your medication.

0 = no problems
1 = few problems
2 = some problems
4 = many problems
Appendix F

Patients' Impressions of TBRCC Scale
PATIENT'S IMPRESSIONS OF THE
THUNDER BAY REGIONAL CANCER CENTRE

Please read the following statements carefully. This is not a test, for your responses merely reflect your opinions and experiences. All responses will remain strictly confidential.

Please note that some of the statements are worded positively and some are deliberately worded negatively so that you may express your opinions accurately.

Use the following scale when indicating the degree to which you agree with each statement. Please place the appropriate number on the line found next to each statement.

-3 strongly disagree
-2 moderately disagree
-1 mildly disagree
0 neither agree nor disagree
+1 mildly agree
+2 moderately agree
+3 strongly agree

PART A:

1. I was satisfied with the care I received at the Thunder Bay Regional Cancer Centre (TBRCC).

2. In general, during my visits at the TBRCC, the amount of time I spent waiting was unreasonable (i.e. waited too long for treatment, check-ups, blood-work, etc.).

3. I would recommend to others that they make use of the services available at the Thunder Bay Regional Cancer Centre.

4. In general, I was not pleased with my contact with the staff at the Thunder Bay Regional Cancer Centre.
**PART B:**

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>-3</td>
<td>Strongly disagree</td>
<td>1. I am satisfied with the relationship I had with the physicians.</td>
<td></td>
</tr>
<tr>
<td>-2</td>
<td>Moderately disagree</td>
<td>2. The physicians encouraged me to participate in the decision about what treatment would be best for me.</td>
<td></td>
</tr>
<tr>
<td>-1</td>
<td>Mildly disagree</td>
<td>3. I am satisfied with the relationship I had with the nurses.</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>Neither agree nor disagree</td>
<td>4. The physicians were not able to answer my questions to my satisfaction.</td>
<td></td>
</tr>
<tr>
<td>+1</td>
<td>Mildly agree</td>
<td>5. In my dealings with the nurses I felt free to express myself and ask questions.</td>
<td></td>
</tr>
<tr>
<td>+2</td>
<td>Moderately agree</td>
<td>6. The physicians decided what treatment would be best for me and expected me to follow their advice.</td>
<td></td>
</tr>
<tr>
<td>+3</td>
<td>Strongly agree</td>
<td>7. The nurses were not able to answer my questions to my satisfaction.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>8. In my dealings with the physicians I felt free to express myself and ask questions.</td>
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</tbody>
</table>

**LEASE INDICATE YOUR OVERALL SATISFACTION WITH THE CARE YOU RECEIVED**

[Scale from extremely dissatisfied to extremely satisfied]

(please place a mark along the line that reflects your degree of satisfaction)
Appendix G

Patient Information Sheet
TO BE COMPLETED BY MEDICAL ONCOLOGIST

PATIENT HAS SIGNED CONSENT FORM:  YES ___  NO ___

NAME: _______________________________________________________

DIAGNOSIS: ___________________________________________________

PRESENT STATUS: _______________________________________________

ECOG PERFORMANCE SCORE:

[ ] [ ] [ ] [ ] [ ]

0 1 2 3 4

RATE YOUR ESTIMATE OF THIS INDIVIDUAL'S COMPLIANCE:

___________________________

extremely noncompliant

compliant

(please place a mark along the line that reflects your estimation)

COMPLETED BY: _______________________________________________

DATE: _________________________________________________________

PLEASE RETURN TO DEPARTMENT OF PSYCHOSOCIAL SERVICES. THANK YOU.
Appendix H

ECOG Rating Scale

ECOG RATING SCALE

0 = Fully active, able to carry out all pre-disease activities without restrictions.

1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (e.g. light housework, office work).

2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.

3 = Capable of only limited self-care - confined to bed or chair more than 50% of waking hours.

4 = Completely disabled. Cannot carry out any self-care and confined to bed or chair.
Appendix I

Initial Phone Call Information
Initial Phone Call Information

My name is Tena Jackson. I'm a clinical psychology student at the Thunder Bay Regional Cancer Centre. I've been working with Dr. Scott Sellick and some of the physicians at the Centre. I understand that you have been a patient at the Centre and I'm calling to ask if you would be interested in helping me out with a research project that would involve you completing a few questionnaires.

We are trying to learn more about difficulties patients may have with treatment and with coming to the Centre in general so that we can identify areas where we can make improvements.

It will involve a time commitment. I will meet with you at Amethyst House - directly across from the Centre - four times over a six week period. The first meeting will take approximately half an hour and the second, third and fourth meetings will take about 15 minutes each.

Are you at all interested in helping me with this project or do you have any questions?

**For statistical purposes, I will need for you to bring any medication that has been prescribed to you to each meeting.
Appendix J

Informed Consent Form
INFORMATION AND CONSENT FORM
FOR PARTICIPANTS IN A STUDY OF
ATTITUDES, BELIEFS AND BEHAVIOURS
OF WOMEN WHO HAVE HAD BREAST CANCER

This is a brief outline of the nature and purpose of the study in which we hope you will agree to participate. We are interested in learning more about difficulties that cancer patients may have with their ongoing treatment, so that we can identify areas where improvement can be made to benefit those people who have had cancer.

Participants will be asked to complete some questionnaires that will contain questions about their beliefs, attitudes and behaviours, and will be asked to meet with the investigator every two weeks, for six weeks. This will take approximately one hour of your time for the first meeting, and approximately 15 minutes for each of the second, third and fourth meetings.

Participants will be assigned a number that they are to use when completing the questionnaires, and only the researcher will know their identity. Their physician(s) will be aware of their participation but will not have access to any of the information given in the questionnaires. All responses will remain strictly confidential.

If you have any questions about the study or about your role, please feel free to contact Dr Sellick or myself at any time. We can be reached by calling the Thunder Bay Regional Cancer Centre between 8:30 and 4:30, at 343-1680. If you leave a message, we will return your call.

Thank you for your consideration.

*********************************************************************************************************

I have read the above and have spoken with the investigator, Mrs. Tena Jackson. I am willing to participate in the above mentioned study and understand what will be expected of me. I have been assured that my participation is voluntary, and that should I not choose to participate, I may still make use of the psychological services available at the Centre. I also understand that I may withdraw from the study at any time.

NAME: ____________________________________________

SIGNATURE: ____________________________________

DATE: __________________________________________
Appendix K

Medication Diary
INSTRUCTIONS TO PARTICIPANTS

In order to learn more about difficulties that cancer patients may have with their ongoing treatment, we are asking a number of patients to complete some questionnaires. We wish to identify areas where improvement can be made for the overall benefit of people who have had cancer. In addition, we are asking participants to keep track of all medication, prescribed by a physician, that they are presently taking. Please bring those medications (and the record sheets) with you when you meet with the researcher. A new record sheet will be given to you.
RECORD SHEET

<table>
<thead>
<tr>
<th>SUBJECT NUMBER</th>
<th>DATE &amp; TIME</th>
<th>MEDICATION TAKEN</th>
<th>NO. OF TABLETS</th>
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<tr>
<td></td>
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### Appendix L

Mean Compliance Prediction For Attending Oncologists

<table>
<thead>
<tr>
<th>Oncologist</th>
<th># Patients</th>
<th>Mean</th>
<th>Standard Deviation</th>
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<tbody>
<tr>
<td>1</td>
<td>8</td>
<td>6.125</td>
<td>1.126</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>6.2</td>
<td>.447</td>
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<tr>
<td>3</td>
<td>5</td>
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<td>2.167</td>
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<tr>
<td>4</td>
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<td>6.5</td>
<td>.707</td>
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### Appendix M

Paired T-Tests of FLIC Scores

<table>
<thead>
<tr>
<th>Time 1</th>
<th>Time 2</th>
<th>Time 3</th>
<th>Time 4</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time 1</td>
<td>t=-.87</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=.396</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time 2</td>
<td>t=-1.05</td>
<td>t=-.50</td>
<td>t= -.50</td>
<td>p= .624</td>
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<tr>
<td></td>
<td>p=.306</td>
<td>p=.306</td>
<td>p=.624</td>
<td></td>
</tr>
<tr>
<td>Time 3</td>
<td>t=-.45</td>
<td>t=.28</td>
<td>t=.76</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=.660</td>
<td>p=.780</td>
<td>p=.456</td>
<td></td>
</tr>
<tr>
<td>Time 4</td>
<td>t=.34</td>
<td>t=1.01</td>
<td>t= -.18</td>
<td>p= .859</td>
</tr>
<tr>
<td></td>
<td>p=.740</td>
<td>p=.323</td>
<td>p=.859</td>
<td></td>
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Appendix N

Multiple Regression for Pill Count

With All Other Variables

\[ R = .2542, F (1,18) = 6.13, p < .05 \]

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<thead>
<tr>
<th>Variable</th>
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<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>.50417</td>
<td>2.477</td>
<td>&lt; .05</td>
</tr>
</tbody>
</table>
Appendix O

Multiple Regression for Oncologist Compliance

Prediction With All Other Variables

\[ R = .5038, \ F(1,18) = 18.28, \ p < .001 \]

<table>
<thead>
<tr>
<th>Variable</th>
<th>Beta</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Months since first treatment</td>
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<td>-4.28</td>
<td>&lt; .001</td>
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</table>