

ADAPTATION TO THE DEMANDS OF ORAL ANTICOAGULATION THERAPY:  
THE IMPORTANCE OF INDIVIDUAL AND FAMILY RESILIENCY FACTORS

By

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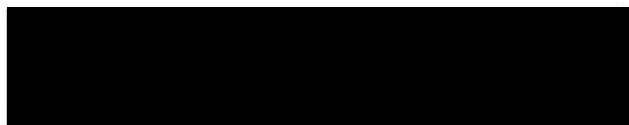
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## ABSTRACT

TITLE: Adaptation to the Demands of Oral Anticoagulation Therapy: the Importance of Individual and Family Resiliency Factors

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This cross-sectional study explored which individual (hardiness, neuroticism, conscientiousness, extroversion) and family (problem solving communication, hardiness) characteristics predicted the two oral anticoagulation therapy (OAT) outcomes of therapeutic control (TC) and quality of life (QOL). The final sample consisted of 112 subjects (55% ( $n = 62$ ) females, 91 % ( $n = 102$ ) Caucasian) ranging in age from 24 to 91 years ( $M = 59$ ,  $SD = 16$  years) who attended a metropolitan university hospital anticoagulation clinic. The indications for anticoagulation were atrial arrhythmia (36%,  $n = 40$ ), venous thromboemboli (28%,  $n = 32$ ), mechanical heart valve (17%,  $n = 19$ ), and other (19%,  $n = 21$ ), which included arterial emboli, hypercoagulable state, cardiomyopathy, and cerebral vascular accident.

Prothrombin test dates and results for the past 3 months were recorded prior to subjects completing seven 7 questionnaires: Background Information, *NEO Five Factor Inventory*, *Health Related Hardiness Scale*, *Family Inventory of Life Events and Changes*, *Family Hardiness Scale*, *Family Problem Solving Communications*, and *Quality of Life Scale*. Multiple linear regression analyses tested separately for prediction of therapeutic control and quality of life. Adjusted R squared was the primary measurement of goodness of fit for the regression models. No significant relationships were found between individual or family characteristics and TC, after controlling for age

and the number of prescriptive medications. In six independent regressions, the control variables of chronic conditions and income were entered at the first step; all individual and family variables explained significant amounts of QOL variance when entered separately as the second step. Additional variance in QOL was accounted for by neuroticism (16%), conscientiousness (20%), extroversion (16%), hardiness (27%), family problem solving communication (18%), and family hardiness (24%).

The final predictive model for TC revealed that age and number of medications explained 6% of the total therapeutic control variance ( $TC\% = 53.46 + .24(\text{age}) - .22(\text{number of prescription medications})$ ). Half of QOL was predicted by hardiness, family problem-solving communication, and neuroticism ( $QOL = 21.48 + .36(\text{hardiness}) + .88(\text{family problem solving communications}) - .38(\text{neuroticism})$ ).

Due to the omission of three outliers, the generalizability of the results is limited. Results are not transferable to middle age African American women whose prothrombin tests do not reach a therapeutic range, middle age men with extremely low QOL and whose prothrombin tests do not reach a therapeutic range, and elderly Asian males who have extremely low family hardiness and problem solving.

Fit between TC and QOL is a combination of multiple factors that come together to support a risk profile. Anticoagulation management clinicians, who typically see patients more frequently than other providers, may be in a unique position to identify and address risk. This investigation elucidates key risk-related factors and suggests approaches to the growing population of anticoagulated persons.

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## CHAPTER 1

### Introduction

Patients at risk for thromboembolism have benefited from oral anticoagulation therapy (OAT) for over 50 years. Overwhelming clinical trial evidence supports the use of OAT for an increasing number of conditions (CHEST, 2001). This, along with the aging of our population and advances in tertiary care, increases the number of those requiring OAT. The effectiveness and safety of OAT are dependent on maintaining therapeutic blood levels of anticoagulants. Therapeutic control - how well individuals are maintained at the desired intensity of anticoagulation - is at best a dynamic state where anticoagulation intensity fluctuates around the target level. In practice, the percentage of poorly controlled patients on OAT ranges from 11% to 69% (Ansell et al., 2001) and the mean time OAT persons spent in therapeutic range is reported to be 54% (Matchar, et al., 2002), despite international standards recommending 70% (van den Besselaar, van der Meer, & Gerrits-Drabbe, 1988).

The empirical analytical medical paradigm dominates the substantial body of OAT research. Laboratory control, the organization of the monitoring system, patient warfarin sensitivity, intercurrent diseases, multiple drug interactions, lifestyle changes, and medication-taking behaviors have all been factors proposed to account for unstable anticoagulation control. Research on how to extend the time spent by patients in the therapeutic range has received little systematic focus.

Nursing has much to contribute to the understanding required for improving therapeutic control in the OAT population. Yet, surprisingly, the nursing contribution to

care of the OAT population is limited. A literature search of MEDLINE and CINAHL, using a combination of words (e.g., “warfarin”, “oral anticoagulation”, “nursing” and “nursing research”) identified only two nursing research articles related to OAT between 1996 and 2004 (Allen, Mihalovic, & Narveson, 2000; Delmore, Mooney, Paplanus & Sutton, 2000; Cheah & Martens, 2003; Wheatley, Cox & Nemis-White, 2003). This paucity of literature in the domain of nursing, which is concerned with facilitating adaptation to chronic illness and chronic therapies, calls for consideration. Nursing, with its family perspective, assumes both individual and family factors contribute to the objective and subjective outcomes of OAT.

Family Ecology Theory expands the understanding of OAT therapeutic control to be the result of multiple internal and external factors and influences creating a certain pattern that ultimately either supports or hinders therapeutic control. Why some individuals meet the demands of OAT and are able to maintain therapeutic control, while others remain poorly controlled remains to be explained. Clinical observation suggests that individual characteristics and family strengths may be related to how a person succeeds in meeting the demands of OAT and maintaining therapeutic control.

The Resiliency Model of Family Stress, Adjustment and Adaptation states that the ability to adapt to the demands of OAT may depend on the degree of harmony that exists between the demands and the resources of an individual and his or her family. When the demands of OAT are compatible with the individuals' and their family's characteristics, behavior is more likely to be supportive of OAT and maintaining therapeutic control of anticoagulation. The purpose of this study is to explore which individual and family

characteristics promote optimal OAT, and to identify a supportive profile for OAT. Specifically, questions asked include: 1) Do family resiliency factors (hardiness and problem solving communication) influence therapeutic control and quality of life in people on OAT?, and 2) Do individual resiliency factors (hardiness and personality) influence therapeutic control and quality of life in people on OAT?

### Review of Literature

Family ecology theory (FET) explains and describes the influences and connections between genetic endowments, biologic requirements, intimate relationships, social organizations and the physical environment (Bubolz & Sontag, 1993). Because of the ability to address context, complex phenomena, and a broad scope of issues, the theory contributes to developing nursing understandings and interventions with populations such as the OAT population. The complexity of the nursing role within practice environments, along with the goals and values of nursing as they relate to human needs, are supported through an approach which identifies humans as requiring interactions with others and with material goods around them. An exploration of major concepts, within the context of OAT, follows.

#### *Human Development in Levels of Environmental Systems*

Theoretically, by virtue of their human development, individuals on OAT engage in a process of ongoing and interrelated changes in their ability to perceive, conceptualize, and act in relation to their OAT. Over time, they interact with more differentiated and complex physical, social, emotional and cognitive responses (Bronfenbrenner, 1979). This dynamic state is reflected in their ability, as therapy progresses, to avoid missed

doses of warfarin, to participate more fully in self-care by contacting providers when changes occur in diet or health status, and to “normalize” chronic OAT.

The developing person’s environment is divided into four levels (micro-, meso-, exo- and macrosystems) differentiated on the basis of their proximity to the individual (Bronfenbrenner, 1979). Most distal, the macrosystem represents the broad ideological values, norms, and institutional patterns of the person’s culture. The beneficence of medicine, the right to health care, and the stigma of the chronically ill, are examples of macrosystem influences. The exosystem comprises systems in which others participate and affect the OAT individual. For example, social networks, health insurance companies, and pharmaceutical companies offering generic warfarin can impact a patient’s access to warfarin. Mesosystems include the individual’s work setting, health care system, and extended family. The family is the principal microsystem, most proximal, within which development takes place.

Three clinical situations experienced by this author illustrate the need to broaden the scope of OAT inquiry to include the Family Ecology Theory dimensions. First, a young 12-year-old experienced stable control of her OAT for several years. However, with the onset of menses, her physiological changes caused a period of uncontrolled OAT. Second, a 40-year-old gentleman, with a hypercoagulable state, struggled with poorly controlled OAT ... until he married. His wife implemented a medication management system that supported therapeutic control. Yet a third individual, a man on OAT for a history of arterial thromboses, experienced stable OAT control until he was laid off at

work and lost his health insurance coverage. Subsequently, he missed office visits and his infrequent blood tests reflected subtherapeutic control.

Understanding OAT within this larger context of systems, each with their own set of characteristics and processes, allows us to explore the therapeutic control of OAT patients in greater detail and with more complexity. Key OAT-related factors of the individual, the family microsystem and the health care mesosystem are discussed below. The macro- and exosystems are not addressed within the scope of this study.

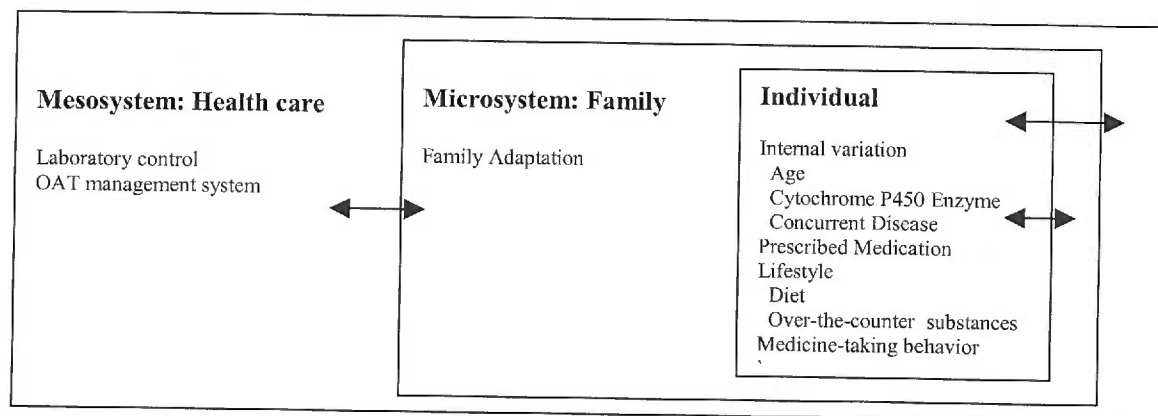


Figure 1. Family Ecology Theory Applied to Oral Anticoagulation Therapy



### *Individual Factors*

Variation occurs in the required drug dose between individuals and within an individual over time. Evidence gathered primarily within the medical model suggests biological and lifestyle factors contribute to variation. Related research is reviewed in five sections: 1) internal metabolism, 2) concurrent disease, 3) prescribed medication, 4) lifestyle, including diet, over-the-counter medication use, and natural remedies, and 5) medicine-taking behavior.

#### *Internal Variation*

##### *Mechanism of Action and Pharmacokinetics.*

Warfarin acts by inhibiting vitamin K dependent clotting factor (Factors II, VII, IX and X) synthesis, and synthesis of the anticoagulant proteins C and S. The resultant effect is a sequential depression of Factor VII, IX, X and II activities. The dosage administered dictates the degree of depression. Therapeutic doses of warfarin decrease the total amount of the active form of each vitamin K dependent clotting factor made by the liver by approximately 30% to 50%.

Gastrointestinal absorption of warfarin is rapid with peak concentration occurring within the first 4 hrs. Warfarin is 99% bound to plasma proteins, primarily albumin. Warfarin has a half-life of 40 hours in the circulation. Warfarin elimination occurs almost entirely by cytochrome p450 enzymes in the liver. The metabolites are principally excreted into the urine, and to a lesser extent into the bile.

### *Age.*

Four studies concluded that advanced age leads to a reduced warfarin dosage requirement. Routledge and colleagues (Routledge, Chapman, Davies & Rawlins, 1979) found patients 35 years or younger needed an average of 3.7 mg per day more than patients 75 years or older to maintain similar anticoagulation levels. James and colleagues reported an average of 10.9% per decade decrease in required warfarin for 2305 adults (55% males) between the ages of 35 and 85 years (James, Britt, Raskino & Thompson, 1992). In a retrospective study of 530 patients ( $M = 61.5$  years,  $SD = 14.7$ , range 12 – 90, 55% male), the mean daily dose of warfarin decreased each decade for groups < 50 years, 50 – 59 years, 60 – 69 years, and > 70 years ( $p < .001$ ); mean warfarin doses were 6.4, 5.1, 4.2, and 3.6 mg respectively (Gurwitz, Avorn, Ross-Degnan, Choodnovsky & Ansell, 1992). Redwood found dosing requirements dropped by 25% to 33% for patients 70 years old compared to patients 30 years old in 494 patients age 15 to 89 years (Redwood, Taylor, Bain & Matthews, 1991).

Shepherd demonstrated that warfarin pharmacokinetics did not differ in younger versus older subjects (Shepherd, Hewick, Moreland & Stevenson, 1977). An increased effect of warfarin in the elderly was hypothesized to result from an increased intrinsic sensitivity to warfarin. This altered sensitivity may reflect a decreased affinity for vitamin K or an increased affinity for warfarin in the elderly, or it might be due to inherent vitamin K deficiency (reduced intake, defective absorption, or altered pharmacokinetics of vitamin K) (Wieland & Wittowsky, 2001). Thus, we have begun to explore the physiology of age variability in OAT.

### *Cytochrome P450 Enzyme System.*

Warfarin is a racemic mixture of (R) and (S) enantiomers, which differ with respect to both pharmacodynamic and pharmacokinetic properties (Wittowsky, 2001). (S)-warfarin has a greater potency (approximately five times) than (R)-warfarin, a greater clearance (3.2-4.2 ml/hr/kg compared with 2.1-3.5 ml/hr/kg), and a slower elimination half-life (24-38 hours compared to 35-58 hours). Hepatic microsomal enzymes vary in their metabolism of the enantiomers. (S)-warfarin is primarily oxidized to 7-hydroxy-warfarin with a smaller degree of 6- and 4'-hydroxy-warfarin formation, and approximately 10% formation of SS and SR alcohols. In contrast, (R)-warfarin undergoes approximately 60% oxidation, primarily to 6-hydroxy-warfarin and, to a lesser extent, to 7-, 8-, and 10-hydroxy-warfarin. Additionally, approximately 40% of (R)-warfarin is reduced, primarily to RS-alcohol.

Oxidation of warfarin occurs in the cytochrome p450 enzyme system. Thirty distinct enzyme components of the cytochrome p450 superfamily have been identified. Each enzyme promotes certain distinct oxidative reactions involved in the metabolism of warfarin compounds. (R)-warfarin is metabolized by the enzyme p450-1A2 to 6-, 7-, and 8-hydroxy-warfarin and by p450-3A4 to 10-hydro-warfarin. In contrast, (S)-warfarin is oxidized to 6- and 7-hydroxy-warfarin by p450-3A4.

This stereoselective, regioselective oxidative metabolism of warfarin provides us with an understanding of how individuals can differ in their warfarin response. They may also vary with respect to other metabolic factors, such as vitamin K receptor affinity. Further, variability in patient response is likely explained, at least in part, by differences in p450

enzyme availability, activity, or both, and the influence of these enzyme differences on the pharmacokinetic characteristics of warfarin. A genetic variant of p450-2C9 displays impaired ability to metabolize the more potent (S)-warfarin to its 6- and 7-hydroxy metabolites in experimental medium (Rettie, Wienkers, Gonzalez, Trager & Korekwa, 1994). Fifty eight out of 185 (mean age = 58, males = 83%) primarily Caucasian participants were found to have variant forms of the CYP2C9 enzyme (Higashi et al., 2002). The presence of this variant, expressed in a significant proportion of the population, influences individual response to maintenance warfarin dosing.

#### *Concurrent Disease.*

Individuals on OAT frequently experience comorbidities, many of which influence the OAT illness trajectory (Landefeld, Cook, Flatley, Weisberg & Goldman, 1987). Warfarin is well absorbed from the gastrointestinal tract and the bioavailability is almost 100% (Scott, 1989). Disease effects on warfarin absorption include short bowel syndrome, malabsorption, and protein-losing enteropathy (Brophy, Ford & Crouch, 1998).

Warfarin is extensively bound (97-99.5%) to albumin in plasma (O'Reilly, 1973; Scott, 1989). Since free drug is active, small changes in binding can result in major changes in free drug. In renal failure, warfarin binding is reduced in the presence of uremia. This is mainly due to the presence of endogenous protein binding inhibitors (Bachmann, Shapiro & Mackiewicz, 1977). In hypoalbuminemia, warfarin binding is decreased (Piroli, Passanati, Shively & Vessell, 1981).

The liver is the primary site of warfarin metabolism. Impaired hepatic function may cause an increase in the hypoprothrombinemic response to warfarin due to decreased

metabolism (Wieland & Wittkowsky, 2001). Clotting factor synthesis takes place in the liver. Reduced synthesis of precursors may occur in cirrhosis (Brodie, Burns & Weiner, 1959), viral hepatitis (Kliesch & Young, 1960), and hepatic congestion due to cardiac failure (Killip & Payne, 1960). The rate of clotting factor degradation is altered in thyroid disease with increased rate of breakdown in hyperthyroidism and reduced breakdown in hypothyroidism (Shetty, Fennerty & Routeledge, 1989).

Positive correlations exist between the risk of major hemorrhage and certain comorbidities. These comorbid conditions include: heart, liver, or kidney dysfunction, cancer, or severe anemia (Landefeld, Rosenbaum & Goldman, 1989). A history of stroke, gastrointestinal bleed, recent myocardial infarction, renal insufficiency, severe anemia, or atrial fibrillation (Landefeld et al., 1989) also increase the risk of major hemorrhage. Those with hypertension (Launbjerg et al., 1991) or who have three or more comorbidities (Finh et al., 1993) share similar bleeding vulnerability.

These studies explain the direct effects of comorbidities on OAT therapeutic control and adverse outcomes. Any single comorbidity or combination of comorbidities may vary with respect to magnitude of effect on OAT therapeutic control. Prescribed medications also have a range of impact on OAT outcomes.

### *Prescription Medication*

Hansten and Wittowsky concluded “more is known about the drug interactions of warfarin than perhaps any other drug” (Hansten & Wittowsky, 2001). Four factors contribute to this knowledge. First, clinical experience with warfarin spans over 4 decades. Objective monitoring (via coagulation blood testing) of all warfarin patients

provides a measure of interaction influences and adverse outcomes of interactions producing observable bleeding or clotting. Finally, warfarin's properties predispose it to drug interactions.

Warfarin's ready absorption from the intestine decreases the chance of drug interactions interfering with its bioavailability. One such rare interaction is cholestyramine, which can bind with warfarin and reduce its absorption (Jahnchen, 1978).

Protein-bound displacement drugs increase the unbound warfarin, but any hypoprothrombinemic response is transient as the increased unbound warfarin is also available to sites of elimination. However, this compensatory increase in warfarin elimination is prevented if the patient is also receiving a drug that inhibits warfarin metabolism.

Many drugs have been shown to inhibit warfarin hepatic metabolism to a greater (trimethoprim-sulfa) or lesser (diltiazem) extent (Quinn & Day, 1995). Other drugs, such as phenobarbital (Orme, 1976), cause induction of warfarin metabolism subsequently reducing the hypoprothrombemic response.

The many drug interactions involving warfarin have been characterized with respect to mean or typical response (Hansten & Wittowsky, 2001). However, patients vary significantly in their susceptibility to various interactions, the magnitude of response, the time of onset, and the duration of effect (Hansten & Horn, 1993). Clinically significant drug interactions can occur when an interacting drug is added, changed or discontinued during warfarin therapy, thus causing an alteration in prothrombin response. The

incidence and prevalence of these interactions are currently being studied (A.K. Wittkowsky, personal communication, June 2, 2002) but as yet remain unknown. These interactions are frequent and severe as evidenced by the large number of warfarin interaction case reports, the large number of medications known to interact with warfarin, and the fact that 7% of all new drug interaction studies specifically evaluate warfarin interactions (Wittkowsky, 2001).

### *Lifestyle*

#### *Diet.*

Many foods contain vitamin K, a warfarin antagonist. A very high vitamin K diet has been shown to shorten the prothrombin time towards normal in the OAT population (Udall, 1965). Lubetsky and colleagues (Lubetsky, Dekel-Stern, Chetrit, Lubin & Halkin, 1999) concluded in 32% of those on OAT, under usual dietary conditions, experience decreased warfarin sensitivity with a vitamin K intake of greater than or equal to 250 mcg per day. Enteral feedings high in vitamin K, as well as vegetable-rich, weight reducing diets also show a similar effect (Qureshi, Reinders, Swint & Slate, 1981). Vitamin K produced by intestinal bacteria may play a smaller role, especially when reduced by broad-spectrum antibiotics (Scott, 1989).

Despite this information, a dose-response of vitamin K on the effect of warfarin anticoagulation is lacking and OAT individuals are encouraged to maintain a consistent dietary vitamin K intake. Specifically, a vitamin K intake of 65-80 micrograms/day, the current dietary recommendation for all adults, is proposed (Booth, & Centurelli, 1999).

This consistency in vitamin K intake may be difficult to attain. Vitamin K has the greatest individual daily variation in both dietary intake and the corresponding plasma concentrations (Booth, Tucker, McKeown, Davidson, Dallal, & Sadowski, 1997) of all vitamins. Americans do not commonly or consistently consume dark green vegetables, a primary source of vitamin K (Block, 1991). Furthermore, certain plant oils are high in vitamin K (primarily soybean, canola, cottonseed, and olive) while others are not (peanut, corn, safflower and sesame) (Booth & Centurelli, 1999). Therefore, foods containing oils, such as baked goods, margarines, and salad dressings, may vary significantly in vitamin K content and further contribute to fluctuations in vitamin K intake.

Some foods consumed in large quantities, such as garlic, may interact with warfarin. More commonly, concentrated amounts of naturally occurring substances sold as natural remedies impact OAT.

*Over-The-Counter Medications, Natural Remedies, and Tobacco Smoking.*

Expanding over-the-counter medication options of single and combined pharmaceuticals complicate OAT. Common medications, such as acetaminophen (Shek, Cham & Nutescu, 1999), can influence the response to warfarin. The frequency and extent with which an individual self-medicates can contribute to therapeutic control.

Dietary supplement use in the U.S. is an 8.4 billion dollar industry and 60% of those using natural remedies (substances derived from plant, mineral and/or animal sources) do not report usage to their health care providers (Eisenberg, Bridgers & James, 1998). The four top selling botanicals (substances derived from plant sources) in the U.S. are ginkgo, St. John's Wort, ginseng, and garlic (Roufogalis, 1999). These all interact with warfarin



(Heck & DeWitt, 2000). Botanicals that contain coumarins with potential anticoagulant effects include alfalfa, Dong Quai, aniseed, arnica, asafoetida, bogbean, boldo, buchu, capsicum, cassia, celery, chamomile, dandelion, fenugreek, horse chestnut, horseradish, licorice, meadowsweet, nettle, passionflower, prickly ash, quassia, red clover, sweet clover, sweet woodruff, tonka beans, wild carrot, and wild lettuce (Jellin, Batz, & Hitchens, 1999). Herbal substances that have coagulant properties include agrimony, coenzyme Q10, goldenseal, green tea, mistletoe, and yarrow (Jellin et al, 1999). Many additional natural and botanical supplements may affect anticoagulation but remain untested.

A small amount of vitamin K is absorbed from tobacco smoke through mucous membranes (Olson, 1987). Tobacco smoke also may inhibit or induce cytochrome P450 enzymes in the liver (Zevin & Benowitz, 1999), thus influencing warfarin metabolism. Changes in smoking behavior may influence OAT therapeutic control. In pursuing self-treatment, and when smoking, the individual encounters daily exposure to substances that can cause changes in OAT.

#### *Medication-Taking Behavior*

Patient compliance is described as a critical and frustrating variable in anticoagulation control (Peric-Knowlton, 2001). Despite education about the benefits and risks of warfarin, patients frequently do not take it correctly. Kumar and colleagues, using a phenobarbitone marker, found that in a sample of 30 adult patients (age >50, 43% males) missed between 10% and 40% of their prescribed phenobarbitone-marked warfarin (Kumar et al., 1989). Intentional or accidental misuse of warfarin contributes to 25% to

30% of non-therapeutic prothrombin time, or protime (PT), tests (Kumar et al., 1989). Decreased adherence to warfarin regimens has been associated with those less than 60 years, especially those less than 53 years (Arnsten, Gelfand & Singer, 1997). Medical texts conclude “when no other causative agent can be identified to account for PT test variations, compliance is usually the culprit, despite patient denials” (Loken, 1992). Inadequate exploration of OAT adherence suggests this conclusion is premature and misleading. What role cognitive competency, substance use, language and cultural barriers, life events, negotiating the health care system, access to pharmaceuticals, cost, and family factors play remains unexamined.

Morris and Schulz (1993) discussed medication-taking behavior, and explored the influence of physical, economic, psychological, and social factors that influence medication use. He concluded that patients evaluate medication based not only on its clinical effectiveness, but also on how it affects aspects of their lives. Patients, according to Morris, actively formulate ideas that affect their use of medication. Four studies reported medication taking behaviors were differentially influenced by contextual factors related to unique patterns of the specific treatment regimens. O'Brian (1980) studied 63 hemodialysis patients ( $M = 44.5$  years,  $SD = 14$ , range 21 – 75, 54% male) and found persons may initiate a "reasoned" approach to dietary, fluid, and medication taking management more particular to individual needs than to strict adherence to treatment regimen. Epileptic patients were reported to have reduced or stopped taking their medication to determine how long they could go before they had a seizure, and whether their epilepsy was improving (Conrad, 1985). Rheumatoid arthritis patients' desired

outcomes were found not always to be identical to those desired by health care personnel and their taking medication was influenced by whether they could resume certain activities (Arluke, 1989). Using a series of six case studies, Barsky (1983) described factors influencing medication taking behaviors of three male (ages 33, 42, 77) and three female (ages 38, 61, 67) patients, including the social meaning medication holds for the patient in assuming the sick role, and medication as a reminder of his disease.

Three clinical examples from this author's experience demonstrate the implications of these studies for the OAT population. A Rodeo barrel-racer's "reasoned" approach involved discontinuing medication several days prior to a race in anticipation of potential trauma. Another individual never consumed alcohol except at a rare social event and would subsequently skip his anticoagulant that day. Yet another individual sensed the "thickening" of his blood as it moved through a temporal artery and would take additional warfarin.

OAT requires frequent office visits and prothrombin blood tests, avoidance of physical trauma and contact sports, abstention from alcohol, and careful monitoring of diet and concurrent medications. In addition, individuals on warfarin are susceptible to both minor and major bleeding events. Adult subjects (age 67.5 years  $\pm$  9.4, 74% male) in clinical trials of warfarin withdrew due to noncompliance or general refusal to continue at a rate of 8% to 26% (Connolly et al., 1991; Ezekowitz et al., 1992; Peterson, Godtfredsen, Boysen, Anderson, & Anderson, 1989). This demonstrated variation with respect to medication-taking behavior shows that individuals differ in the amount of impact they are willing to accept from OAT.

To summarize, the literature concerning individual physiological and lifestyle differences, and the influence of these differences on the therapeutic control of anticoagulation therapy, dominates OAT research. Evidence delineates multiple biological and lifestyle factors that may explain the variable response to OAT, and the many individual perturbations seen clinically. The evidence addressing the impact of behavioral influences on medication therapies is encouraging, yet no OAT research has explored this relationship. One could argue that psychological influences may play a role in how well an individual adapts to OAT. Despite this omission, a significant amount of literature documents the impact of individual factors influencing OAT therapeutic control. Less is known about the influence of microsystem factors, such as family characteristics. Family has always been a key nursing focus, and nursing literature suggests family characteristics, along with individual characteristics, may play a role in how an individual meets the demands of OAT. Broadening OAT research to include family factors, and attending to the family perspective, may improve the quality of research questions posed in this area. Support for attending to family factors in OAT is described below.

#### *Microsystem: Family Factors*

The Family Systems-Illness model (Rolland, 1990) provides a framework for understanding how OAT management and therapeutic control are dependent on illness, individual, and family factors. By creating a psychosocial typology and time phases of illness, the development of the individual, family and illness can be understood in a single context. For example, consider this contrast: anticoagulation management of a

young adult woman in her first year of college who experiences a deep-vein thrombosis shortly after starting birth-control pills vs. that of an older adult father of school-age children in the end stages of cancer who develops a subclavian thrombosis associated with his central line. The former involves a non-fatal and temporarily incapacitating illness in an individual who may have a genetic hypercoagulable state and is developmentally differentiating from her family. The latter involves an incapacitating progressive illness in an individual who is dying and the family is experiencing a major transition. No inquiry explores how families under various circumstances mobilize to impact the many demands of OAT.

The construct “demands of illness” (Woods, Haberman & Packard, 1993) defined illness-related events as either difficulties or challenging opportunities for growth to which families respond. These events are further categorized into three groups of demands: disease-related, personal disruption, and environmental transactions. Disease-related demands are the physical and psychological responses directly attributed to the illness. Prolonged bleeding and worrying about hemorrhage exemplify OAT disease-related events. Personal disruption demands refer to changes in integrity, continuity, and normality. This disruption may be dramatic in a life-long athlete engaged in contact sports who, because of OAT therapy, may need to discontinue sport activities. Those with other chronic illnesses on fixed income may find adding the cost of another lifetime medication requires relinquishing something of similar monetary value. Further, frequent blood testing may interfere with normal daily activity and cause a shift in personal meaning of activities and a preoccupation with OAT. Finally, environmental transactions

refer to interactions with the social environment of family members, work, and health care providers. Requesting time off work for medical appointments and blood tests, restricting children's access to warfarin in the home, and communicating about significant changes with health care providers are typical environmental transactions required by OAT. Which families adapt positively to these demands depends, in part, upon family resiliency characteristics. Research specific to OAT is lacking. However, related research findings that may provide insights for OAT are discussed below.

### *Adaptation*

Theoretical and empirical evidence supports attending to family characteristics when addressing adaptation to chronic illness. Hill (1949) recognized the importance of family strengths and resiliency when observing family separation and reunion during World War II. His ABCX Family Crisis Model, a family stress theory model, describes the variation in family functioning displayed by different families adjusting to the same stressor. McCubbin and Patterson (1983) expanded this model, based on observations of families during the Vietnam War, into the Double ABCX Model, which included the cumulative effect of stress and coping variables.

The Resiliency Model of Family Stress, Adjustment and Adaptation (McCubbin & McCubbin, 1993) represents further refinement and emphasizes the difference between "adaptation" and "adjustment". The latter is defined as a short-term response to a normative event that is characterized by first-order change. Family rules, roles, and relationships are slightly modified but not redefined. Adaptation is defined as long-term response to a nonnormative event that involves more significant second-order change,

where rules, roles and/or relationships are redefined. Nursing research using this model to explore adjustment and adaptation historically has focused on families with a chronically ill child. A review of these studies follows and depicts the importance of resiliency factors when studying outcomes of chronic illness.

McNelís and colleagues (McNelís et al., 2000) explored the complex relationship between asthma severity and adjustment in 134 children and their mothers. Results demonstrated that child and family variables were closely related with adaptation. Significant child variables included coping behaviors and negative attitudes toward their illness. The significant family variable was family stress. Other studies have confirmed the role family stress plays with respect to adaptation and outcomes in a variety of illnesses. In 63 families of children with heterogeneous brain tumor, families with fewer negative life changes had children with fewer behavioral problems (Carlson-Green, Morris, & Krawiecki, 1995). In a study of 217 families with a child diagnosed with cerebral palsy, pile-up of family stressors was positively correlated with family imbalance (McCubbin & Patterson, 1983). Family resources, defined as the family's personal resources, family system internal resources, and social support, were positively related to family adjustment in 124 mother and father pairs experiencing the birth of a sick neonate (Pinelli, 2000). In a study of 53 children diagnosed with diabetes mellitus, Auslander and colleagues (Auslander, Bubb, Rogge & Santiago, 1993) revealed that family stress and resources were more strongly related to metabolic control than were disease variables. Thus, adequate family resources may influence how health care demands are met. Family stress was related to adaptation during the first year post-

transplant in 58 families with children receiving a liver transplant (LoBiondo-Wood, Bernier-Henn, & Williams, 1992). However, family stress was unrelated to adaptation after the first year post-transplant. The relationship of family stress and illness outcomes thus appears dynamic, fluctuating over time.

Two studies using this model with the adult chronically ill population have been reported. Family stress was negatively related to health measures in 249 adult family practice patients (Parkerson, Broadhead, & Tse, 1991). Families of persons with AIDS were studied along with individuals receiving hospice care for other terminal illnesses (Atkins, & Amenta, 1991). Persons with AIDS and their families experienced significantly greater stressors and strains in comparison to hospice clients and their families. The relationship of family stress and illness outcomes fluctuates with the type of illness, and possibly with the severity of illness.

These studies suggest family stress and resiliency factors may play a significant role in helping an adult meet illness demands. Nurses continue to provide care to the families incorporating changes caused by a chronic illness. Helping persons on anticoagulation to integrate their therapy into the fabric of their lives is dependent on understanding the influence of family stress and strengths on adapting to OAT.

#### *Mesosystem: Health Care Factors*

Two mesosystem health care factors, laboratory control and OAT management systems, have been identified as barriers to tight control of anticoagulation. A brief discussion of these two factors characterizes the influence of this dimension.



### *Laboratory Control*

The coagulation blood test used to monitor level of warfarin is the prothrombin time (PT). The PT measures the procoagulant activity of factors VII, X, V, and II in seconds to clot. The sensitivity of the thromboplastin to warfarin-induced reductions in clotting factor activity is a critical variable in the test that varies from one laboratory to another. Sensitive thromboplastins produce longer PTs than those less sensitive. To address this variability, a mathematical calculation factoring in the sensitivity of the thromboplastin is performed and is termed the International Normalized Ratio (INR). For any blood sample of a given intensity of anticoagulation, the INR will not vary irrespective of the sensitivity of the thromboplastin used, and comparison across laboratories is possible. The INR is the value used for OAT management and warfarin dosage adjustment.

Appropriate collection of the PT sample, the choice of reagent and instrumentation, and reporting of the results are sources of lab error in the protime measurement (Triplett, 2001). McCurdy and White (1992) reported a wide 95% confidence limit of repeat protime measurement INRs ( $\pm .38$  INR units). They concluded appreciable changes might certainly be caused by measurement error when targeting a usual therapeutic range of one INR unit. Lassen and colleagues (Lassen, Brandslund & Antonsen, 1995) studied a cohort of 32 patients (M = 61 years, range 21 – 77, 60% male) and found persons at pharmacological steady-state reported analytical and biological variability of the prothrombin test in consecutive measurements (M = 3.16, SD = 0.32, coefficient of variation (CV) = 10.1% compared to this study site's M = 3.16, SD = 0.31, CV = 9.91%).

### *Management System*

Ansell examined 23 studies and concluded that the model of anticoagulation management is an important risk factor for the development of adverse outcomes related to poor therapeutic control (Ansell, 1998). Management systems focused predominantly on OAT were compared to those in which OAT patients are cared for along with other patients in a physician's panel. This latter system typically lacks a specific organized program of anticoagulation management. The OAT-focused management systems showed a 50% reduction in major hemorrhagic and thrombotic events based on the results of 13 (mostly observational) studies. Further, there was nearly an 80% reduction in adverse events based on six retrospective studies. Other research has shown that a model of care involving self-testing and/or self-monitoring by those on OAT can improve therapeutic control outcomes (Anderson, Harrison & Hirsh, 1993; White, McCurdy & Marensdorff, 1989) as well as provide greater convenience (Sickles, Elston-Lafata & Ansell, 1999). A meta-analysis of nine randomized trials, that assessed usage of computer-assisted OAT prescription systems, revealed a 29% increase in the proportion of visits where patients were appropriately treated when using a computer-assisted model (Chatellier, Colombet & Degoulet, 1998). The OAT-focused management system was used at this study site.

Therapeutic control is the dominant medical outcome in the individual, microsystem, and mesosystem research reviewed. However, quality of life (QOL) is an important outcome in chronic illness. Improving QOL of all persons is a major goal (Healthy People 2000: National Health Promotion and Disease Prevention Objectives, 1990).

Further, the Agency for Health Care Policy and Research uses QOL to modify treatment and guide patient and family teaching to facilitate adaptation (Konstam, Dracup, & Baker, 1994). QOL is a common outcome focus of nursing research and a discussion of QOL with respect to OAT is warranted.

### *Quality of Life*

The concept of quality of life (QOL) enjoys considerable attention in philosophy, sociology, religion, politics, and other domains. The domain of health care relatively recently embraced QOL and for the past 30 years has continued to grapple with its definitions and utility.

The International Medical Outcomes Trust, a complex mix of nonprofit organizations, academic researchers, public sector agencies, and commercial firms, created a Scientific Advisory Committee (SAC) in 1994. The mission of SAC was to provide some guidance for the rapidly expanding development of QOL measures and the refinement of existing measures. In 2002, the SAC published key attributes of QOL instruments and their related review criteria (Aaronson, Alonso, Burnam, Lohr, Patrick, Perrin, & Stein, 2002). The eight attributes guiding review criteria include: conceptual and measurement model, reliability, validity, responsiveness, interpretability, respondent and administrative burden, alternative forms, and cultural and language translations. These attributes and criteria give direction to the proliferation of instruments that vary widely in their method of development, content, breadth of use, and quality. However, they cannot identify the single best QOL definition or instrument for use in a specific study.

In this void, researchers debate QOL definitions and applications. Varying definitions and instruments result in the measurement of multiple concepts and serve to impede any unifying approach to QOL research. Currently, the purpose of the study normally dictates the QOL conceptualization.

A single QOL study with an OAT sample was identified (Lancaster et al., 1991). Its purpose was to determine the effect of long-term warfarin therapy on quality of life. Perceived health status was measured with a combination of generic and disease specific QOL scales in 333 adult patient's (M = 67 years, 74% male) participating in a randomized anticoagulation trial. Functional status, well-being, and overall evaluation of health in general were measured. Well-being was further defined as anxiety, depression, psychological well-being, energy/fatigue levels, and extent of bodily pain. No difference was found between warfarin-treated individuals and control patients with respect to study variables.

However, the experience of bleeding during anticoagulation treatment was associated with a significant decrease in the perception of health. One study had parallel findings with respect to disease specific QOL and its association with physical outcomes. In 211 subjects with heart failure, disease-specific QOL instruments were superior to generic instruments in differentiating adults (M = 57 years, SD 12, range 20 – 90, 51% male) with respect to the severity of their heart illness (Bennette et al., 2002). There was a direct relationship between disease specific QOL and the amount of heart disease.

Rather than differentiate OAT individuals with respect to disease severity, this current study seeks to identify which family resiliency factors are related to physiological

adaptation and a sense of well-being. Therefore, a definition of QOL not specifically related to health status is appropriate. Perhaps the most useful QOL definition for this study is the one proposed by Anderson and Burckhardt (1999). QOL was defined as an individual's subjective satisfaction with life in domains identified as important to most people, and distinguished from concepts such as symptoms, mood, functional status, and general health status. No studies related to OAT were found to use this definition.

Brown and colleagues, using such a definition, studied 44 cancer patients ( $M = 54$  years,  $SD = 14$ , 57 % males) and found coping and psychological adjustment accounted for significant ( $p < 0.001$ ) amounts of the QOL variability between patients. Although a proportion of the anticoagulated population has cancer (less than 10 % in this study's target population), the diabetic population may be more representative.

OAT and diabetes therapy differ in the immediate outcomes related to failure of therapy. After several days of missed OAT, a life-threatening thrombosis may occur. The result of missed diabetic medications promotes the slower development or progression of the microvascular and neuropathic complications of the disease. However, similarities between these two therapies exist. Both require daily medications that fluctuate routinely, frequent blood testing, frequent contact with health care providers, and careful regulation of activity and diet. The psychological factors important for QOL for those living with diabetes may be similar to those living with OAT. Higher QOL, as defined by physical, psychological, and social domains, of 625 adults ( $M = 57$  years,  $SD 9.61$ , 53% male) with diabetes was found in those with strong beliefs in self-efficacy and an optimistic outlook on life (Rose, Fliege, Hildebrandt, Schirop, & Klapp, 2002). The prominence of

individual factors in those with higher QOL in this study suggests individual characteristics may be significantly related to a sense of well-being. Greater depression, greater degree of upset with coping with diabetes, and lower self-efficacy were found to associate with decreased QOL. First, this study shows the influence of metabolic control on QOL does not occur in isolation. Furthermore, this study explicates the role an individual's characteristics may play with respect to QOL.

The clinical significance of QOL has been debated, especially from 3 distinct perspectives: patient, clinicians, and the general public (Frost, Bonomi, Ferrnas, Estwing, Wong, & Hays, 2002). Once QOL has been assessed, there is little guidance in how to interpret score changes reported by subjects and interpretation varies with respect to perspective. An active 75 year-old man diagnosed with atrial fibrillation started on warfarin therapy. He defined the medication as "rat poison". Further, he was disturbed knowing his sister had died from a cerebral hemorrhage while on warfarin. His health status remained relatively unchanged and his QOL scores in the physical domain were most likely stable. Thus, his primary care provider saw little need to alter treatment or therapy. However, each time the man took his anticoagulant, and several times during the day, he experienced anxiety. His QOL psychological domain scores most likely would reflect a change. This change was significant enough to the patient that he soon stopped his medication. He was willing to restart his anticoagulation with the agreement that his protime be checked weekly rather than monthly, as would be indicated by his stable condition.

If we consider the population's perspective of this incident, QOL would be viewed in terms of resource cost and benefits derived for the greatest number of individuals. One can imagine a third party deeming the change in QOL scores minimal and the costly every-week blood tests unnecessary or non-reimbursable. This study seeks to understand which individual and family resiliency factors are related to an individual's sense of well-being during adjustment to OAT. Thus, the subject's perspective of QOL, not the clinician's nor the public's, is paramount.

### *Summary*

The goal of oral anticoagulation therapy is to maintain a therapeutic level of anticoagulation while making achievable a relatively normal QOL. OAT is a demanding therapy requiring significant lifestyle changes. Although benefits are clear, so are the bleeding risks. Tight control is not guaranteed despite strict adherence to therapy, and periods of poor control frequently need to be endured. The problem of OAT therapeutic control framed in Family Ecology Theory is understood to be the result of multiple factors. With this understanding, particular constellations of individual, microsystem, and mesosystem factors contribute to therapeutic control. In general, investigators of factors influencing OAT therapeutic control variability have not utilized the full extent of constructs to explain differences. Particularly disturbing is the void of discussion on family and individual resiliency factors impacting adaptation to OAT. The importance of knowing whether there is a family and personal profile of characteristics related to positive adaptation to OAT therapy is clear. If such a profile could be detected, and resiliency factors identified, this would have practical relevance to planning nursing care

of those on OAT. For example, an individual with high anxiety and a family unable to communicate cooperatively may be at a greater risk for poor OAT adaptation than an individual with perseverance and family support.

### *Conceptual Framework*

The Resiliency Model of Family Stress, Adjustment and Adaptation (McCubbin & McCubbin, 1993) provides a framework for understanding OAT as a demand on a family member. This model emphasizes the importance of both individual and family strengths as resiliency factors contributing to individual family member well being. Key concepts include family type, levels of family perception, and problem solving capability.

Family types are defined by family system characteristics that determine how a family appraises, operates, and behaves. Several characteristics include family hardiness, family coherence, and family use of time and routines. Family appraisal includes three levels of stressor assessment. First, the family's defining of the event is the stressor appraisal. Second, the family's judgment of their current demands in relation to their resources is the situational appraisal. Third, the family's beliefs, values, shared identity and goals are the global assessment. Family problem solving incorporates coping and communication. Coping strategies procure resources, manage tension and demands, and change the meaning of a situation. Family member communication may amplify or palliate the event stress.

Stressors/strains and transitions (A) cause a family crisis (X). Family resources (B), family types and patterns of functioning (R), family's appraisal of the situation (C), and their problem solving and coping abilities (PSC) all work to influence the family's



adaptation. Positive adaptation, bonadaptation, is when the family stabilizes and achieves a sense of coherence and congruency when faced with a crisis. Negative adaptation, maladaptation, is when family members sacrifice personal development and growth, and the family functions in a chaotic state. The family demonstrates low overall sense of well-being, trust, sense of order, and coherence. Maladaptation is considered a crisis situation (X).

This model posits that family resources contribute to OAT adaptation. Therapeutic control, an objective measure of adaptation, reflects how much time the individual spends in a state protected from thrombosis. The subjective level of impact that OAT and its sequelae have on the individual adapting to therapy demands is reflected in QOL measurement.

The burden of OAT contributes to the pile-up of life changes (A) such as normative transitions, prior strains, and intrafamily and social ambiguity. Family may readily adapt to OAT demands when these are superimposed on family demands that are at a relatively lower level. OAT demands superimposed on an already high level of demands experienced by the family may contribute to diminished adaptation. Resiliency factors buffer the effects of demands and facilitate adaptation over time. These include family members' personal resources (B), personality and hardiness, and family system characteristics, family problem solving (PSC) and family hardiness (R).

Consider a family with a grandparent requiring assistance with activities of daily living and transportation to medical services (A), and a father recently diagnosed with atrial fibrillation requiring OAT (A). The hardiness of the father (B), defined by his

commitment to manage his OAT and his belief that he can influence the outcome of his OAT, supports him in obtaining blood tests in a timely manner and in making the required frequent medication adjustments, thus increasing his likelihood of bonadaptation. Further, family problem solving communication (FPSC), reflected in affirming communication that allows members to express needs and to cooperate, could support actions such as the father transporting the grandparent to a medical appointment and arranging to obtain his blood test at the same time prior to sharing lunch together. These activities support a more positive adaptation.

Figure 2 represents a conceptual model applicable to this situation, and includes the study variables. The concepts in the model were selected because of their relevance to the situation of families in which a member is receiving OAT. Family resiliency factors are discussed below in two sections. First, individual characteristics are addressed, followed by family characteristics. Related hypotheses are noted.

## DEMANDS

## RESILIENCY FACTORS

## OUTCOMES

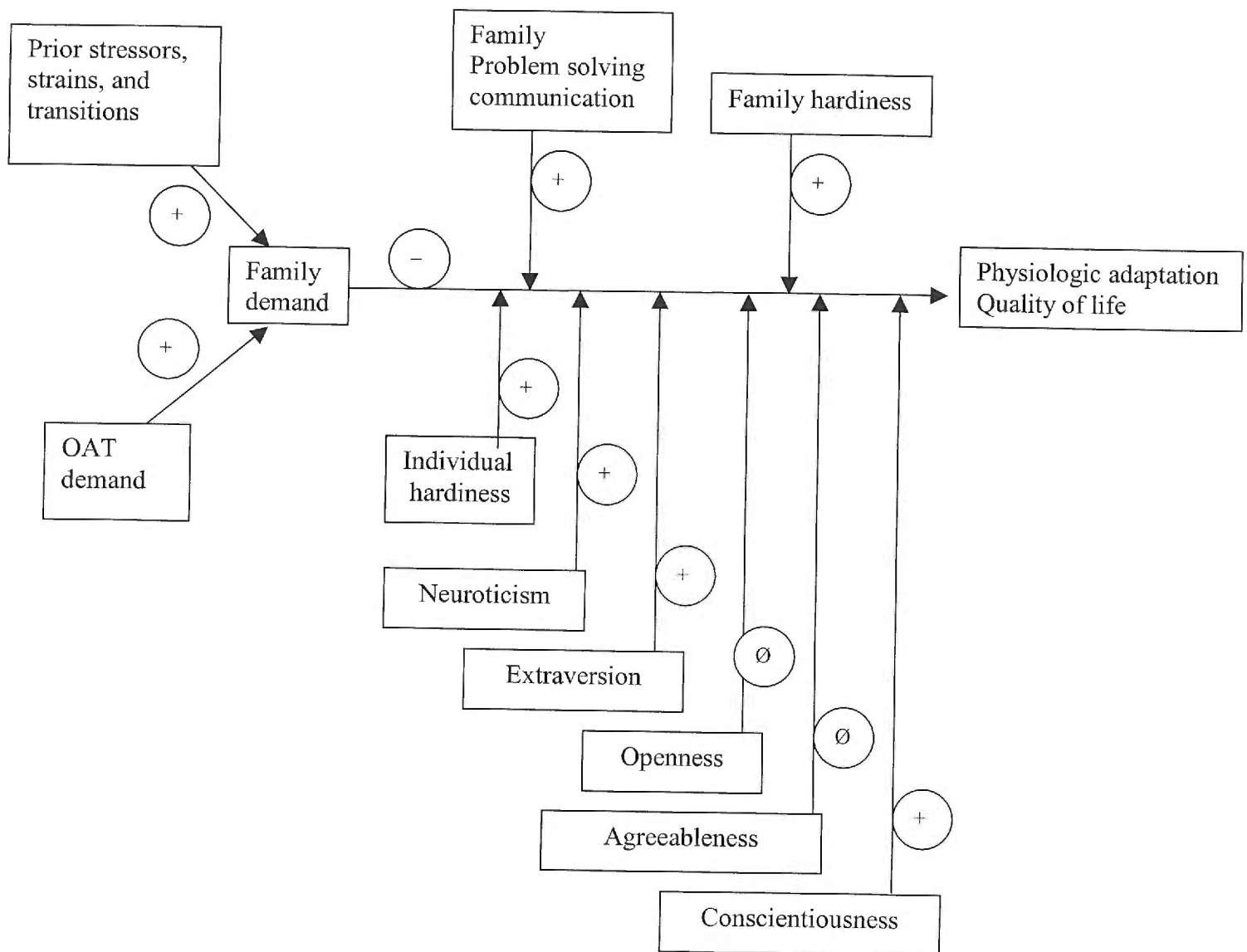


Figure 2. Conceptual Model:  
Resiliency factors in Oral Anticoagulation Therapy Adaptation

### *Individual Characteristics*

Nurses have always acknowledged the enduring dimensions of personality. Tanner, Benner, Chesla and Gordon (1993) reported that knowing patients and their personalities, modes of expression, and personal habits are central to expert nursing care. Nursing literature is silent regarding the personality resources of the individual that are clinically relevant to the ability to adapt to a complex medical regimen such as OAT. However, related literature regarding personality and hardiness of an individual demonstrates the link between personality characteristics and healthcare outcomes. This literature is reviewed below.

### *Individual Personality.*

In the fields of behavioral medicine and health psychology rests the literature of the influence of personality on health and disease (Suls & Rittenhouse, 1987). Theorists and researchers have explored three general issues: 1) the possible effect of personality traits on the development and course of disease, 2) the extent to which personality traits are causally related to specific health behaviors, and 3) the ways in which personality characteristics moderate the impact of acute medical stressors such as hospitalization, surgery and the transitions of chronic medical illness (Smith & Williams, 1992).

Smith and Williams (1992) argued that the five-factor model of personality contributes to the study of how personality influences health. The five-factor model addresses the individual differences in behavior tendencies, which are present early in life and are relatively stable across time and situation. Although personality is subject to changes caused by maturation and environment factors, its dimensions have been shown

to be rather stable (Carmichael & McGue, 1994). Personality traits are defined as biologically rooted and enduring characteristics that influence one's thoughts, feelings, and behaviors (Digman, 1990; McCrae & John, 1992). Neuroticism or emotional stability, extroversion, openness to experience, agreeableness, and conscientiousness compose the dimensions of the five-factor model. Developed over several decades, the five-factor model demonstrated temporal stability and convergent validity across sources of information, and measurement devices and validation procedures (Smith & Williams, 1992). Support for using the model within the context of OAT is presented below.

#### *Neuroticism.*

Neuroticism (N) is characterized by anxiety, tension, worry, poor inhibition of impulses, and helplessness, which may promote more maladaptive coping behavior. Neuroticism is not a robust predictor of actual physical health outcomes or mortality (Watson & Pennebaker, 1991). Many studies suggest individuals scoring high on measures of N also report more frequent physical illness, as well as more frequent and severe physical symptoms (Costa & McCrae, 1987; Watson & Pennebaker, 1991). Neuroticism was a predictor of poor health habits and practices (sleeping, eating breakfast, smoking, physical activity) in 978 Dutch men and women (Vingerhoets, Croon, Jennings & Menges, 1990). Neuroticism was positively correlated to avoidance coping and N was negatively associated with "coping by counting your blessings" in a study of 204 persons undergoing cardiac catheterization (Bosworth, Feaganes, Vitaliano, Mark & Siegler, 2001). In 200 persons successfully treated for primary head and neck squamous cell carcinoma, high neuroticism was associated with a low self-reported

quality of life (Aarstad, H., Aarstad, K., Birkhaug, Bru & Olofsson, 2003). Additionally, neuroticism was associated with decreased quality of life in 116 individuals living with HIV and AIDS (Penedo et al., 2003). Two longterm studies were identified. Neuroticism was a consistent predictor of poor adaptation (heightened levels of anxiety and depressed mood) to rheumatoid arthritis in 78 patients at 3 and 5-year follow-up visits (Evers, Kraaimaat, Greenen, Jacobs & Bijlsma, 2002). Neuroticism at diagnosis predicted poorer subjective quality of life at 4 and 12 months post-diagnosis in 84 adults (M = 31 years, 57% males) (Taylor, Frier, Gold & Deary, 2003).

The relationship between N and adaptation to OAT has yet to be explored. The impulsiveness and higher levels of anxiety associated with N may serve to impede adherence to OAT demands regardless of one's best intentions. Based on the above observations, increased N may correlate with decreased therapeutic control indirectly through decreased adherence to the demands of OAT. An individual who scores high in N may be more likely to react impulsively with respect to diet and activity, thus experiencing greater swings in vitamin K intake, abrupt changes in exercise patterns, and greater likelihood of engaging in risk behaviors. Feelings of helplessness may interfere with the individual taking control of his or her OAT therapy. Therefore, it is hypothesized that a decrease in neuroticism will lead to an increase in therapeutic control and quality of life (Hypothesis 1).

#### *Conscientiousness.*

Weibe and Christensen (1996) suggested that Conscientiousness (C) is the strongest trait descriptor of the qualities found important to the health behavior of adherence. This

construct is characterized by dependability, perseverance, self-discipline, will, and ability to delay gratification. It was the most consistent predictor of health behaviors in healthy samples of male military personnel (Booth-Kewley & Vickers, 1994).

Conscientiousness accounted for a significant increment in physiologic adaptation after accounting for age in a sample of 72 mixed aged adults ( $M = 46$ , 39% male) receiving renal dialysis (Christensen & Smith, 1995). In the study of women's breast screening behaviors, women who were high on conscientiousness were 64% (odds ratio 1.64, 1.2 – 2.3) more likely to engage in the positive health behavior (Siegler & Costa, 1994). Conscientiousness was associated with increased quality of life in 116 men and women living with HIV/AIDS (Penedo et al., 2003).

Conscientiousness is positively linked to health behavior through increased adherence and greater likelihood of engaging in proactive, health-promoting activities. Thus, increased conscientiousness may be linked to increased adherence to OAT demands through greater self-control in taking medications in a timely manner, and through more highly purposeful OAT management activities such as reporting the initiation of new prescriptive medications and over-the-counter herbal remedies. Further, increased conscientiousness has been linked with improved quality of life. Thus, it is hypothesized that an individual with high levels of conscientiousness will have a greater increase in therapeutic control and QOL (Hypothesis 2).

#### *Extroversion.*

Extroversion is defined as having a disposition towards positive emotions, sociability, and high activity. Extroversion was negatively related to avoidance coping in 204 adults

undergoing cardiac catheterization (Bosworth et al., 2001). In a study of 756 women and their breast screening behaviors, breast self-exam, and mammography, highly extroverted women were 44% (odds ratio 1.44, 1.05 – 1.97) more likely to engage in positive health behaviors (Siegler & Costa, 1994). Because of the frequent communication demands of OAT and the highly interactive activity required, an individual with high levels of extroversion is hypothesized to have a greater increase in therapeutic control, and, because of a tendency towards positive emotions, a corresponding greater QOL (Hypothesis 3).

*Openness to Experience.*

Openness to experience refers to a receptive orientation toward varied experiences and ideas. It was not related to coping in 204 adults undergoing cardiac catheterization (Bosworth et al., 2001). Openness was not significantly related to physiologic adaptation in a sample of 72 mixed aged adults ( $M = 46$ , 39% male) receiving renal dialysis (Christensen & Smith, 1995). Finally, women who scored high on openness to experience were no more or less likely to engage in positive health behaviors than women who scored low on openness to experience in the study of women's breast screening behaviors (Siegler & Costa, 1994). These studies suggest an individual's level of openness to experience is not related to therapeutic control and QOL (Hypothesis 4).

*Agreeableness.*

Agreeableness is an inclination towards interpersonal trust and consideration of others. Like openness, agreeableness is less likely than neuroticism, conscientiousness, and extraversion to be related to meeting the demands of a chronic illness. Agreeableness was



not related to coping (Bosworth et al., 2001), to physiologic adaptation (Christensen & Smith, 1995), or positive health behaviors (Siegler & Costa, 1994). Thus, it is hypothesized that individual's level of agreeableness is not related to therapeutic control and QOL (Hypothesis 5).

### *Individual Hardiness*

The individual hardiness resiliency factor was originally described as an individual personality characteristic to explain why, under challenging stressful life experiences, some individuals stay physically healthy and others become ill (Kobasa, 1979; Kobasa, Maddi & Kahn, 1982). Kobasa (1979), coming from an existential psychology background, developed the concept of individual hardiness. Hardiness is defined as “a constellation of personality characteristics that function as a resistance resource in the encounter with stressful life events” (Kobasa et al., 1982, p. 169). Three key dimensions of hardiness include: 1) control - the belief that individuals can influence life events, 2) commitment – the ability to sustain curiosity and feel deeply involved in life's activities, and 3) challenge – a view of change as normal and an exciting incentive for further development (Kobasa, Maddi, & Courington, 1981).

In a study of 230 liver transplant recipients (M = 50 years, S.D. 11.4, 57% male), higher levels of hardiness was found to be correlated with higher return to work rates (Newton, 1999). Hardiness explained 36% of the variance in compliance of 50 adults (M = 68, range 65 – 80, 60% male) with type II Diabetes (Ross, 1991). In a study of 50 families with children with disabilities, high levels of family support significantly

correlated with higher levels of hardiness, suggesting hardiness acted as a resistance resource that minimizes the effect of stress (Snowdon, Cameron & Dunham, 1994).

Jennings and Stagers (1994) criticized Kobasa's hardiness construct for its lack of distinction from other competing and complex constructs such as anxiety, locus of control, or social support. Yet, Pollock (1986) embraced the elements of hardiness which she believed work in combination as a variable that facilitates general resistance to stress, thereby improving chronic illness adaptation. Pollock (1989a) reported that hardiness correlated significantly with physiological adaptation ( $r = .43, p < .05$ ) in a study of 30 diabetic adults ( $M = 40$ , range 21 – 55, 30% male). Four studies confirmed Pollock's findings. First, lack of hardiness predicted decrease coping and increased tender points in 173 persons with fibromyalgia (Akkasilpa, Minor, Goldman, Magder & Petri, 2000). Increased hardiness predicted higher psychological adaptation and perceived quality of life (Farber et al., 2000) in 200 persons with symptomatic HIV and AIDS ( $M = 39$  years, 73% male). Third, hardiness also buffered the effects of stress on illness in 100 low-income women (Williams & Lawler, 2001). Finally, hardiness significantly contributed to psychological and physical function in 81 older adults ( $M = 75$  years, 90% female) with osteoarthritis (Byrdine, 2003). A single study (Taylor, Frier, Gold & Deary, 2003) examining 84 persons ( $Mdn = 31$  years, 57% male) with diabetes found increased hardiness was related to increased positive subjective (quality of life) but not significantly related to objective (glucose control) adaptation. Another study examining 122 women ( $M = 57$  years, range 21 – 80) with a chronic illness (rheumatoid arthritis) showed hardiness ( $p < .001$ ), and physical symptoms ( $p < .05$ ) significantly correlated with a

woman's ability to meet the demands of their disease (Lambert, Lambert, Klipple, & Mewshaw, 1990). Brooks (2003) performed a synthesis of health-related hardiness and chronic illness research, based on 125 articles published from 1966 to 2002, and concluded that increased health-related hardiness was significantly related to positive outcomes in psychological and physiological adaptation.

These results suggest a hardy individual on chronic anticoagulation therapy would be more likely to show improved adaptation. A person scoring high in hardiness may exhibit diligent medication-taking behavior and a greater sense of control over and engagement in OAT. A sixth hypothesis, then, asserts that an individual with high levels of hardiness will have a greater increase in therapeutic control and QOL (Hypothesis 6).

In summary, despite support for individual hardiness and personality factors having an association to chronic illness adaptation, there is surprisingly little nursing research examining these relationships. Addressing this unexplored area could increase our understanding of the role of individual characteristics in OAT adaptation and has the potential to help nurses to target those at risk for maladaptation. The nursing approach to someone who may be less hardy, and possesses personality characteristics at odds with successful management of OAT, may be very different than someone who is hardy, with personality characteristics compatible with OAT. The number of interventions potentially available to help an individual adjust to OAT may be greatly expanded by research focused on these individual resiliency factors.

### *Family Characteristics*

The information accumulated through the family focus of nursing promotes caring within the family context. The prominence of the family's role in a person adapting to a chronic illness is well established in the literature (Rankin & Weekes, 2000). Factors prevalent in families where successful adaptation occurs are the basis of our understanding. The Resiliency Model of Family Stress, Adjustment and Adaptation (McCubbin & McCubbin, 1993) seeks to describe these family factors and relationships.

Family problem solving and family hardiness are two influences that are related to chronic illness adaptation and seem particularly important in OAT adaptation. OAT demands include significant lifestyle changes frequently involving other family members. Consider the person on OAT who needs to stop smoking and is married to someone who smokes as well. Significant family problem solving needs to occur to meet the challenges of the required behavior change. Alternatively, consider a person with early cognitive dysfunction who demonstrates poor adherence to OAT and is unwilling to relinquish control of medicine-taking, yet is dependent on other family members for transportation to obtain the increased number of blood tests required due to missed pills. In this case, the ability of the family to endure and manage stress may direct successful adaptation. Tight control is not guaranteed despite strict adherence to therapy. Periods of poor control require more blood testing and involve increased physical risks, and frequently need to be endured both by the patient and the family. Although no specific research has addressed how family problem solving and hardiness impact these issues in OAT, related work is reviewed below.

*Family Problem Solving Communication.*

Family problem solving is recognized as a significant variable in family adaptation and functioning (Buehler, 2000). When confronting challenges, such as when families are adjusting to a member needing OAT therapy, families exhibit specific patterns of communication. The pattern may reflect a positive or a negative style of conflict resolution and problem solving. Problem solving refers to the family's ability to organize a stressor such as OAT therapy into manageable components, determine alternative courses of action, and cultivate patterns of communication needed to deal with the situation (McCubbin & McCubbin, 1991). McCubbin, Thompson and McCubbin, (1996) identified two key types of communication: 1) incendiary communication – inflammatory in nature and tending to exacerbate a stressful situation, and 2) affirming communication – conveys support and care and tending to exert a calming influence. Incendiary communication may contribute to unsuccessful adaptation in families, whereas affirming communication may contribute to successful adaptation.

Communications that include expressiveness, cohesion, and cooperation among family members have been linked to positive adjustment among people with disabilities (Alston & McCowan, 1995). In a study of 54 paired Caucasian parents and their children with disabilities incendiary communication was negatively related to family adaptation (Olsen, Marshall, Mandeleco, Allred, Dyches & Sansom, 1999). Earlier family problem solving was found to have contributed to positive outcomes for parents of young children with handicaps (Frey, Greenberg & Fewell, 1989). In a study of 51 adults ( $M = 37$  years,  $SD = 11.1$ , 25% male) in families with a critically injured family member, Leske and

colleagues (Leske & Jiricka, 1998) found that family strengths and capabilities explained an additional 44% of the variance in family adaptation after accounting for prior family stressors. In this study, problem solving communication was the only family strength and capability variable that contributed significantly to the overall variance in family adaptation ( $t=3.57$ ,  $p<.001$ ). In yet another study, Van Riper (2000) found family problem solving communication was significantly associated with sibling well-being in families of children with Down syndrome.

It is expected, in the current proposal, families demonstrating high problem solving communication may adapt to the needs of the family member on OAT more effectively. Such adaptation would be manifested by the family assisting the in transportation of the member to obtain blood tests, supporting medication-taking behaviors during family vacations and other transitions, and/or promoting stable dietary habits. No studies addressed family problem solving communication and QOL, but it is reasonable to expect more affirmative communication would be related to higher QOL through the domains of relationships and social support. Therefore, it is hypothesized that an individual reporting high levels of family problem solving communication will demonstrate increased levels of therapeutic control and QOL (Hypothesis 7).

#### *Family Hardiness.*

Family hardiness is a concept developed by McCubbin and McCubbin (1991) to “measure the characteristics of hardiness as a stress resistance and adaptation resource in families which would function as a buffer or mediating factor in mitigating the effects of stressors and demands ... “ (McCubbin & Thompson, 1987, p. 124). Key dimensions

include control, challenge, commitment, and confidence. This family hardiness refers to the internal strengths and durability of the family unit. Family hardiness is characterized by a sense of control over outcomes of life, a view of change as growth producing, and an active rather than passive orientation in adapting to stressful situations (McCubbin, & McCubbin, 1996).

Family hardiness has been explored as a dependent variable and an indicator of successful adaptation. In a sample of 54 parents of preschool-age children with disabilities, hierarchical regression analyses revealed perceived family support as a significant predictor of family hardiness for both parents (Olsen et al., 1999). Further, in the same study, hardiness was positively associated with family support in fathers ( $r = .51, p < .001$ ), and negatively associated with incendiary communication in mothers ( $r = -.49, p < .001$ ). Family hardiness directly related to the well-being of 76 families with young children diagnosed with asthma (Svavarsdottir, McCubbin, & Krane, 2000). In the best-fit model for 75 mothers the two main effects were individual sense of coherence and hardiness. Together, they accounted for 56% of the variance in mothers' well-being. In the best-fit model for 62 fathers there were three main effects including family systems demands, individual sense of coherence, and hardiness. These three accounted for 67% of the variance in fathers' well-being. A positive relationship has been found between family hardiness and family function (Failla & Jones, 1991) and family hardiness has been shown to be a facilitator of family adjustment and adaptation (McCubbin et al., 1991), and family cohesion and adaptability (Donnelly, 1994). Most studies have explored family hardiness in families with children. One study (Leske, 2003) explored

the family hardiness of 127 adult ( $M = 44$  years, 64% females) family members of trauma victims in critical care and found family hardiness scores were lower than the national norm. Investigators indicated that these vulnerable families have difficulty coping with family problems. This finding suggests the levels of family hardiness may vary in different adult populations depending on the types of health care stress they experience, and subsequently their adaptation may vary accordingly.

The research points to family hardiness as reflective of the family strengths that enhance adaptation. These family strengths include well-being, support, coherence, cohesion, and positive functioning, adjustment and adaptability. A family with a high degree of hardiness may demonstrate more successful adaptation to having a member confront the demands of OAT through increased family effort and participation in OAT management, and a willingness to cooperate with each other to meet OAT demands. Based on these findings, it is hypothesized that an individual reporting greater levels of family hardiness will demonstrate greater therapeutic control and QOL (Hypothesis 8).

In summary, there are clear conceptual links between adaptation and family hardiness and problem solving communication, and demonstrated association between these family factors and adaptation. Nonetheless, nursing research addressing these issues in OAT management is lacking. Exploring these associations within the anticoagulation population could contribute to identification of those at risk, and understanding the factors influencing successful nursing OAT interventions.



## Summary

The information gathered from the substantial body of OAT research is difficult to evaluate systematically because of the diversity in concept origins and the absence of an overriding theory. Family ecology theory provides the needed structure to begin to organize OAT information related to two specific outcomes, therapeutic control and quality of life. A synthesis of research within this framework makes noticeable two gaps in our knowledge. First, no studies address the influence of family despite a nursing assumption that chronic illness occurs within the context of family. Also overlooked is the influence of an individual's personality. Identification of the role family and personality resiliency factors play in the adaptation to OAT is the purpose of this study. Specific hypotheses are:

Hypothesis 1. A decrease in neuroticism will lead to an increase in therapeutic control and quality of life.

Hypothesis 2. An individual with high levels of conscientiousness will have a greater increase in therapeutic control and QOL.

Hypothesis 3. An individual with high levels of extroversion is hypothesized to have a greater increase in therapeutic control greater QOL.

Hypothesis 4. An individual's level of openness to experience is not related to therapeutic control and QOL.

Hypothesis 5. An individual's level of agreeableness is not related to therapeutic control and QOL.

Hypothesis 6. An individual with high levels of hardiness will have a greater increase in

therapeutic control and QOL.

Hypothesis 7. An individual reporting high levels of family problem solving communication will demonstrate increased levels of therapeutic control and QOL.

Hypothesis 8. An individual reporting greater levels of family hardiness will demonstrate greater therapeutic control and QOL.

## Methods

This crosssectional design was chosen to examine a representative model of OAT related resiliency factors as they occur in a natural setting. An ex post-factor or correlational design was used to examine individual study hypotheses.

### *Sample*

The target population was community-dwelling, independent men and women on long- term OAT. Subjects were recruited from an outpatient anticoagulation clinic of a major metropolitan university hospital. As the clinic serves the same number of males and females, equal gender distribution was targeted. Caucasians make up 70% of the clinic population. The minority distribution of the clinic includes 7% African-American, 6% Asian, 2 % Hispanic, and 1% Native American. Mean age of the clinic population was 59 years (range 13 to 92). Inclusion criteria was individuals who are age 18 years or older, had the ability to complete measures, were English speaking, and were currently on long-term anticoagulation, and had been so for 3 months or longer. Exclusion criteria included those with documented cognitive impairment, and those who were blind.

The required sample size was estimated by the equation that states 50 subjects plus 8 times the number of variables (9) in the study is needed for multiple regression (Tabachnick & Fidell, 1996, p.132-133). Further, 104 subjects plus the number of variables are required for individual predictors. The greatest sum of either of these is the latter, requiring 122 subjects. Both equations assume a medium-size relationship between the independent variable and the dependent variable, with  $\alpha = .05$  and  $\beta = .20$ .

### *Protection of Human Subjects*

Prior to study initiation, the Oregon Health and Sciences University's Institutional Review Board examined and approved the research to assure protection of the participants' rights. Participation was voluntary, and subjects were informed they may withdraw at any time during the study. Participants were informed that they would not benefit directly from participating in this study, but that the information gained may be used to assist health care providers to improve care of those on OAT. Confidentiality was maintained throughout the study. Participants were identified with a three-digit identification number. All records were kept in a locked cabinet in a locked office. The data from individuals was encoded into a personal computer using identification numbers only.

### *Data Collection/Procedures*

A poster identifying the study was posted in the OHSU anticoagulation clinic where patients are used to looking for study opportunities. Those individuals verbalizing an interest in the study to clinic clinicians were given further information on how to contact the research assistant at that time or at a later date. The research assistant reviewed consent elements with potential subjects. These subjects were given the opportunity to discuss their participation with family and friends. The principle investigator was available for any questions the research assistant was not able to answer. If the individual agreed to participate, the research assistant obtained a signed consent form (Appendix A) from the interested subject. After consent had been obtained, the research assistant randomly picked an unmarked study packet envelope from a box of similar envelopes.

Opening the envelope, the research assistant recorded the subject's INR test dates and results for the past 3 months on the INR code sheet (Appendix B). This sheet was the top sheet in the study packet. The INR code sheet was previously labeled with a random three-digit study number on the back (and therefore not visible to the research assistant).

The study number was the only identifying mark on the remaining data collection sheets in the study packet. Participants were given the packet and a pencil. A quiet place was provided for the subjects to complete the remaining measures undisturbed. A research assistant was available for questions during this time. The last page of the study packet asked subjects to check all pages of the study packet for unanswered items, to complete them, and then to return their forms in the study packet envelope. At that time, the subjects were reimbursed \$30 for their time and inconvenience. They were asked to sign for the monies received. All study materials were kept in a locked file cabinet in a locked office accessible only to the researcher and research assistant.

### *Measures*

Each of the instruments selected for use in the study are described in this section. The concepts measured include individual personality, individual hardiness, family level of stress, family problem solving, family hardiness, adherence, physiological adaptation, and quality of life. Table 1 summarizes the variable definitions, measures that were used, and psychometric characteristics.

### *Background data*

Standard demographic data were collected (Appendix C), including age, ethnicity, gender, completed education, and income. In addition, the number of chronic illnesses,

the number of current prescriptions, and the number of current non-prescription medications were counted.

### *Medicine-taking behavior*

Measuring medication-taking behavior is frequently problematic. Biochemical measures are not sensitive to daily variations in adherence or to overall levels of adherence (Kumar, 1989). Although there are many electronic devices available for use in studies of compliance (Scisney-Matlock et al., 2002), these devices are not routinely used by the study population. Because this study seeks to profile the population in a natural setting, the enhanced adherence accompanying electronic devices and medication diary measures was undesirable. Self-report had been the primary measure of adherence and was used in this study. The major tendency of this type of measure is for overestimation of actual adherence. This limitation is insignificant in this study, which is not concerned with actual adherence as an independent variable, but rather in identifying a clinically useful profile of an individual on OAT. Unfortunately, no validated questionnaire to measure general medication adherence has been identified. Medication compliance self-report measures for use with specific disease states, such as hyperlipidemia (Pineiro, Gil, Domis, Orozco, Torres & Merino, 1997), arthritis (de Klerk, van der Heijde, van der Tempel, & van der Linden, 1999), HIV (Duong et al., 2001), and psychiatric illnesses (Mulaik, 1992; Thompson, Kulkarni & Sergejew, 2000), have been developed and shown to be valid. Despite the estimation that 25% to 30% of individuals taking warfarin intentionally or accidentally misuse warfarin (Loken, 1992), no self-report measure exists to assess warfarin adherence. Therefore, as part of the background sheet, self-report of

adherence with oral anticoagulation medications was elicited with the following question:

In the past 4 weeks, have you missed or taken extra doses of your warfarin? If yes, the respondent was asked to identify number of missed and/or additional doses.

### *Five-Factor Personality*

Scientific study defines eight measurable components of personality, including the unconscious, the ego, the cognitive, the biological, the conditioning/shaping, the humanistic, the personal situation interaction, and the traits (Friedman & Schnskack, 1999). The trait component is based on an inductive model derived from research spanning over forty years, and concerns itself with the dimensions of personality. Controversy exists over whether as many as sixteen or as few as three dimensions exist. However, the utility of five dimensions has been confirmed in cross-cultural research, as well as research in populations of young and old, educated and uneducated (McCrae & John, 1992). Further, the emergence of the five dimensions has been found across units of analysis (self ratings, peer ratings, and spouse ratings) and across measures (self reports, behavioral observations, and biological testing).

Costa and McCrae (1992) operationalized the five-factor model with the NEO Five Factor Inventory (NEO-FFI) to be used when global information on personality is considered sufficient (Appendix D). A snowball sample of 983 adults (M 58 years, range 21 – 96 years, 50% male) from the Augmented Baltimore Longitudinal Study of Aging provided the normative sample. Extroversion, Agreeableness, Conscientiousness, Neuroticism, and Openness to Experience are the five domains of the measure. Internal consistency for the five scales is high with coefficients of .78, .76, .82, .86, and .71

respectively (median  $\alpha = .77$ ; range = .71 - .86). The current study's internal consistency is comparable for the five scales showing coefficients of .76, .79, .80, .82, and .74 respectively. The NEO-FFI scales correlate highly with the longer NEO-PI-R measure that has 181 items (median  $r = .90$ ). The convergent and divergent validity in their associations with other scales and ratings has been described (Costa & McCrae, 1992). The 60 items are rated on a five-point scale. This questionnaire is a convenient and reliable self-report consisting of a 60-item instrument, with 12 items each measuring the five major constructs. Items are rated on a 5-point scale (0=strongly agree, 1=disagree, 2=neutral, 3=agree, 4=strongly disagree). The NEO-FFI has a grade six reading level, and requires 10 – 15 minutes to complete. Reported normative scores for extroversion, agreeableness, conscientiousness, neuroticism, and openness are 27.69 (SD = 5.85), 32.84 (SD = 4.97), 34.57 (SD = 5.88), 19.07 (SD = 7.68) and 27.03 (SD = 5.84) respectively.

The NEO-FFI is a prominent measure of the five-factor model of normal personality traits. Researchers substantiated the model's psychometrics over the past several decades. The NEO-FFI is a useful and convenient measure for ascertaining the nature and degree of an individual's personality. Its developers focused on how the five domains are related to other measures of mental, social, and occupational functioning rather than on measures of health care outcomes. To address this limitation, a second measure was used and is described below.



### *Individual Hardiness*

The Health Related Hardiness Scale (HRHS) (Appendix E) is appropriate for this study as it was developed specifically for use in healthcare. Pollock (1989b) developed the HRHS to measure the hardiness characteristic in people with potential or actual health problems. Through vigorous psychometric testing (Pollock & Duffy, 1990), Pollock reported item to concept validity assessments for her HRHS measurement in the chronically ill population, supporting the multidimensional hardiness construct. These psychometrics are presented below.

Theoretical definitions of health-related control, commitment, and challenge were used to generate items that measured the presence of hardiness. In a sample of 389 subjects with chronic illness (diabetes mellitus  $N = 205$ ; multiple sclerosis  $N = 124$ ; hypertension  $N = 32$ ; rheumatoid arthritis  $N = 24$ ), two factors were isolated using principal components analysis. The two factors were Challenge/Commitment (CC) and Control (C). Together, these two factors accounted for 32.1% of the initially extracted common variance. The first factor, CC, had an eigenvalue of 8.2, and accounted for 24.0% of the variance. Factor C, with an eigenvalue of 2.9, accounted for 8.1% of the variance. Factor loadings were strong, ranging from .49 to .68. No significant side loadings were noted in the pattern matrix. The reliability for both the 20-item CC scale and the 14-item C scale was .87. Item-total correlations for all subscores and total scores exceeded .30. Cronbach's alpha for the 34 items in the HRHS demonstrated high internal consistency with  $\alpha = .91$  (current study showed slightly less internal consistency with  $\alpha = .78$ ). Test-retest total scale reliability was .76 in a subgroup of 150 subjects with diabetes who

completed the test on two separate occasions divided by a 6-month interval. Subscale test-retest reliabilities were .74 and .78 for the CC and C subscales respectively.

Convergent validity was demonstrated in a pilot study of 50 healthy adults who were given both the Hardiness Scale and the HRHS. A statistically significant correlation of .54 was recorded. Further, the HRHS score, but not the Hardiness Scale score, was positively correlated with perceived health status ( $r = .28, p < .05$ ), engagement in health promotion activities ( $r = .23, p < .05$ ), and the use of social resources ( $r = .45, p < .05$ ).

Table 1

*Summary of Individual Personality Measures*

Concept and Conceptual definition	Measure Name, Number of Items, Response Format, Example of Items	Meaning of Scores and Time to Complete	Reliability (Cronbach's alpha)
<b>Personality.</b> Stable traits that determine thoughts, feelings, and behaviors. Traits include neuroticism, extroversion, openness to experience, agreeableness, and conscientiousness.	NEO-Five Factor Inventory (Costa & Costa, 1992). A 60-item 5-point Likert scale (0=strongly agree, 1=disagree, 2=neutral, 3=agree, 4=strongly disagree). <u>Sample item:</u> "Once I find the right way to do something, I stick to it." (conscientiousness).	Higher scores reflect greater presence of trait. 10 – 15 minutes to complete.	Overall scale reliability .77
<b>Individual Hardiness.</b> Personality characteristics that function as a resistance resource in the encounter with stressful life events. These characteristics include control/commitment, and challenge.	Health Related Hardiness Scale (Pollock). A 34-item 6-point Likert scale (Strongly Agree to Strongly Disagree). <u>Sample item:</u> "The main thing that affects my health is what I do." (control), "No matter how hard I try to maintain my health, my efforts will accomplish very little." (challenge/commitment).	Higher scores reflect greater presence of hardiness. 8-12 minutes to complete.	Overall scale reliability = .91, 6-month test-retest = .76

The 34 question HRHS is a 6-point Likert-type scale with responses ranging from 1 (agree strongly) to 6 (disagree strongly). Several items are reverse-coded to address bias in response. Items are totaled for an overall score, which ranges from 34 to 204, with higher score indicating presence of hardiness. Comparative scores in 60 chronically ill individuals ( $M = 42$  years, 63% female) out of which 20 had diabetes, 20 had arthritis, and 20 had hypertension, showed a mean score of .....(Pollock's z-score article).

### *Family Stress*

The Family Inventory of Life Events and Changes (FILE) (Appendix F) assesses the normative and non-normative pile-up of life events and changes a family experienced in the past year and is a measure of family stress (McCubbin, Patterson, Wilson, 1983). It has been used with families who have a member with chronic illness, such as cancer, cystic fibrosis, myelomeningocele, cerebral palsy, AIDS, diabetes mellitus, and congenital heart disease. Each item is written to identify a change of sufficient magnitude to require some adjustment in the interaction of family members.

A sample of 322 adults with a member in their family having a chronic illness diagnosis was used to assess internal consistency. The overall internal consistency (Cronbach's  $\alpha$ ) for the FILE is .81 (this study showed slightly increased internal consistency with  $\alpha = .84$ ). Subscale reliability scores are more variable (.73 - .30), indicating internal consistency of the total scale is established, but subscales are less stable and therefore not recommended to be used separately. Discriminant analysis showed the measure identified low conflict families as significantly different from high conflict families. Construct validity of the FILE was shown by correlating the ten scales

from FILE with a measure of family functioning – the Family Environment Scale (FES) (Moos, 1974). Significant correlations were found for cohesion ( $r = -.24$ ) and conflict ( $r = .23$ ). A test-retest reliability study was conducted on 150 subjects over a four-week period. Pearson's correlations for each of the nine scales ranged from .64 to .84, with the total scale correlation equal to .80.

The FILE (Form C) is a 71-item self-report scale with 9 subscales including Intrafamily Strains, Marital Strains, Pregnancy & Childbearing Strains, Finance and Business Strains, Work-Family Transitions & Strains, Illness & Family "Care" Strains, Losses, Transitions "In and Out", and Family Legal Violations. The family member records whether the life events happened to any member of the family in the last year (Yes /No). Responses are summed for the subscales and total scale with a higher score indicating greater stress. Normative mean score (McCubbin, Patterson & Wilson, 1983) was 8.81 (SD = 5.85) and was obtained from a sample of 980 couples (1,960 individuals) that ranged from young couples to those retired (mean age was not reported).

#### *Family Hardiness*

Several instruments exist to measure family strength. Despite lacking theoretical clarity on how hardiness was extrapolated from the individual to the family (Jennings, 1994), the Family Hardiness Index (FHI) (Appendix G) remains the most frequently used measure (McCubbin, McCubbin, & Thompson, 1991). It was created specifically for measuring the characteristic of hardiness as a mediating factor to family stress, as conceptualized in the Resiliency Model of Family Stress, Adjustment and Adaptation. Three subscales including Commitment (the family's sense of internal strengths,

dependability and ability to work together), Challenge (the family's efforts to be innovative, active, to experience new things and to learn), and Control (the family's sense of being in control of family life rather than being shaped by outside events and circumstances). The measure has been used in families with members with a chronic illness such as asthma, physical disability, and mental retardation (McCubbin, et al., 1991).

The overall internal reliability is .82, with subscale coefficients of .81 (Commitment), .80 (Challenge), and .65 (Control). The current study showed overall internal consistency  $\alpha = .83$ . The test-retest reliability was reported as  $r = .86$ . No content validity is reported. A factor analysis of the subscales provided evidence for construct validity (factor loading .52 to .85) and supports conceptualization of family hardiness as a multidimensional construct. Concurrent validity was demonstrated by correlations with other measures of family functioning. Correlations with FACES II ( $r = .22$ ) and Family Time and Routines ( $r = .23$ ) were originally reported. Subsequently, the Family Functioning Style Scale was reported to correlated with the total FHI at  $r = .67$  (Trivette, Dunst, Deal, Hammer & Propst, 1990).

The FHI is a 20-item scale composed of 3 subscales: control, challenge, and commitment. The family member assesses the degree to which each statement describes his or her current family situation. Responses vary from False=0, Mostly False=1, Mostly True=2, True=3. After reversing several item scores, all scores are summed to obtain a value ranging from 0 to 60, with the larger score indicating greater family hardiness. Normative data on this instrument are not available. Comparison data are available from

304 families (McCubbin, McCubbin, & Thompson, 1991) who displayed a mean score of 47.38 (SD = 6.72).

### *Family Problem Solving and Communication*

The Family Problem Solving and Communication Index (FPSC) (Appendix H) was developed to assess positive and negative patterns of communication needed for family coping (McCubbin & Thompson, 1988). It was developed specifically for family stress and resiliency research. An underlying assumption is that the quality of family communication determines to a measurable degree how families manage tension and strain and acquire a satisfactory level of functioning, adjustment, and adaptation.

Overall reported reliability is .89 (current study  $\alpha = .87$ ). Incendiary communication had an alpha coefficient of .78 and affirming communication had an alpha coefficient of .86. Construct validity has been confirmed through two independent factor analyses. Concurrent validity was confirmed through the correlations of the FPSC with other established criterion measures of family functioning (McCubbin & Thompson, 1989), specifically family hardiness, family cohesion, family system distress, and self actualization. Test-retest reliability for the two subscales and overall FPSC was  $r = .86$ .

The FPSC is a 10-item instrument consisting of two 5-item subscales: incendiary communication and affirming communication. The items are scored with a Likert scale (0=False, 1=Mostly False, 2=Mostly True, 3=True). Incendiary and affirming communication may be scored separately. In addition, a total score may be obtained by reversing certain items to obtain a positive score for all affirming and non-incendiary

communication. Comparative data (McCubbin, McCubbin & Thompson, 1988) from 233 adults (50% male) showed a mean score of 22.69 (SD = 4.65).

To the knowledge of this investigator, this measure has not been used in families with members experiencing chronic illness, and its psychometric rigor is less established. However, its complementary development with both FHI and FILE support its use in this study.



Table 2

*Summary of Family Measures*

Concept and Conceptual definition	Measure Name, Number of Items, Response Format, Example of Items	Meaning of Scores and Time to Complete	Reliability (Cronbach's alpha)
<b>Family Stress.</b> The pile up of changes and demands, both normative and non-normative, experienced by a family in the past year to which a subsequent stressor is added.	Family Inventory of Life Events and Changes (McCubbin, Patterson, & Wilson, 1983). A 71-item self-report checking Yes or No. <u>Sample item</u> : "During the last 12 months a (family) member went on welfare."	Higher scores reflect a greater pile-up of demands and family stress. 15 minutes to complete.	Overall scale reliability = .81, 4-week test retest = .80
<b>Family Hardiness.</b> The basic strength families call upon to manage the hardships and difficulties.	Family Hardiness Index (McCubbin, McCubbin, & Thompson, 1986). A 20-item 4-point Likert scale (0=false, 1=mostly false, 2=mostly true, 3=true). <u>Sample item</u> : "We have a sense of being strong even when we face big problems."	Higher score indicates greater family hardiness. 8 minutes to complete.	Overall scale reliability .82, test-retest = .86
<b>Family Problem Solving.</b> The context of family interaction reflecting coping strategies and problem solving that a family uses to respond to and resolve physical hardships and difficulties.	Family Problem Solving Communication (McCubbin, McCubbin, & Thompson, 1988). A 10-item 4-point Likert scale (0=false, 1=mostly false, 2=mostly true, 3=true). <u>Sample item</u> : We work to be calm and talk things through.	Higher scores indicate greater problem solving communication. 5 minutes to complete.	Overall scale reliability .89

### *Therapeutic Control*

Therapeutic control was measured by the time an individual spends therapeutically anticoagulated during the 3 months preceding the study. An assumption was made that the INR value between two consecutive measurements is linear; the method used to calculate time spent therapeutically controlled is described elsewhere (Rodendaal, Cannegieter, van der Meer, & Briet, 1993). The percent time spent in range will be approximated by dividing the period between two consecutive INR measurements in days, and to use small incremental steps of increasing or decreasing INR over the range of the time interval. For example, a two-week period separates two INR measurements of 2.6 and 3.3. We divide the period between measurements in days (14), and use 0.1 INR increments over the time interval. Thus, two days are allocated to an INR of 2.6, 2 days to an INR of 2.7, and so on. The number of days spent below range, in range, and above range were summed, and percentages computed for supratherapeutic, therapeutic, and subtherapeutic periods.

### *Quality of Life*

The subjective feelings a person may have about the quality of their lives while adapting to OAT was measured by a quality of life measure. The Quality of Life Scale (QOLS) (Appendix I) measures a persons subjective perceptions and includes the constituent domains of life that are important to person's with chronic illness (Burkhardt, Woods, Schultz and Ziebarth, 1989). These domains include material comforts and financial security, health, relationships, learning, work, social life, and spirituality.

The original 15-item instrument was developed on a random sample of 3000 American men and women (Flanagan, 1982). Factor analysis of the scale items demonstrated construct validity and the multidimensional nature of the instrument. A qualitative study revealed the need for an additional item reflecting the importance of independence in the chronically ill population (Burckhardt et al., 1989) and a 16<sup>th</sup> item was added. The 7-point Delighted-Terrible Scale was shown to be more sensitive and less negatively skewed than the 5-point satisfaction scale (Andrews & Crandall, 1976).

Internal consistency reported averaged .87 (range .82 - .92) (Burckhardt, Archenholtz, & Bejelle, 1992; Burckhardt, Woods, Schultz & Ziebarth, 1989; Neumann & Buskila, 1997; Wahl, Burckhardt, Wiklund & Hanestad, 1998). Test-retest reliability over 3 weeks was .78 in the American version (Burckhardt et al., 1989), .83 in the Norwegian version (Wahl et al., 1998), .84 in the Swedish version over 4 weeks (Burckhardt et al., 1992), and .98 in the Hebrew version over 1 week (Neumann & Buskila, 1997). The current study had internal consistency  $\alpha = .88$ . The QOLS correlates with other quality of life instruments including The Life Satisfaction Inventory-Z ( $r = .67 - .75$ ) (Burckhardt et al., 1989) and a measure of global well-being ( $r = .69$ ) (Neumann & Buskila, 1997). QOLS scores (Burckhardt, Clark & Bennett, 1993), from 223 subjects with fibromyalgia ( $n = 60$ ), rheumatoid arthritis ( $n = 31$ ), osteoarthritis ( $n = 41$ ), permanent ostomies ( $n = 29$ ), chronic obstructive pulmonary disease ( $n = 27$ ), and insulin dependent diabetes ( $n = 35$ ), demonstrated a mean score of 76.42 (SD = 11.93). A comparative group of well adults in the same study demonstrated a mean QOLS score of 83.2 (SD = 7.5).

Table 3

*Summary of Dependent Variable Measures*

Concept and Conceptual definition	Measure Name, Number of Items, Response Format, Example of Items	Meaning of Scores and Time to Complete	Reliability (Cronbach's alpha)
<b>Therapeutic control</b> The amount of time an individual spends therapeutically anticoagulated.			Coefficient of variability 4.70.
<b>Quality of Life.</b> The subjective feelings persons who are coping with a chronic illness have about the quality of their lives.	Quality of Life Scale (Flanagan, 1978). A 15-item 7-point summated rating scale (7=delighted, 6=pleased, 5=mostly satisfied, 4=mixed, 3=mostly dissatisfied, 2=unhappy, 1=terrible). <u>Sample item</u> : "Independence, doing for yourself."	A higher score indicates a higher quality of life. 8 minutes to complete.	Overall scale reliability .87, 3-week test-retest = .78

### *Data analysis*

SPSS (version 9.0) was used to carry out all analyses. Central tendency statistics were calculated to describe the study sample and all variables. The variables portrayed include background variables (age, ethnicity, gender, education, relationship status, income, number of chronic conditions, number of current prescriptions, and the number of over-the-counter medications), family variables (family stress, family hardiness, and family problem solving), individual characteristics (individual hardiness and personality) and dependent variables (therapeutic control and quality of life).

Frequency and explore programs checked the accuracy of data entry, missing values, and the fit between the variable distributions and the statistical test assumptions. Normal probability plots and the Kolmogorov-Smirnov statistic tested normality. The Levene test statistic was used to confirm homogeneity of variance. Outliers were identified by the boxplot and stem-and-leaf method.

Internal consistency reliabilities (Cronbach's  $\alpha$ ) were computed for all of the scales and subscales. Only cases containing all items for the scale being calculated were utilized.

Bivariate correlational analysis assessed relationships between variables, Pearson's correlation coefficient for continuous linear variables and Spearman rho for nominal, ordinal, and non-normally distributed variables. Pearson's chi-square tested nominal and ordinal variable differences of means; t-test for independent samples and ANOVA tested differences in means of categorical independent variables.

Multiple linear regression analyses tested the hypotheses after forcing in variables controlled for. Predictive models were built using variable selection based on correlations and theoretical considerations. The statistical assumptions of normal distribution, linearity, homoscedasticity, and uncorrelated residuals of multiple regression were examined. A normal probability plot of the residuals, which plots each residual against its expected values under normality, assessed the skewness, kurtosis, outliers and the normality of the error distribution. The criterion for Mahalanobis distance identifying outliers was  $p < .001$ . A plot of the residuals against the fitted values was used to assess the appropriateness of the multiple regression function and the constancy of the variance of error terms. Partial regression plots were used to examine the relationship between independent variables given the other variables. For main effects, statistical significance was set at  $p < 0.05$ ; significance for interactions was set at  $p < 0.10$ . A case was considered to impact parameter estimates if its removal resulted in a change of more than 2% in one or more coefficient estimates. Adjusted R squared was the primary measurement of goodness of fit for the regression models.

## Chapter 4

### Results

#### *Characteristics of the Sample*

The final sample consisted of 62 females (55%) and 50 males (45%). The total number of individuals was 112, 10 subjects short of the number required for regression analysis. The two variables, openness and agreeableness, whose null hypothesis suggested no relationship to the dependent variables, were dropped from analysis. Thus, adequate power of analysis was assured with the least impact on the study's aim.

Three individuals omitted income status and two omitted employment status. Three outliers, who were outliers with respect to two or more variable, were dropped from the sample in order to meet assumptions of statistical tests. The subjects dropped included one 42 year old African American female and one 57 year old Caucasian male, both who were never therapeutically controlled, and the male had an extremely low quality of life score (40). In addition, one 84 year old Asian male with an extremely low family hardiness score (28) and family problem-solving score (5) was excluded from analysis. Seven other outliers who were more representative of the target population but were outliers with respect to a single variable were retained. Their scores were adjusted and remained in the analysis, but steps were taken to reduce their impact by substituting a raw score on the offending variable that was one unit larger (or smaller) than the next most extreme score in the distribution (Tabachinick & Fidell, 1996, p. 69). This method has a tendency to make it harder to identify relationships, but this trade-off was chosen as it

allowed normality assumptions to be met without the need to consider transformations, which clinically are sometimes hard to conceptualize.

### *Background Characteristics*

Background data included demographic and health characteristics. Demographic characteristics are shown in Table 4 (age and education) and Table 5 (ethnicity, gender, income, marital and employment status). The participants were predominantly Caucasian ( $n = 102$ , 91%). Six were Native American, one was African American, one was Asian, and two marked the “other” category. This homogeneity precludes ethnic-specific analysis. The mean age of the participants was 59 years ( $SD = 16$ ). Age ranged from 24 to 91 years (normally distributed). This age range is reflective of the indications for warfarin, many of which increase with age. More than half of the participants were married or living with a partner ( $n = 69$ , 62%). Over one third ( $n = 43$ , 38%) did not have a partner. Seventeen (15%) participants were divorced, 16 (14%) were single, and 10 (9%) were widowed. The majority of the sample had more than a high school education, with the mean number of years of education being 14 years ( $SD = 2.21$ ). The education level in the sample ranged from 8 to more than 17 years. Seven percent ( $n = 8$ ) had not obtained a high school education; fourteen percent ( $n=16$ ) had graduated from college.

Half the sample was retired ( $n = 55$ , 50%), 27 (24%) were unemployed, 21 (19%) were employed full time, and 8 (7%) were employed part-time. Over one half had an income less than \$24,000, with a third ( $n = 45$ , 41%) having an income between \$5,000 and \$24,000, and 12% ( $n = 13$ ) less than \$5,000. One third (25%,  $n = 27$ ) had an annual



income between \$25,000 and \$49,999, and one fifth (22%,  $n = 24$ ) had gross annual incomes of \$50,000 or more. More than half of the sample had medicare funding ( $n = 62$ , 54%), again reflecting the older population. A third ( $n = 41$ , 35%) had other health insurance, 11 (9%) had Medicaid, and one was self-pay.



Table 5

*Sample Characteristics: Ethnicity, Gender, Marital Status, Income, Employment Status*

Characteristic	N	%
Ethnicity		
Caucasian	102	91
Native American	6	5
African American	1	1
Asian	1	1
Other	2	2
Gender		
Female	62	55
Male	50	45
Marital Status		
Married/living with partner	69	62
Single	16	14
Divorced	17	15
Widowed	10	9
Income		
< \$5,000	13	12
\$5,000 - \$24,999	45	41
\$25,000 - \$49,999	27	25
\$50,000 and greater	24	22
Employment Status		
Full time	21	19
Part time	8	7
Unemployed	27	24
Retired	55	50

Health characteristics are summarized in Table 6. The most common indication for anticoagulation was atrial arrhythmia ( $n = 40$ , 36%). Venous thromboemboli (deep vein thrombosis and/or pulmonary emboli) was the indication for 28% ( $n = 32$ ) of the participants. Mechanical heart valve was the indication for 28 (17%) of the participants. Other less frequent indications ( $n = 21$ , 19%) included arterial emboli, hypercoagulable state, cardiomyopathy, and cerebral vascular accident.

By far, the majority ( $n = 95$ , 85%) took 5 or fewer over-the-counter (OTC) medicines. Fourteen (13%) participants regularly took 5 to 9 OTC medications, and 3 participants took between 10 and 14 OTC medications. Thirteen percent ( $n = 14$ ) of participants took prescription aspirin, reflecting the growing number of individuals on combined anticoagulant and antiplatelet therapy. The majority of the participants ( $n = 96$ , 86%) reported they had adhered to the prescribed warfarin schedule during the past week. Twelve missed at least one dose, four reported having taken at least one additional dose, and one individual reported having missed a dose and taking an extra dose. Sixteen (13%, males = 50%) individuals regularly used tobacco. This rate is less than the United States median prevalence of 23.4% and Oregon's 20.5% prevalence (MMMR weekly 2003; 52:303-07). The mean age of those who smoked tobacco ( $M = 51.6$ ,  $SD = 14.4$ ) was less than those who did not smoke tobacco ( $M = 60.5$ ,  $SD = 15.8$ ). Three-fourths ( $n = 88$ , 78%) reported using some memory enhancing device to assist them in taking medications as ordered. The number of prothrombin tests ( $M = 10.22$ ,  $Mdn = 9.64$ ,  $SD = 5.39$ ) in the 3 month period was positively skewed (1.90) and kurtotic (3.45).

Table 6

*Health Characteristics: Anticoagulation (AC) Indication, Prescription Medications, Over-The-Counter (OTC) Medications, Prescription Aspirin, Adherence, Tobacco, Memory Device*

Characteristic	N	%	<u>M</u>	<u>SD</u>
AC Indication				
Atrial Fibrillation	40	36		
Venous Thrombosis	32	28		
Mechanical Heart Valve	19	17		
Other	21	19		
OTC Medications				
<5	95	85		
5 - 9	14	13		
10 - 14	3	3		
Prescription Aspirin	14	13		
Adherence	96	86		
Tobacco	16	13		
Memory Device	88	78		
Chronic Conditions			2.6	1.9
Prescription Medications			6.5	4.1
Prothrombin tests			10.2	5.4
<u>M</u> =Mean, <u>SD</u> =Standard Deviation				

The number of prescription medications ranged from 0 – 18, with most subjects taking 6 medications (  $M = 6.5$ ,  $SD = 4.1$ ). The number of chronic conditions (Table 7) in addition to indication for anticoagulation ranged from 0 to 8 ( $M = 2.6$ ,  $SD = 1.9$ ). Conditions represented, in descending order (see Table 7), included heart disease ( $n = 55$ , 49%), hypertension ( $n = 46$ , 39%), hypercholesterolemia ( $n = 36$ , 32%), thyroid disease ( $n = 22$ , 20%), obesity ( $n = 21$ , 18%), gastrointestinal disease ( $n = 14$ , 12%), diabetes mellitus ( $n = 15$ , 13%), lung disease ( $n = 12$ , 11%), mental illness ( $n = 11$ , 10%), cancer ( $n = 10$ , 9%), liver disease ( $n = 6$ , 5%), renal disease ( $n = 6$ , 5%), alcohol or illicit drug use ( $n = 3$ , 3%), and other ( $n = 29$ , 25%).

#### *Individual Variables*

Neuroticism (N), conscientiousness (C) and extroversion (E), were measured by the NEO-FFI personality test. Three individuals omitted one response on the NEO-FFI and the average or neutral responses were substituted. One individual triple answered a single question and the middle value was used. Each of the five personality variable scores had a possible range of 0 – 60, with a higher score representing greater presence of the characteristic. No outliers were found and assumptions of normality were met, eliminating the need for data transformation.

The mean score on neuroticism (anxiety, poor inhibition of impulses, and helplessness) was 17.49 (range = 2-45,  $SD = 8.02$ ). For conscientiousness (dependability, perseverance, self-discipline, will, and ability to delay gratification), the mean score was 33.97 (range = 4 - 48,  $SD = 6.64$ ). The mean score of extroversion (positive emotions, sociability, and high activity) was 27.79 (range = 8 - 46,  $SD = 6.62$ ).

Table 7

*Additional Chronic Conditions*

Condition	N	%
Heart Disease	55	49
Hypertension	44	39
Hypercholesterolemia	36	32
Thyroid Disease	22	20
Obesity	21	18
Gastrointestinal	14	12
Diabetes Mellitus	15	13
Lung Disease	12	11
Mental Illness	11	10
Cancer	10	9
Liver Disease	6	5
Renal Disease	6	5
Alcohol or illicit drug use	3	3
Other	29	25

Except for neuroticism, central tendency scores are similar to normative scores with slightly larger standard deviations, most likely reflecting a smaller sample size (see Table 8). The study sample had a lower than normal neuroticism mean (17.49 compared to 19.07 respectively).

Individual hardiness (sustaining curiosity, feeling deeply involved in life, viewing change as normal and exciting, and believing that individuals influence events) was measured by the Health Related Hardiness Scale (HRHS). One subject omitted a response on the HRHS questionnaire; a neutral response was substituted. Individual hardiness scores had a possible range of 0 - 204 and an actual range of 101 – 171. The higher score reflects greater presence of the hardiness trait. The mean score was 142.57 (SD = 15.58). No outliers were found and the assumption of normality was met.



Table 8

*Individual Characteristics: Neuroticism, Conscientiousness, Extroversion, and Individual Hardiness (HRHS)*

Characteristic	Range	Study Population		Normative Population	
		<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>
Neuroticism	2 – 45	17.49	8.02	19.07	7.68
Conscientiousness	14 – 48	33.97	6.64	34.57	5.88
Extroversion	8 – 46	27.79	6.62	27.69	5.85
HRHS	101 - 171	142.5	16.6		

M=Mean, SD=Standard Deviation

### Family Variables

Central tendency statistics for family problem-solving communication, family hardiness, and family related stress are summarized in Table 9 and approximate the comparative population statistics. Family problem-solving communication (positive and negative patterns of communication in coping families) was measured by the Family Problem Solving Communication test. This measure has a possible range of 0 – 30, with a higher score indicating more positive family communication. In this study, scores ranged from 5 to 30. The mean score was 21.33 ( $SD = 5.19$ ) and distribution was positively skewed. Six outliers with scores ranging from 5 to 10 were found. The two with the lowest scores also were outliers with respect to therapeutic control and family hardiness, respectively, and therefore were dropped from analysis. The remaining four outliers had scores ranging from 8 – 10 and a score of 13 was substituted (lowest score excluding outliers was 14). The new mean score was 22.76 ( $SD = 4.38$ ) and scores were normally distributed.

Family hardiness scores (internal strength, dependability, ability to work together and to learn, controlling family life rather than being shaped by outside events) as measured by the Family Hardiness Index (FHI) had a possible range of 0 to 60. A larger score indicates greater family hardiness. The sample scores ranged from 28 to 59 with a normal distribution. The mean was 47.81 ( $SD = 6.73$ ), comparable to the comparative mean of 47.37 ( $SD = 6.72$ ).

Family related stress (the normative and non-normative pile-up of life changes a family experienced in the past year) was measured by the Family Inventory of Life's Events and changes (FILE) test. This measure had a possible score range of 0 to 71. Actual scores ranged from 0 to 33, with a sample mean of 8.91 ( $SD = 6.47$ ). Two outliers with extreme scores of 28 and 33 were identified. In the present study model this variable was not a predictor variable but a variable to be controlled. Rather than omit data from these individuals who otherwise were representative of the study population, a score of 25 was substituted for both scores (one unit above the next highest score of 24). The resulting mean was 8.85 ( $SD = 6.18$ ) and scores were normally distributed.

Table 9

*Family Characteristics: Family Hardiness (FHI), Family Stress (FILE), Family Problem-Solving Communications (FPSC)*

Characteristic	Study Population			Comparative Population	
	Range	<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>
FHI	31 - 59	47.81	6.47	47.38	6.72
FILE	0 - 25	8.85	6.18	8.81	5.85
FPSC	13 - 30	22.76	4.38	22.69	4.65

M=Mean, SD=Standard Deviation

### *Dependent Variables*

The two dependent outcomes were quality of life (QOL) and therapeutic control (TC). One individual omitted a single response on the QOL measure of quality of life. An average or “neutral” response was substituted. Study QOL scores ranged from 41 to 112 out of a possible range of 16 to 112. The mean QOL score was 85.74 (SD = 13.82), somewhat higher than the reported mean 76.42 (SD = 11.93) of chronically ill persons, and slightly higher than the reported mean 83.2 (SD = 7.5) of a comparative group of well persons. Two outliers were identified. One was also an outlier for TC and was dropped. The second outlier reported a score of 41 which was retained and replaced with a score of 63 (one unit below the next highest score of 64). The resulting mean was 86.15 (SD = 12.77) and scores were normally distributed.

Percent time spent in TC ranged from 11% to 100% with normal distribution. The mean was 64.58 (SD = 20.76) and was higher than the reported mean of 54% for dedicated anticoagulation clinics (Matchar, Samsa, Cohen, Oddone & Jurgelski, 2002). Slightly less than a quarter ( $n = 25$ , 22%) of the participants had greater than or equal to the recommended 70% level of TC in addition to a QOL that was greater than or equal to 86, the study’s mean QOL score. A similar number ( $n = 25$ , 22%) of participants spent less than 70% of the time in therapeutic control and reported a QOL score of less than 86. A quarter ( $n = 27$ , 24%) of participants had greater than or equal to the recommended 70% level of TC in along with a QOL score that was less than 86. A third ( $n = 35$ , 31%) of participants had a level of TC less than 70% accompanied by a QOL score greater than or equal to 86.

### *Gender Differences*

Independent samples t-test and Pearson's Chi square tested for background gender differences. Significant difference was found by gender on the variable of chronic conditions. The Levene statistic for test of homogeneity of variance suggested the assumption of equal variance was violated and the t-test was re-run with equal variance not assumed. Significance differences were confirmed with women having more chronic illnesses than men ( $t(112) = -2.82, p = .006$ ; female  $M = 3.06, SD = 2.186$ , male  $M = 2.10, SD = 1.41$ ). Females were also more likely to be single ( $\chi^2(112) = 19.29, p < .001$ ) and more likely to use a memory-enhancing device ( $\chi^2(112) = 3.94, p = .047$ ).

Independent samples t-test assuming equal variance assessed gender differences on the independent and dependent variables. No significant differences were found. However, a trend, identifying females ( $M = 61.32\%, SD = 20.17$ ) as spending less time in therapeutic control than males ( $M = 68.62\%, SD = 20.97$ ), was explored further. There was also a trend for females ( $M = 7.2, SD = 4.32$ ) to take more prescription medications than males ( $M = 5.7, SD = 3.8$ ). Finally, a trend for females ( $M = 13.84, SD = 16.98$ ) to spend more time subtherapeutic than males ( $M = 8.20, SD = 15.11$ ) was noted. There was no such trend for time spent supratherapeutic ( $M = 24.83, SD = 19.19$  and  $M = 23.18, SD = 20$  respectively).

Table 10

*Gender Differences: Continuous Variables*

Characteristic	t (N = 112)	p	Female <u>M</u> ( <u>SD</u> )	Male <u>M</u> ( <u>SD</u> )
Age	-.06	.95		
Education	.88	.38		
Chronic Illness	-2.82	.01**	3.06 (2.186)	2.10 (1.41)
Prescription Medication	-1.90	.06		
FHI	-1.52	.13		
FILE	-1.49	.14		
FPSC	-.26	.79		
HRHS	-.32	.75		
Neuroticism	-.84	.41		
Extroversion	-1.18	.24		
Conscientiousness	-1.35	.18		
Therapeutic Control	1.87	.06		
Quality of Life	-1.75	.08		

M=Mean, SD=Standard Deviation, \*p < .05, \*\*p < .01.

Table 11

*Gender Differences: Categorical Variables*

Characteristic	Pearson's $\chi^2$	p
Income	3.01	.391
Marital Status	19.29	.000*
Employment	6.75	.08
OTC	1.72	.42
Aspirin	1.65	.20
Tobacco	.03	.87
Adherence	1.36	.24
Memory Device	3.94	.047**

\*p < .05, \*\*p < .01.



### *Correlational Analysis*

Relationships among continuous variables were examined with bivariate Pearson's correlations. Scatter plots for each pair of variables were examined for outliers and the presence of subpopulations that might mask or falsely enhance a relationship. The direction of association for many of the relationships was unknown so the two-tailed test was used unless otherwise noted.

#### *Independent Variable Correlations*

Table 12 presents results for bivariate correlations for independent variables. The majority of relationships (19) were weak ( $< .4$ ), six were moderate ( $.40 - .69$ ), and one was strong ( $.70$  and above). Higher scores on neuroticism (N) were related to higher scores of family stress ( $r = .361, p < 0.01$ ) and lower scores on family hardiness ( $r = -.39, p < 0.01$ ) and family problem-solving communication ( $r = -.38, p = 0.01$ ). This pattern was reversed for the conscientiousness (C) subscale. Higher scores on conscientiousness were significantly correlated with lower family stress scores ( $r = -.28, p < 0.01$ ), and higher scores on family hardiness ( $r = .48, p < 0.01$ ) and family problem-solving communication ( $r = .49, p < 0.01$ ). Higher extroversion (E) scores were related to family hardiness scores ( $r = .44, p < 0.01$ ) and higher family problem-solving communication scores ( $r = .28, p < 0.01$ ;  $r = .25$ ). The individual hardiness scores were positively correlated with the family hardiness ( $r = .44, p < 0.01$ ) and family problem-solving communication scores ( $r = .24, p < 0.05$ ), and negatively related to the family stress score ( $r = -.21, p < 0.05$ ). Higher hardiness scores were linked to lower scores on neuroticism ( $r$

= -.34,  $p < 0.01$ ) and higher scores on extroversion ( $r = .41$ ,  $p < 0.01$ ) and conscientiousness ( $r = .46$ ,  $p < 0.01$ ).

Individual and family hardiness were correlated ( $r = .44$ ,  $p < 0.01$ ). Family hardiness and family problem solving were highly correlated ( $r = .70$ ,  $p < 0.01$ ). As expected, family hardiness and family problem-solving were negatively correlated with family stress scores ( $r = -.35$ ,  $p < 0.01$ ).

Table 12

*Correlations Among Individual and Family Characteristics: Family Hardiness (FHI), Family Stress (FILE), Family Problem Solving Communications (FPSC), Neuroticism (N), Extroversion (E), Conscientiousness (C), and Individual Hardiness (HRHS)*

Characteristic	1	2	3	4	5	6	7
1. FHI	-	-.35**	.70**	-.39**	.44**	.48**	.44**
2. FILE		-	-.35**	.36**	-.11	-.28**	-.21*
3. FPSC			-	-.38**	.28**	.49**	.24**
4. N				-	-.47**	-.40**	-.34**
5. E					-	.41**	.41**
6. C						-	.46**
7. HRHS							-

\* $p < .05$ , \*\* $p < .01$ .

*Background and Outcome Variable Correlations*

All significant relationships between background factors and outcome variables were weak (see Table 13). Therapeutic control correlated positively with age ( $r = .22$ ,  $p < 0.05$ ), with older age linked to greater therapeutic control. Further, time spent subtherapeutic was negatively correlated with age ( $r = -.26$ ,  $p < .01$ ), showing as age increased the time spent in the subtherapeutic range decreased. Not surprising, therapeutic control was negatively correlated with prescription medications ( $r = -.17$ ,  $p < .05$ ), showing subjects with an increased number of prescription medications had decreased therapeutic control. Therapeutic control was correlated negatively with the number of prothrombin tests (Sperman's rho, preferred for non-normally distributed variables such as prothrombin tests, was used;  $r = -.19$ ,  $p < .05$ ). QOL scores were negatively correlated with chronic conditions ( $r = -.26$ ,  $p < .01$ ), so the greater the number of chronic conditions reported, the lower the QOL score.

Table 13

*Correlations Among Continuous Background Variables and Quality of Life (QOL) and Therapeutic control (TC), Time Spent Subtherapeutic (SUB), and Time Spent Supratherapeutic (SUP).*

Characteristic	QOL	TC	SUP	SUB
Age	.15	.22*	-.02	-.26**
Education	.17	.15		
Chronic Conditions	-.26**	-.13		
Prescription Medications	.35	-.20*		

\* $p < .05$ , \*\* $p < .01$ .

*Background and Independent Variable Correlations*

Correlations between demographics and individual characteristics are summarized in Table 14. Those that were significant were weakly related. Younger age was related to higher neuroticism scores ( $r = -.22, p < .05$ ). In addition, the greater the education reported, the lower the neuroticism reported ( $r = -.23, P < .05$ ). The more chronic conditions listed, the greater the neuroticism ( $r = .18, p < .05$ ) and the lower the extroversion score ( $r = -.23, p < .05$ ). In addition, the lower the individual hardiness score, the greater the number of prescriptions ( $r = .21, p = < .05$ ).

Table 14

*Correlations between Demographics and Individual Characteristic Individual Hardiness (HRHS), Neuroticism (N), Extroversion (E), and Conscientiousness (C).*

Characteristic	HRHS	N	E	C
Age	.01	-.22*	-.04	-.03
Education	-.02	-.23*	.04	.04
Chronic Conditions	-.14	.18*	-.23*	-.17
Prescription Medication	-.21*	-.14	.02	-.02

\* $p < .05$ ; \*\* $p < .01$ .

*Background and Family Variable Correlations*

Correlations between background and family characteristics are summarized in Table 15. Increased age was negatively correlated with family stress scores ( $r = -.33, p < .01$ ), as was increased education ( $r = -.22, p < .05$ ). Not unexpected, chronic illness was positively correlated with family stress ( $r = .14, p < .05$ ). Increased education was additionally correlated with increased family problem solving communication scores ( $r = .19, p < .05$ ).



Table 15

*Correlations between Background Variables and Family Hardiness Index (FHI), Family Inventory of Life Events and Changes (FILE), and Family Problem-solving Communication (FPSC)*

Characteristic	FHI	FILE	FPSC
Age	-.01	-.33**	.08
Education	.10	-.22*	.19*
Chronic Conditions	-.08	.14*	-.12
Prescription Medications	-.01	.09	-.03

\* $p < .05$ ; \*\* $p < .01$ .

*Independent and Dependent Variable Correlations*

Correlations between individual and family characteristics and the two outcome variables of quality of life (QOL) and therapeutic control (TC) are summarized in Table 16. QOL was significantly correlated with all individual and family resiliency factors. With the exception of family stress (weakly related), all relationships were moderate in strength. Those with higher QOL were more likely to have higher scores on conscientiousness ( $r = .52, p < .01$ ), extroversion ( $r = .47, p < .01$ ), individual hardiness ( $r = .59, p < .05$ ), family hardiness ( $r = .55, p < .01$ ), and family problem solving communication ( $r = .49, p < .01$ ). Higher QOL scores were, in turn, related to lower scores on neuroticism ( $r = -.50, p < .01$ ) and family stress ( $r = -.22, p < .05$ ). Therapeutic control (TC) was not correlated with any of the independent individual and family variables.

Table 16

*Correlations between Individual (Health Related Hardiness Scale = HRHS) and Family Characteristics (Family Hardiness Index = FHI, Family Inventory of Life Events and Changes = FILE, Family Problem-solving Communication = FPSC) and the Two Outcomes Quality of Life and Therapeutic Control*

Scale	QOL	TC
FHI	.55**	-.04
FILE	-.22*	-.09
FPSC	.49**	-.01
Neuroticism	-.50**	.11
Extroversion	.52**	-.04
Conscientiousness	.52**	-.02
HRHS	.59*	.07

1-tailed, \* $p < .05$ ; \*\* $p < .01$ .

### *Between Group Differences*

Independent samples t-test and one-way ANOVA statistics were used to describe differences among categorical background variables and the independent and dependent variables. The Levene statistic tested for homogeneity of variance. Post hoc tests explicated relationships when significant differences were found.

#### *Background and Outcome Variable Between Group Differences*

Differences between groups with respect to outcomes are reported in Table 17. A significant difference between income and QOL was found ( $F(3,198) = 4.14, p = .008$ ) and post hoc tests showed as reported income increased, so did QOL scores. Those earning less than \$5,000 had a mean QOL score of 79. Those earning between \$5,000 and \$24,999 displayed a mean of 84. A slightly greater QOL mean of 88 was shown in the group earning between \$25,000 and \$49,999. The greatest QOL mean score, 92, resulted in the group of participants earning \$50,000 or greater. Those who did not smoke tobacco reported a significantly higher QOL score ( $M = 87, SD = 12.1$ ) than those who did not smoke ( $78, SD = 14.5$ ). However, those who did smoke tender to be younger in age than those who did not smoke ( $M = 51.6$  and  $M = 60.5$  respectively).

Table 17

*Between group differences for Categorical Background Variables and the Outcomes Quality of Life (QOL) and Therapeutic control (TC).*

Characteristic	QOL		TC	
	Test Statistic	p	Test Statistic	p
Income	F(3,108) = 4.1	.008**	F(3,108) = 1.30	.28
# OTCs	F(2,111) = .70	.41	F(2,111) = 1.81	.17
Aspirin	t(112) = .24	.80	t(112) = -.47	.64
Tobacco	t(112) = 2.59	.01*	t(112) = .68	.50
Adherence	t(112) = .58	.56	t(112) = 1.40	.16
Device	t(112) = -.78	.43	t(112) = .21	.83

\*p < .05, \*\*p < .01.

*Background and Individual Variable Between Group Differences*

Differences between groups with respect to individual characteristics are reported in Table 18. Only one significant difference was found, that between those who took aspirin and those who did not ( $t(112) = 2.55, p = .02$ ). Those not taking aspirin reported a mean conscientiousness score of 34.7, those who did take aspirin reported a mean score of 30.2. Given the mean conscientiousness score and standard deviation, this difference is clinically insignificant.

Table 18

*Between group differences for Categorical Background Variables and Individual Characteristics Individual Hardiness (HRHS), Neuroticism (N), Extroversion (E), and Contentiousness (C).*

Characteristic	HRHS		N		E		C	
	Statistic	p	Statistic	p	Statistic	p	Statistic	p
Income	F(3,108) = .26	.85	F(3,108) = 4.22	.01	F(3,108) = .57	.64	F(3,108) = .73	.54
# OTCs	F(2,111) = .32	.72	F(2,111) = 1.95	.15	F(2,111) = .15	.86	F(2,111) = .49	.61
Aspirin	t(112) = .10	.91	t(112) = .43	.66	t(112) = .67	.50	t(112) = 2.55	.02*
Tobacco	t(112) = .86	.39	t(112) = -1.83	.07	t(112) = .59	.56	t(112) = .08	.93
Adherence	t(112) = .32	.75	t(112) = .16	.87	t(112) = -.26	.79	t(112) = .45	.65
Device	t(112) = -.56	.58	t(112) = .33	.74	t(112) = 1.2	.22	t(112) = .41	.68

\*p < .05; \*\*p < .01.

*Background and Family Variable Between Group Differences*

Differences between groups with respect to family characteristics are reported in Table 19. Only one difference between groups was identified. Those reporting decreased income reported an increase in family stress. Those making below \$5,000 reported the highest mean family stress score ( $M = 12.5$ ,  $SD = 6.6$ ), those making between \$5,000 and \$24,000 reported the next lowest mean family stress score ( $9.1$ ,  $SD = 6.2$ ), those reporting an income \$25,000 to \$49,000 reported a mean family stress score of  $7.8$  ( $SD = 5.7$ ). Finally, those reporting an income greater than \$50,000 displayed the lowest family stress score mean,  $7.0$  ( $SD = 5.0$ ).



Table 19

*Between group differences for Categorical Background Variables and Family Hardiness Index (FHI), Family Inventory of Life Events and Changes (FILE), and Family Problem solving Communications (FPSC)*

Characteristic	FHI		FIL		FPSC	
	Statistic	p	Statistic	p	Statistic	p
Income	F(3,108) = .26	.85	F(3,108) = 4.22	.01*	F(3,108) = .57	.64
# OTCs	F(2,111) = .32	.72	F(2,111) = 1.95	.15	F(2,111) = .15	.86
Aspirin	t(112) = .10	.91	t(112) = .43	.66	t(112) = .67	.50
Tobacco	t(112) = .86	.39	t(112) = -1.83	.07	t(112) = .59	.56
Adherence	t(112) = .32	.75	t(112) = .16	.87	t(112) = -.26	.79
Device	t(112) = -.56	.58	t(112) = .33	.74	t(112) = 1.2	.22

\*p < .05; \*\*p < .01.

### Hypothesis Testing

To identify the role family and personality resiliency factors play in the adaptation to Oral Anticoagulation Therapy (OAT), a series of linear regression modeling was performed. Three sequential steps produced Control Models, Hypothesis Models, and Predictive Models.

First, linear regression was used to identify any interactions between background variables with the outcomes QOL and TC. These models were built containing only demographic and health characteristic variables. All possible interaction terms were considered in these models. These models can be treated as final models that control for background variation in the relationship between independent and family characteristics with the outcome variables QOL and TC. These models are Control Models.

Next, linear regression was used to test specific hypotheses. Control Model variables were entered as the initial block thus controlling background variable influences. Then, the specific family or individual characteristic variable was entered as the second block to test for a significant relationship. These models are Hypothesis Models.

Finally, expanded models were developed for each outcome variable using the variables found to be significant by hypothesis testing. Variables were removed if they became non-significant. Final predictive models depict variables explaining significant amounts of QOL and TC variance. These models are Predictive Models.

### *Therapeutic Control*

#### *Control Model*

Linear regression was used to identify statistical interaction between demographic and health characteristics with TC. This Control Model was built containing the background characteristic variables with significant associations with TC: age and prescription medications. Age explained about 4% of the variability in therapeutic control. Prescription medication explained an additional 4% (Table 20). Since in the current conceptual framework family stress was a possible confounding variable, it was also regressed. Adjusted R<sup>2</sup> decreased and so this variable was eliminated.

Table 20

*Therapeutic Control: Control Model Linear Regression Analysis for Age, # Prescription Medications, and Family Stress (FILE) (N=112)*

Variable	R <sup>2</sup>	Adjusted R <sup>2</sup>	$\Delta F$	Significance $\Delta F$	B	beta
Step 1 Age	.049	.041	5.7	.02	.31	.24
Step 2 # Prescription Medications	.10	.08	5.7	.02	-1.1	-.22
Step 4 FILE	.10	.07	.00	.99	.00	.00

### *Hypothesis Models*

To test specific hypotheses, age and # prescription medications were entered as the first block, and the specified independent variable as the second block. See Table 21 for summary. No individual or family characteristics explained TC variance after controlling for age and number of prescription medications.

The first hypothesis (Hypothesis 1) asserted that increased neuroticism would predict an increase in therapeutic control. Regression analysis revealed that neuroticism had no effect on therapeutic control ( $\Delta F(2,109) = .54, p = .46$ ). The hypothesis (Hypothesis 2) that high levels of conscientiousness would increase therapeutic control was also not upheld; conscientiousness had no effect on therapeutic control ( $\Delta F(2,109) = .78, p = .80$ ). Similarly, it was hypothesized (Hypothesis 3) that high levels of extroversion would predict greater increase in therapeutic control but extroversion had no effect on therapeutic control ( $\Delta F(2,109) = .18, p = .74$ ).

An individual with high levels of hardiness was hypothesized (Hypothesis 6) to have greater therapeutic control whereas, according to linear regression, the level of hardiness had no effect on therapeutic control ( $\Delta F(2,109) = .13, p = .72$ ). Contrary to expectations, hypotheses for higher scores on family problem-solving communication and family hardiness to predict therapeutic control were not upheld. Family problem-solving communication (Hypothesis 7) did not affect therapeutic control ( $\Delta F(2,109) = .012, p = .72$ ), nor did family hardiness (Hypothesis 8) affect therapeutic control ( $\Delta F(2,109) = .22, p = .64$ ).

Table 21

*Therapeutic Control: Hypothesis Models: Linear Regression Analysis for Predictor Variables (N=112)*

	<b>R2</b>	<b>Adjusted R2</b>	<b>ΔF</b>	<b>Significance ΔF</b>
Step 1				
Age, #Prescription Medications	.10	.08	5.8	.01
Step 2				
N	.10	.08	.54	.46
Step 2				
C	.10	.07	.08	.78
Step 2				
E	.10	.07	.18	.74
Step 2				
HRHS	.10	.07	.13	.72
Step 2				
FPSC	.10	.07	.12	.10
Step 2				
FHI	.08	.07	.22	.64

*Predictive Model*

Individual and family characteristics did not significantly increase prediction of therapeutic control. Therefore, the final model (Table 22), which predicts a modest 8% of the therapeutic control variance, includes only the variables of age and # prescription medications. Each 4 years of increased age leads to an increase in the mean of the probability distribution of therapeutic control of close to 1%. Each additional 4 prescription medications added leads to a decrease of therapeutic control of about 1%. TC

$$\% = 53.46 + .24 (\text{age}) - .22 (\# \text{ Rx medications}).$$

Table 22

*Therapeutic Control: Predictive Model Linear Regression Analysis (N=112)*

Model Age, Prescription Medications	<b>R2</b>	<b>Adjusted R2</b>	<b>SEE</b>	<b>F</b>	<b>p</b>	<b>B</b>	<b>Beta</b>	<b>t</b>	<b>p</b>
Constant						53.46			
Age	.03	.04	20.34	5.71	.02	.31	.22	2.59	.01
Prescription Medications	.10	.08	19.92	5.84	.00	-1.09	-.22	-2.34	.02



### *Quality of Life*

#### *Control Model*

Linear regression was used to identify statistical interaction between demographic and health characteristics with quality of life (QOL). First, the background variables with significant Pearson's correlations (income, chronic conditions) were each entered stepwise. These two background variables explained a total of 11% of the variability in QOL. In the current conceptual framework, family stress was a possible confounding variable. Therefore, it was regressed with the two other predictors. Family stress was significantly related to QOL (adjusted R<sup>2</sup> increased from a .11 to .13) and was retained in the model as no significant multicollinearity was demonstrated. The final Control Model regression (Table 23) explained 13% of the QOL variance.

Table 23

*Quality of Life: Control Model Linear Regression Analysis for Chronic Conditions, Income, and Family Stress (FILE) (N=112)*

<b>Variables</b>	<b>R2</b>	<b>Adjusted R2</b>	<b>SE of Estimate</b>	<b><math>\Delta F</math></b>	<b>Significance <math>\Delta F</math></b>	<b>B</b>	<b>Beta</b>
Income	.11	.09	12.20	14.10	.00	3.11	.23
Chronic Conditions	.13	.11	12.11	7.16	.11	-.93	-.14
FILE	.15	.13	11.98	2.97	.07	-.36	-.17

### *Hypothesis Models*

To test specific hypotheses, income, chronic conditions, and family stress were entered as the first block (thus controlling for these influences) and the specified independent variable as the second block. This process was repeated seven times to test the total of 8 hypotheses. See Table 24. It was first hypothesized (Hypothesis 1) that lower scores on neuroticism would predict higher QOL scores. After controlling for income, chronic illness and family stress, neuroticism accounted for an additional 16% of the variance in QOL ( $\Delta F(3,108) = 24.01, p = .00$ ). Next, it was expected that high levels of conscientiousness would predict greater QOL scores (Hypothesis 2). After controlling for income, chronic illness and family stress, conscientiousness accounted for an additional 20% of the variance in QOL ( $\Delta F(3,108) = 432.01, p = .00$ ). Similarly, higher extroversion scores were hypothesized to affect greater QOL (Hypothesis 3) and regression analysis revealed the higher the level of extroversion, the higher the QOL score ( $\Delta F(3,108) = 25.32, p = .00$ ). After controlling for income, chronic illness and family stress, extroversion accounted for an additional 16 % of the variability in QOL. High levels of hardiness were expected to predict a greater increase in QOL (Hypothesis 6). Accordingly, regression analysis found that the higher the level of hardiness, the greater the QOL score ( $\Delta F(3,108) = 49.62, p = .00$ ). After controlling for income, chronic illness and family stress, individual hardiness accounted for an additional 27 % of the variability in QOL. In summary, conscientiousness, extroversion, and individual hardiness were all found to predict higher QOL and neuroticism was found to predict lower QOL.

It was posited that high levels of family problem-solving communication would predict greater levels of QOL (Hypothesis 7). The finding from regression analysis was that higher levels of family problem solving communications predicted higher QOL scores ( $\Delta F(3,108) = 27.94, p = .00$ ). After controlling for income, chronic illness and family stress, agreeableness accounted for an additional 18 % of the variability in QOL. Finally, the hypothesis that greater levels of family hardiness would predict greater QOL (Hypothesis 8) was supported ( $\Delta F(3,108) = 42.06, p = .00$ ). After controlling for income, chronic illness and family stress, family hardiness accounted for an additional 24 % of the variability in QOL.

Table 24

*Summary of Linear Regression Analysis for Hypothesis Testing of QOL (N=108)*

	R2	Adjusted R2	$\Delta F$	Significance $\Delta F$	B	Beta
Step 1						
Income, Chronic Illness, FILE	.15	.13	11.98			
Step 2						
N	.32	.29	24.01	.00	-.72	-.44
Step 2						
C	.35	.33	32.01	.00	.91	.41
Step 2						
E	.32	.29	25.32	.00	.83	.42
Step 2						
HRHS	.43	.40	49.62	.00	.45	.51
Step 2						
FPSC	.33	.31	27.94	.00	1.32	.45
Step 2						
FHI	.40	.37	42.06	.00	1.08	.54

### *Predictive Model.*

A series of hierarchical regression equations tested for the family and individual characteristic predictors of QOL. First, all six individual characteristic variables (hardiness, extroversion, openness, agreeableness, conscientiousness, neuroticism) were evaluated using error sum of squares (SSE), error mean square (MSE), adjusted R square, and the Cp criterion  $((SSE \div MSE) - (n - 2(\text{number of variables})))$  as described by Neter and colleagues (Neter, Kutner, Nachtsheim & Wasserman, 1996). The model with the lowest Cp value included variables hardiness, conscientiousness, and neuroticism. Cp decreased an insignificant amount with the addition of E so this variable was dropped. Next, the two family characteristics were likewise explored; entering both FHI and FPSC yielded the lowest Cp score. Finally, individual hardiness, neuroticism, conscientiousness, family hardiness (FHI), and family problem-solving communication (FPSC) were evaluated. FHI and conscientiousness were dropped due to multicollinearity problems (Condition Index = .30 with two variance proportions > .50). The final model contained three variables: individual hardiness (HRHS), family problem-solving communication (FPSC), and neuroticism. This model explained 51% of QOL variance. (Table 25). For roughly each 3 point increase in hardiness score, QOL increased by about one unit. For roughly each 1 point increase in family problem solving communication, QOL increased one unit. For roughly each 3 point increase in neuroticism score, QOL decreased about one unit.  $QOL = 21.475 + .359(\text{hardiness}) + .883(\text{family problem solving communications}) - .383(\text{neuroticism})$ . The Beta coefficients suggest that individual hardiness is the most important predictor of QOL.

Table 25

*Quality of Life: Predictive Model Linear Regression Analysis (N=112)*

Model HRH*FPSC*N	R2	Adjusted R2	SEE	F	ΔF	B	Beta	T	p
Constant						21.475			
HRH	.343	.337	10.40	57.53	57.53	359	.434	6.09	<.001
FPSC	.477	.467	.32	49.696	27.83	883	.301	4.15	<.001
N	.521	.508	8.96	39.228	10.045	-.383	-.237	3.17	.002

### Summary

The final sample of 112 subjects was primarily Caucasian with a mean age of 59 years ( $SD = 16$ ). Most subjects had about 3 additional chronic conditions in addition to the indication for OAT. Except for neuroticism, QOL, and TC, sample means for all independent and dependent variables approximated those of the normative population. The sample displayed a somewhat lower neuroticism mean, and a somewhat higher QOL mean, and a somewhat higher TC. Correlations among independent variables were weak to moderate, with one correlation, family hardiness and family problem-solving, being strong. No significant relationships were found between TC and the independent variables. All of the independent variables were moderately correlated with QOL. No significant relationships were found between individual and family characteristics and TC, after controlling for age and the number of prescriptive medications. All QOL hypotheses were upheld. After controlling for chronic conditions and income, QOL significantly related to all individual and family variables. The final predictive model for TC showed age and number of medications explained 6% of the total therapeutic control variance. Half of QOL is predicted by hardiness, family problem-solving communication, and neuroticism. Due to the omission of three outliers, the generalizability of the results is limited. Results are not transferable to middle age African American women who are never in therapeutic range, middle age men with extremely low QOL and who are never in therapeutic range, and elderly Asian males who have extremely low family hardiness and problem solving.



## CHAPTER 5

### Discussion

This discussion of the current investigation includes findings pertaining to clinical indicators of therapeutic control, clinical indicators of quality of life, clinical implications, recommendations for future study, and study limitations. The study aim was to expand the understanding of the oral anticoagulation therapy (OAT) population through reframing OAT within a nursing context. The Family Ecology Theory applied to the Oral Anticoagulation Model depicted in Figure 1 and discussed in the Review of Literature directs nursing understanding of OAT within a larger context of systems. The individual and family microsystem relationships, heretofore unexamined, were explored in hopes of broadening the scope of OAT investigation beyond the extensive but incomplete OAT literature. This examination yielded information surrounding OAT with respect to therapeutic control and quality of life.

The convenience sample in this investigation was drawn from an ambulatory care anticoagulation clinic affiliated with a metropolitan university hospital. Primarily Caucasian, with most participants being between the ages of 45 and 75 years, the sample was heterogeneous with respect to indication for OAT. In this sample, four clinically relevant OAT subgroups were identified. The first group of participants displayed the recommended or better levels of therapeutic control along with an average or higher subjective quality of life (TCQOL). The second group exhibited the recommended or better levels of therapeutic control accompanied with a lower than average subjective quality of life (TCqol). A third group consisted of participants with lower than

recommended levels of therapeutic control who exhibited an average or higher subjective quality of life (tcQOL). The last group demonstrated lower than the recommended levels of therapeutic control combined with lower than average subjective quality of life (tcqol). To understand these groups better, clinical indicators of therapeutic control and quality of life are discussed.

### *Clinical indicators of therapeutic control*

The individual OAT microsystem proposes several potential correlates of therapeutic control. This study examined background, individual, and family characteristics. These included individual hardiness, neuroticism, conscientiousness, extroversion, family hardiness and family problem-solving communication. Study findings support relationships, discussed below, between two background variables and therapeutic control. The surprising lack of significant findings with respect to individual and family characteristics is also discussed.

#### *Background variables*

As expected, based on a previous report correlating greater age with improved warfarin therapy (Arnsten, Gelfand & Singer, 1997), age correlated positively with therapeutic control. In that investigation, adherence was measured objectively and was positively related with therapeutic control. No such pattern between adherence and therapeutic control was observed in this study, where adherence was measured subjectively. It was not the intent of this study to change or improve adherence, a probable result of stringent pill counting and other objective adherence measures (Matsuyama, Mason & Jue, 1993), but rather to explore relationships surrounding normal

medication-taking behavior. The tendency for participants to overestimate their own adherence is a likely bias in this study and over-reporting of positive adherence may have concealed the expected correlation between adherence and therapeutic control.

Interestingly, younger OAT adults in this study appear to have greater risk for medication errors, presumably medication omissions. Age was not related to supratherapeutic levels. However, results show that lower age was weakly correlated with greater time spent in subtherapeutic range ( $r = -.26, p < .01$ ) and with less time spent in therapeutic control ( $r = .22, p < .05$ ). This corroborates previous results (Park et al., 1999) exhibited by a sample of the rheumatoid arthritis population. According to Park and colleagues, three aspects of this phenomenon are clinically relevant to medication adherence: cognitive load, monitoring health and seeking health care vigilance, and busy lifestyles. Related OAT implications are considered.

Cognitive load is the combination of information processing speed, working memory function, episodic memory, and reasoning (Park et al. 1999). Warfarin therapy, relative to other medications, imposes a greater cognitive load. First, rather than a consistent daily dose, variable warfarin dosing is the rule. A different daily dose is frequently required, and dosing often changes with a protime test visit. For example, a person may be on a weekly dose of 5 mg every day except 2.5 mg Monday, Wednesday, and Friday. After a subtherapeutic protime test, this dose may be changed to 5 mg every day except Monday and Friday. Adhering accurately to variable dosing increases cognitive load, as do other therapy factors. Attending to diet constancy is an ongoing requirement with respect to vitamin K foods. If a gastric illness occurs with emesis or diarrhea, or another illness

impacts dietary intake, or access to stable amounts of vitamin K foods is limited due to vacation, changing jobs, desire to gain or lose weight, cognizant individuals need to use reason to decide whether to change their diets and/or to obtain protime tests. Third, with each prescribed medication or over-the-counter remedy addition, change or withdrawal, the influence on warfarin therapy requires evaluation. Reasoning and judgment are required for deciding whether or not to notifying the health care provider, or to check a protime test. Finally, bleeding events and body injury need assessing and evaluation. If unusual gingival bleeding is observed, or a new headache is experienced, the amount of reasoning and information processed is more complicated for a person on OAT. Parks and colleagues found despite older adults demonstrating significant cognitive decline relative to younger adults, this decline did not hinder medication adherence. Likewise, according to the results of this study, older OAT adults are able to contend with the cognitive load of OAT.

Vigilance in monitoring health and seeking health care is paramount in OAT. For optimal therapeutic control, not only does the generalizable OAT information contained in the health care domain contribute to therapy success, but the OAT individual-specific information is necessary as well. Frequent and accessible contact between the health care provider and the person on OAT is attained both by the provider actively inquiring about changes in health status, diet, activity, and adjunct therapies and by the person on OAT informing the health care provider of relevant changes. When compared with younger adults, older adults showed increased vigilance in monitoring health and seeking care

(Leventhal, Leventhal, Schaefer & Easterling, 1993). The results of this OAT investigation are consistent with this finding.

A busy lifestyle is full of rapidly changing situations with many competing tasks and situations occurring simultaneously. Park and colleagues (1999) concluded that a busy life diminishes the likelihood of successful medication therapy. They propose busy people operate under high cognitive load and lowered vigilance in monitoring health and seeking health care. This investigator notes older retired persons seldom request specific appointment dates or times, although they do structure protime visits around other health-related appointments. Conversely, younger adults arrange visits around work schedules and trips, family activities, and caregiver duties. The significant negative correlation found in the study sample between age and amount of family stress also lends merit to this phenomenon of younger adults having more demands. It is reasonable to expect the success of a medical therapy such as OAT which is highly dependent on stability, will be diminished by chaotic and unpredictable daily lives. Plausibly, busy life styles with high cognitive load and decreased health vigilance may partially explain the findings of decreased OAT therapeutic control with younger adults.

Consistent with previous case studies, the number of prescriptive medications correlated negatively with therapeutic control. The trend identifying females as more likely to spend less time in therapeutic control may be partially explained by the trend for females to take more prescription medications. Participants reported the number of prescription medications included in their medical regimen at the time they filled out study questionnaires. Therapeutic control was averaged over the preceding 3-month

interval. Therefore, the impact of prescription medication additions, changes, and withdrawals over the previous 3-month interval on therapeutic control was undetected. Consequently, the impact of prescription medications identified by this study is likely an underestimation.

Further, noting the negative impact of prescription medications on therapeutic control leads one to assume a similar relationship would be found between over-the-counter medications (OTCs) and therapeutic control. The results from this investigation suggest otherwise, and the lack of a significant positive correlation between OTCs and therapeutic control merits discussion. No distinction was made in this investigation between dietary supplements, herbal remedies, and botanical products. However, the study clinic's regular assessment of OTC use and the recommendation to discontinue OTCs unless there is a clear benefit to the consumer and interaction with OAT is unlikely, make it probable that the OTCs used by the study participants were primarily OTCs that did not impact OAT. Whereas prescription medications are taken to treat a medical problem, frequently OTCs, which include vitamins, are taken to maintain health. Seemingly, individuals acting to take OTCs pills for health promotion would be likely to take a pill to prevent stroke. This inclination may have counter acted a negative influence on therapeutic control.

In conclusion, both age and the number of prescription medications were important clinical indicators in this study. The regression model predicted that these two background variables explained 6%, a small portion, of the therapeutic control variance. This has only a slightly increased predictive value over using the mean (therapeutic

control  $SD = 20.77$ , regression standard error of estimate = 20.10). However, OAT therapeutic control is multifactorial, and this investigation reaffirmed the contribution of these two variables and supported their inclusion in any related model. Younger individuals and those individuals taking increased prescription medications are at greater risk for uncontrolled anticoagulation. In general, for each 3 years of increased age there is a corresponding increase in time spent in therapeutic control of about 1%. Similarly, for each 3 additional prescription medication added, time spent in therapeutic control decreases by about 1%. Interventions aimed at ameliorating the effects of a busy life along with a concerted effort to simplify medication regimens may be most useful.

#### Individual characteristic variables

The first hypothesis, stating less neuroticism would lead to better therapeutic control, was not supported. This finding is consistent with previous reports of neuroticism not being a robust predictor of physical health outcomes (Watson & Pennebaker, 1991) and inconsistent with neuroticism as a predictor of poor health habits and practices (Vingerhoets, Croon, Jennings & Menges, 1990). The present sample of OAT participants may have been somewhat negatively selected with respect to levels of neuroticism.

Many adults discontinue OAT at the onset of treatment (Connolly et al., 1991; Ezekowitz et al., 1992; Peterson, Godtfredsen, Boysen, Anderson, & Anderson, 1989). The lower than average neuroticism scores may reflect the self-selection of a population minus those neurotic individuals who are unwilling to accept the demands of conventional OAT therapy. The individuals who continue OAT may exhibit less

avoidance coping and thus neuroticism, which has been positively correlated to avoidance coping (Bosworth, Feaganes, Vitaliano, Mark & Siegler, 2001). The lower rates of neuroticism may have obscured the impact of impulsiveness and higher levels of anxiety in impeding participant ability to maintain steady life style practices. In addition, the increased anxiety, caused by worrying whether anticoagulation was sufficient to prevent stroke in addition to worry about whether over anticoagulation was increasing bleeding risk, may promote therapeutic control by increasing the number of office visits and the attendant number of protime tests. Thus, neuroticism may both promote and counteract therapeutic control by variable influence on different aspects of therapy. The result of these competing relationships would mask an association between neuroticism and therapeutic control.

The study data indicated that conscientiousness was not a predictor of therapeutic control. This finding differs from other studies showing that conscientiousness is positively linked to health behavior through increased adherence and greater likelihood of engaging in proactive, health-promoting activities (Booth-Kewley & Vickers, 1994; Siegler & Costa, 1994; Christensen & Smith, 1995). It is unclear why there was no correlation in this study between adherence and conscientiousness, although the previously noted bias towards over-reporting adherence may have obscured an association.

In some chronic illnesses, adherence to diet, one type of self-care behavior, is often uncorrelated to other types of self-care behaviors, such as exercise (Johnson, 1992; Kurtz, 1990). Similar to neuroticism, conscientiousness may have had variable influence on the



different aspects of OAT, resulting in both therapeutic control promotion and counteraction. However, there was a lack of correlation between conscientiousness and OAT-related health behavior, such as using a memory device, avoiding OTC medications, and abstaining from smoking. These findings suggest this personality factor had little importance in OAT therapeutic control of this study's sample.

It is important to note the construct measurement did not reflect health conscientiousness but, rather, a propensity towards dependability, perseverance, self-discipline, will, and ability to delay gratification in general. Presumably, a highly conscientious person with multiple responsibilities may be less likely to put OAT demands above other, more valued, family, work, or spiritual demands. This investigation suggests that, although general conscientiousness is not related to therapeutic control, health-specific conscientiousness, likely an aspect of the health vigilance discussed above (Parks et al., 1999), may be related to therapeutic control.

Higher levels of extroversion were hypothesized to be associated with higher levels of therapeutic control based on the few studies identifying a role of extroversion on health behavior. The results of this study counter the hypothesis. However, health behavior is not a unitary construct (Mark & Lutgendorf, 1999) and this fact may partially explain why this study found no association. Similar to the neuroticism discussion above, extroversion may both promote and counteract therapeutic control by the variable influence on different aspects of therapy. Extroverted individuals' high sociability may predispose them to a busy lifestyle that may compete with OAT demands. In contrast, extroverts' high activity level and negative correlation to avoidance coping (Bosworth et

al., 2001) may specially suit them for the multiple demands of OAT. Similar to neuroticism, extroversion may both support and thwart therapeutic control by opposing influence on different aspects of therapy.

Surprisingly, an individual's health-related hardiness was not associated with therapeutic control. Although previous studies have shown varying degrees of correlation between hardiness and positive physiological adaptation and health promotion activities (Lambert, Lambert, Klipple, & Mewshaw, 1990; Ross, 1991; Snowdon, Cameron & Dunham, 1994; Newton, 1999; Akkasilpa, Minor, Goldman, Magder & Petri, 2000), this investigation's results showed lack of correlation between hardiness and maintaining a therapeutic level of OAT. High hardiness persons viewed stressful events as less threatening, exhibited higher frustration tolerance, and used more problem-solving than low hardiness people. These behaviors seem to contribute little to whether study participants met the demands of OAT. Hardiness was negatively correlated with the amount of family stress in this study. Therefore, post hoc tests were performed seeking an association between hardiness and therapeutic control in those participants where OAT therapy burden was imposed on an increased level of family stress. No significant relationship was found. This suggests hardiness does not play a role in helping the person experiencing a high level of family stress to maintain therapeutic control. The concept of hardiness was first developed to explain why, during crises, some people adapt better than others. The hardiness characteristic functions to counteract negative effects accompanying stressful life events. The demands of OAT may be diluted compared to a concentrated crisis and not elicit a stress large enough to warrant a hardiness influence. If

so, the hardiness factor may play a role in adapting to more stressful OAT events such as a major bleeding or a thromboembolic event.

#### Family characteristic variables

Although individuals reporting greater levels of family hardiness and family problem-solving communication were hypothesized to demonstrate greater therapeutic control, these hypotheses were not upheld. Two factors may account for these findings. First, the family characteristics may only be related to therapeutic control when demands are such that they tax family resources. This is apparent in specific populations, such as those with cognitive impairment. Due to the inability of these persons to fill out questionnaires, they were excluded from the study. However, these individuals are not only brought to their visits by family members, but their caregivers also help with medication management and frequently assist in assuring stable dietary intake of Vitamin K foods. Thus, family hardiness and problem-solving communication may presumably play a greater role in families where interdependence among family members is strong.

Measurement-related factors are noteworthy. Similar to individual hardiness, family hardiness may play a role in adapting to more stressful OAT events such as a major bleeding or thromboembolic event. The family variables measured were related to the internal strengths and durability of the family unit under stress. Similar to individual hardiness, family variables were negatively correlated with the amount of family stress in this study. Therefore, post hoc tests were performed to assess the association between these family variables and therapeutic control in those participants where OAT therapy burden was added to an already increased level of family stress. No significant

relationships were found. This suggests family hardiness and family problem-solving communication, along with individual hardiness, do not play a role in helping the person experiencing a high level of family stress to maintain therapeutic OAT control.

The family measurements, unlike the health-related individual hardiness tool but similar to the personality scales, did not reflect health-related constructs but rather a general propensity of the family to be resilient in general. The data from this investigation imply general family hardiness and problem-solving communication are not related to therapeutic control. The results do not exclude relationships between general family characteristics and therapeutic control in select populations where family interactions are stronger and family members more interdependent than in the study sample. Neither do they exclude relationships between health related family characteristics and therapeutic control.

Larger influences on therapeutic control, such as lab and individual biological variation (which together may account for up to  $\pm .38$  INR in a therapeutic range of 1.0 INR) (McCurdy & White, 1992), may mask the influence of individual and family resiliency factors. The higher than average mean of time spent in therapeutic control, especially in a metropolitan teaching hospital where client acuity is high, suggests that clinic visitors may obtain more prothrombin tests than average, with subsequent improved therapeutic control by the sample in this study. The study clinic's accessibility is unusual, with over 30% walk-in visits and an average waiting time of 3 minutes. Furthermore, providers are directly available by phone, returning most calls within two hours and all calls within the same day. This convenience and accessibility may

ameliorate risk barriers and may have increased the numbers of therapeutically controlled participants.

Despite the study results showing limited importance of individual and family characteristics in predicting therapeutic control in general, the reader is cautioned against prematurely concluding that these factors make no contribution to successful OAT therapeutic control. Limitations of this study, including sample, measures used, and factors left uncontrolled, may have obscured significant relationships.

#### *Clinical indicators of quality of life*

The individual OAT microsystem proposes several potential correlates of QOL. This study examined individual and family characteristics, including individual hardiness, neuroticism, conscientiousness, agreeableness, openness, extroversion, family hardiness and family problem-solving communication. The findings support strong relationships between the subjective perceptions of all individual and family characteristics and the subjective perceptions of QOL. These are discussed below.

#### *Individual characteristic variables*

The hypothesis that neuroticism would serve as a predictor of QOL in the OAT population was confirmed, aligning this study with the growing body of literature showing that highly neurotic individuals consistently report poor QOL. To the knowledge of this author, no prior study reports the contribution neuroticism makes to identify a high risk QOL profile. Neuroticism is the personality trait that, in conjunction with other factors, optimized a QOL risk profile. As previously noted, the study population had lower than expected levels of neuroticism, and this is attributed to the possible selection

bias of a demanding therapy. It is possible that this may explain the higher QOL reported in this investigation. If this supposition is correct, the OAT population in general may exhibit a higher global QOL. Health related QOL (measuring functional, well-being, and overall health in general) was not different between 177 OAT participants and 156 control participants (M = 67 years, 74% male, 100% atrial fibrillation) (Lancaster, et al., 1991), which contradicts the supposition. However, this population was somewhat older, and included only those with atrial fibrillation as the indication for OAT. To the knowledge of this investigator, no comparison between neuroticism and global versus health-related versus disease specific QOL has been explored. Neuroticism, as a personality factor, may be more strongly related to global perception than perception more focused on health status and function.

The hypothesis that increased QOL is predicted by conscientiousness was confirmed. Conscientiousness has been connected to social support (Mark & Lutgendorf, 1999) and it may be this aspect of conscientiousness that is linked to the social support and relationship QOL domains. The conscientious adult has a greater likelihood of engaging in proactive purposeful behaviors. These behaviors in turn may contribute positively to QOL domains such as material comforts and financial security, learning, work, and spirituality. Although conscientiousness was not included in the final risk profile, it was a notable predictor of QOL.

The hypothesis that extroversion would predict increased QOL was confirmed. It is reasonable to conclude that a tendency towards positive emotions, and a propensity

toward highly interactive activity and frequent communication, correspond to a greater QOL.

An individual with high levels of hardiness was hypothesized to have greater QOL and results from this study confirmed this relationship. Although the body of literature substantiating hardiness as a significant factor in positive psychological and physiologic adaptation continues to grow, previous results have not reported the contribution hardiness makes to identify a high risk QOL profile. Indeed, the hardiness construct was the most potent predictor in the resulting risk profile.

#### Family characteristic variables

OAT demands include significant lifestyle changes that potentially impact family members. Therefore, it was hypothesized that family problem-solving communication and family hardiness would be important factors predicting higher QOL. Both hypotheses were confirmed. Although family hardiness was a stronger independent predictor of QOL than family problem-solving communication, the final risk profile included family problem-solving due to multicollinearity issues between individual and family hardiness.

Interesting to note is that the subjects who used tobacco were more likely to have lower QOL scores. This may be a sample selection bias. All OAT persons are strongly encouraged to discontinue tobacco as part of their anticoagulation management since tobacco smoking contributes significantly to thromboembolic events. Indeed, a thromboembolism sometimes precipitates a person's discontinuing smoking. Increased neuroticism and lack of social support may be contributing factors in this population of

persons who lack success in smoking cessation. This higher neuroticism and weaker social system are linked to decreased QOL.

In conclusion, both individual and family characteristics have important relationships with QOL. It should be noted, however, that these factors were, for the most part, not independently significant when combined with each other in the regression model. The final model highlights the importance of individual hardiness, family problem-solving communication, and neuroticism as an amalgam of factors identifying those at risk for decreased QOL. The predictive model explained half of QOL variance. Overall, the greatest QOL risk is found in OAT persons who have low levels of individual hardiness, exhibit higher neuroticism, and tend to use incendiary rather than affirmative family communication. Interventions aimed at ameliorating the negative effects of these characteristics may be most useful.

### *Clinical Implications*

A major study advantage was the natural setting for the examination of OAT therapy. This included few exclusionary criteria in contrast to the considerable exclusion criteria of OAT clinical trials, the primary source of OAT literature. Therefore, results are more indicative of the general OAT population. Subsequently, the complexity of understanding OAT within the Family Ecology Theory in the general OAT population can now be appreciated. The vulnerability of a person at risk for decreased therapeutic control and QOL is dependent on specific negative factors that come together in one person. The person most at risk for poor outcomes from the Family Ecology Theory perspective is the



person demonstrating lower than the recommended levels of therapeutic control matched with lower than average subjective quality of life.

The goal of increasing the time spent in therapeutic control is paramount in OAT. Therefore, detecting the person with low therapeutic control and decreased quality of life (tcqol) in addition to the person with low therapeutic control and increased quality of life (tcQOL) is highly relevant for clinicians. Those at a younger adult age and using a greater number of prescriptions must be identified as at risk by the clinician. Accordingly, risk should be discussed between the provider and the identified tcqol and tcQOL adults. Every effort can be made to encourage the elimination of nonessential prescriptions. When this is not possible, anticipatory guidance should include preparing the individual for more frequent protime tests, and potential strategies to decrease the cognitive load of OAT. Patient self-testing at home may be particularly appropriate for the younger OAT individual taking multiple prescription medications.

The combination of resiliency factors related to QOL can be used in identifying QOL risk for both those who have a low quality of life and are therapeutically uncontrolled (tcqol) and those who have a low quality of life and are therapeutically controlled (TCqol). Anticoagulation management clinicians, who often see patients more frequently than other providers, may be in a unique position to identify those at risk for decreased QOL as well as to design and implement supportive interventions.

Hardiness may or may not be teachable, but reports suggest it is a modifiable characteristic that can be enhanced (DiBartolo & Socken, 2003, Judkins & Ingram, 2002). Those persons identified as less hardy may benefit from educational interventions

that focus on feeling more in control and on viewing OAT strains and challenges as opportunities for improving health rather than as a threat to well-being.

Recent reports (Srivastava, John, Gosling & Potter, 2003) suggest neuroticism, and indeed other personality traits, are characterized by plasticity and further, culture and critical events may become more influential on personality with age. These findings support the need to assist a highly neurotic person in reframing anxiety and helplessness, especially with respect to anticoagulation therapy. Such reframing in a more positive way can be handled by highlighting the extraordinary effectiveness of warfarin in preventing thromboembolic events. Although conscientiousness, extroversion, and family hardiness were not used in predicting a QOL risk profile, they may be useful in guiding interventions to promote QOL. Tools, such as written dosage directions, weekly pillboxes, and annual refills of OAT medication, all complement conscientious activities. Providing a social milieu encourages extroversion socializing. Individuals who express lower family problem-solving communication may be offered opportunities for learning affirmative communication and how to avoid incendiary communication. Finally, the clinician can promote family hardiness by including family members in discussions, involving family in therapy activities, and welcoming family assistance.

Anticipatory and preventive care for tcqol, tcQOL, and TCqol persons is recommended as discussed above. In addition, protective and preservative care supporting TCQOL, tcQOL, and TCqol persons is warranted. Assessing OAT strategies that maintain a low risk profile and supporting these with interventions can now come into focus. Showing acceptance for family involvement, promoting an inclusive

communication environment for family members, and providing adequate seating for family members during protime test visits are examples of care that promotes family hardiness and problem-solving communication. These activities allow the family to gain the knowledge needed to organize and manage tasks required for OAT and the opportunity to use affirmative communication to plan OAT-related strategies mutually. Further, affirming family involvement in care supports family hardiness by encouraging a family's sense of control over health and an active rather than passive orientation to OAT.

Providing positive reinforcement for adults actively controlling aspects of therapy and adhering to dosing and testing supports low-risk personality characteristics. Three quarters of the study sample utilized a memory device to assist them in remembering to take medication. Validation for this as well as other risk-reducing activities such as changes made to abstain from tobacco, to stabilize diet, and to decrease risk of bleeding is recommended. Encouraging expression of emotions and sociability through active listening by the clinician is supported by study results. Exploring fears of bleeding and clotting along with frustrations of therapy may be particularly helpful for the extroverted individual. For the introverted person who may be less likely to engage in discussion, acknowledging OAT fears and frustrations, in addition to encouraging the person taking anticoagulants to discuss concerns with significant others, may be useful strategies. Mutuality is necessary to sustain individual hardiness and a sense of control and should be a part of OAT management.

### *Future Research*

Although it is reasonable to conclude that the variables of younger adult age and the number of prescriptions caused increased risk of uncontrolled anticoagulation, the cross-sectional design precludes other assertions of causality. Incorporating useful concepts of personality and family, such as neuroticism and family problem-solving communications, into the Family Ecology Theory model of OAT intervention with respect to QOL is supported by this study's Predictive Model. Future longitudinal designs could explore temporal and causal relationships between personality and family factors and QOL. Does personality affect quality of life by influencing how people approach and react to life situations, so that a more neurotic individual is less able to confront and adapt to therapies? Or does QOL affect personality, so that lowered quality of life influences a person's anxiety and helplessness level? Since neither of these is mutually exclusive, both may occur. Longitudinal studies are recommended that seek answers to these questions.

The study findings for individual and family resiliency variables as strong indicators of QOL raise another important question. Do different aspects of resiliency relate to different aspects of QOL, as reported in at least one study (Hagberg, Hagberg & Saveman, 2002)? In addition, both neuroticism and extroversion may promote and at the same time counteract therapeutic control by a variable influence on different aspects of therapy. Investigations identifying how these characteristics related to the different demands of OAT could extend study findings.

One TC risk profile was modeled, based on investigation findings. However, the data also supported the possibility of multiple risk profiles. Further examination of three OAT-related aspects is recommended. First, the decreased therapeutic control experience by younger adult participants in this study suggests exploring how individuals successfully incorporate OAT into a busy life. Concepts related to cognitive load and vigilance may be particularly useful in developing a risk profile for younger OAT adults. Second, stratification according to bleeding experience may be productive. Fear of bleeding, even when the bleeding is minor, creates substantial anxiety for those on OAT (Lancaster et al., 1991). Evaluating resiliency factors as a mediating influence in those persons experiencing bleeding verses those who do not, and the resultant therapeutic control, may prove informative. Lastly, the results do not exclude relationships between family characteristics and therapeutic control in select populations where family interactions are stronger and family members more interdependent than in the study sample. Studies evaluating the relationship of family to therapeutic control in the homebound and cognitively impaired OAT adult are recommended.

Adapting individual and family measures to health-related constructs is recommended. This investigation suggests that although general conscientiousness is not related to therapeutic control, health-specific conscientiousness, likely an aspect of health vigilance, may be related to therapeutic control. In addition, a family's specific sense of control over health, view of health challenges as growth producing, and active rather than passive orientation in adapting to health care stress was not tested and may influence therapeutic control. Similarly, therapeutic control may be influenced by families using

communication that specifically conveys support and care and thereby exerts a calming influence during health-related stress, and avoiding inflammatory communication that exacerbates a stressful health-related situation.

### *Limitations*

The sample was composed of primarily Caucasian participants, and findings are not generalizable to ethnic OAT groups. Study participants appeared to have higher QOL scores than a comparative sample of chronically ill adults (Burkhardt, Clark & Bennett, 1993) so that results may not be generalizable to OAT populations where QOL is more indicative of a chronically ill population. In addition, results obtained at the study site with an OAT management system characterized by walk-in availability and direct phone contact with providers may not be generalizable to OAT populations at other types of OAT management facilities.

All individual, family and QOL information was from self-report instruments. This limited data to the study participant perceptions and introduces reporter bias. This was a trade-off in order to study OAT in a natural setting. Self-reporting bias may have affected the results and may explain why QOL and resiliency measures approximated normal healthy populations. Inconsistency due to self-reporting may also contribute to the results of this study. Use of more objective measures might have revealed relationships obscured by participant variability in reporting adherence, presence of chronic illness, and other health characteristics.

The method used to handle outliers, described in the results section, was chosen in order to avoid transformations which are clinically difficult to conceptualize.

Modifying outlier scores to less extreme scores has a tendency to obscure relationships and this may have influenced relationships involving the variables family hardness, family problem solving communication, and quality of life.

### *Summary*

In summary, nursing's greatest contribution to the investigation of OAT may be to explicate the complexities of relationships connected to the important outcomes of therapeutic control and quality of life. The OAT population is not a homogeneous group with respect to these outcomes. Four groups were identified, TCQOL, TCqol, tcQOL, and tcqol. Fit between therapeutic control and quality of life is a combination of multiple factors that come together to support one of the four constellations. This investigation elucidates key factors related to these groups, and suggests approaches to improve therapeutic control and quality of life in the growing population of anticoagulated persons.

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Appendix A  
Consent Form

**OREGON HEALTH & SCIENCE UNIVERSITY**  
**Informed Consent Form**

**TITLE:** Adaptation to the demands of oral anticoagulation therapy: the importance of individual and family resiliency factors.

**PRINCIPAL INVESTIGATOR:** Gail Houck, PhD (503) 494-3825  
Sara Pascoe, MN (503) 494-7631

**PURPOSE:** You have been invited to join this study because you are taking warfarin. The purpose of the study is to find out which personal and family strengths help people deal with the demands of taking warfarin (such as getting frequent blood tests and eating a steady vitamin K diet). Your part in this study will be for one day. Up to two hundred subjects will be enrolled in the study at OHSU.

**PROCEDURES:** You will be asked to fill out 7 questionnaires that will take you a total of 90 minutes to complete. One will ask questions about your personality. One will ask questions about how you deal with hardships. One will ask about the stresses your family has. Two will ask questions about how your family deals with hardships. One will ask questions about what you think your quality of life is. One will ask you to describe some things about yourself (age, gender, how you take medications, and so on). In addition, a research assistant will record the results of your anticoag (INR) blood test for the past 3 months from your medical record on to another sheet included in the questionnaire packet.

**RISKS AND DISCOMFORTS:** Some of these questions may seem very personal or awkward and may upset you. You may refuse to answer any of the questions that you do not wish to answer. If you become so upset by the questions that you appear to need counseling, you will be referred to a suitable counselor.

**BENEFITS:** You may or may not personally benefit from joining this study. However, by helping, you may add to new information, which may benefit patients in the future.

**ALTERNATIVES:** You may choose not to join this study.

**CONFIDENTIALITY:** Your name and your identity will not be used for study purposes. Study records may be read and/or copied by the OHSU Institutional Review Board (IRB).

**COSTS:** There will be no costs to you. Upon return of the completed questionnaires, you will be paid \$30 for your time and participation.

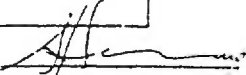
**LIABILITY:** The Oregon Health & Science University is subject to the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you suffer any injury and damage from this research project through the fault of the University, its officers or employees, you have the right to bring legal action against the University to recover the damage done to you subject to the limitations and conditions of the Oregon Tort Claims Act. You have not waived your legal rights by signing this form. For more information on this subject, or if you have further questions, please call the OHSU Research Integrity Office at (503) 494-7887.



**PARTICIPATION:** Sara Pascoe (503) 494-7631 has offered to answer any other questions you may have about this study. If you have any questions about your rights as a study subject, you may call the OHSU Research Integrity Office at (503) 494-7887. You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

Your health care provider may be the investigator of this research protocol, and as an investigator is interested in both your well-being and in this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another provider who is in no way part of this study. You are not under any duty to join any study offered by your provider.

You may be pulled out from the study before the study ends if the investigator thinks it is for the best.

<p>OREGON HEALTH &amp; SCIENCE UNIVERSITY          INSTITUTIONAL REVIEW BOARD          PHONE NUMBER (503) 494-7887          CONSENT FORM APPROVAL DATE</p> <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>JAN 15 2003</p> </div> <p>APPROVED BY           Do Not Sign This Form After The          Expiration Date Of: 1/14/04</p>
---

**SIGNATURES:**

Your signature below means that you have read the above and agree to join this study. You will get a copy of this consent form.

<hr style="border: 0; border-top: 1px solid black;"/> <p><i>Signature of participant</i></p>	<hr style="border: 0; border-top: 1px solid black;"/> <p><i>Date</i></p>
<hr style="border: 0; border-top: 1px solid black;"/> <p><i>Signature of investigator</i></p>	<hr style="border: 0; border-top: 1px solid black;"/> <p><i>Date</i></p>

**Appendix B**  
**INR Code Sheet**



Appendix C  
Demographic Data

## Background Information

<p>1. Age: _____</p> <p><del>2. Date of Birth: _____</del></p> <p>3. Ethnicity:</p> <ul style="list-style-type: none"> <li>1 African American</li> <li>2 Asian</li> <li>3 Caucasian</li> <li>4 Hispanic</li> <li>5 Native American</li> <li>6 Other: _____</li> </ul> <p>3. Sex:</p> <ul style="list-style-type: none"> <li>0 Male</li> <li>1 Female</li> </ul> <p>4. Education : (Please circle last grade completed)</p> <table style="width: 100%; border: none;"> <tr> <td>Grade School</td> <td>1 2 3 4 5 6 7 8</td> </tr> <tr> <td>High School</td> <td>9 10 11 12</td> </tr> <tr> <td>College</td> <td>13 14 15 16</td> </tr> <tr> <td>Post graduate</td> <td>17 or more</td> </tr> </table> <p>5. Gross Annual Income:</p> <ul style="list-style-type: none"> <li>1 less than 5,000</li> <li>2 5,000-24,999</li> <li>3 25,000-49,999</li> <li>4 55,000+</li> </ul> <p>6. Marital Status:</p> <ul style="list-style-type: none"> <li>1 Married/living with partner</li> <li>2 Single</li> <li>3 Divorced</li> <li>4 Widowed</li> </ul> <p>7. Employment status:</p> <ul style="list-style-type: none"> <li>1 Full time</li> <li>2 Part time</li> <li>3 Retired</li> <li>4 Unemployed</li> </ul>	Grade School	1 2 3 4 5 6 7 8	High School	9 10 11 12	College	13 14 15 16	Post graduate	17 or more	<p>6. Number of prescription medications taking daily - do not include vitamins: (Please circle number of medicines not number of pills)</p> <ul style="list-style-type: none"> <li>1 less than 5</li> <li>2 5 - 9</li> <li>3 10 - 14</li> <li>4 15 +</li> </ul> <p>7. Number of over-the-counter medications taken daily - include vitamins and natural or herbal remedies: (Please circle number of medications not number of pills)</p> <ul style="list-style-type: none"> <li>1 less than 5</li> <li>2 5 - 9</li> <li>3 10 - 14</li> <li>4 15+</li> </ul> <p>8. Are you taking aspirin prescribed by your doctor?</p> <ul style="list-style-type: none"> <li>1 No</li> <li>2 Yes</li> </ul> <p>9. Do you currently smoke tobacco?</p> <ul style="list-style-type: none"> <li>1 No</li> <li>2 Yes</li> </ul> <p>10. In the past 4 weeks have you missed or taken extra doses of warfarin/Coumadin ?</p> <p style="padding-left: 40px;">Yes ____ No ____</p> <p style="padding-left: 40px;">If yes, how many missed doses ____</p> <p style="padding-left: 40px;">how many extra doses ____</p> <p>11. Do you use a devise (pillbox) or system (checks on calendar) to help you remember to take your medication?</p> <p style="padding-left: 40px;">Yes ____ No ____</p>
Grade School	1 2 3 4 5 6 7 8								
High School	9 10 11 12								
College	13 14 15 16								
Post graduate	17 or more								

12. Source of health care funding

- 1 Insurance
- 2 Medicare
- 3 Medicaid
- 4 Self pay

13. Number of additional chronic illnesses:  
(Please circle all that apply)

- 1 High blood pressure
- 2 Obesity
- 3 Heart disease
- 4 Diabetes
- 5 High cholesterol
- 6 Lung disease
- 7 Kidney disease
- 8 Thyroid problems
- 9 Alcohol or drug use
- 10 Mental illness
- 11 Cancer
- 12 Liver disease
- 13 Ulcer or other stomach disease
- 14 Other: \_\_\_\_\_
- 15 Other: \_\_\_\_\_

Appendix D  
NEO Five Factor Inventory

## NEO Five-Factor Inventory Form S

Paul T. Costa, Jr., Ph.D., and Robert R. McCrae, Ph.D.

**Instructions:** This questionnaire contains 60 statements. Read each statement carefully. For each statement circle the response that best represents your opinion. Circle only one response for each statement. Respond to all of the statements, making sure that you fill in the correct response. Items are grouped and some are in bold characters to make answering easier.

0=Strongly disagree    1=Disagree    2=Neutral    3= Agree    4=Strongly Agree

- |   |   |   |   |   |   |
|---|---|---|---|---|---|
| 1. I am not a worrier.  | 0 | 1 | 2 | 3 | 4 |
| 2. <b>I like to have a lot of people around me.</b>   | 0 | 1 | 2 | 3 | 4 |
| 3. I don't like to waste my time daydreaming.   | 0 | 1 | 2 | 3 | 4 |
| 4. <b>I try to be courteous to everyone I meet.</b>   | 0 | 1 | 2 | 3 | 4 |
| 5. I keep my belongings neat and clean.   | 0 | 1 | 2 | 3 | 4 |
| 6. I often feel inferior to others.   | 0 | 1 | 2 | 3 | 4 |
| 7. <b>I laugh easily.</b>   | 0 | 1 | 2 | 3 | 4 |
| 8. Once I find the right way to do something, I stick to it.                                  | 0 | 1 | 2 | 3 | 4 |
| 9. <b>I often get into arguments with my family and co-workers.</b>                           | 0 | 1 | 2 | 3 | 4 |
| 10. I'm pretty good about pacing myself so as to get things done on time.                     | 0 | 1 | 2 | 3 | 4 |
| 11. When I'm under a great deal of stress, sometimes I feel like I'm going to pieces.         | 0 | 1 | 2 | 3 | 4 |
| 12. <b>I don't consider myself especially "light-hearted".</b>                                | 0 | 1 | 2 | 3 | 4 |
| 13. I am intrigued by the patterns I find in art and nature.                                  | 0 | 1 | 2 | 3 | 4 |
| 14. <b>Some people think I'm selfish and egotistical.</b>                                     | 0 | 1 | 2 | 3 | 4 |
| 15. I am not a very methodical person.  | 0 | 1 | 2 | 3 | 4 |
| 16. I rarely feel lonely or blue.   | 0 | 1 | 2 | 3 | 4 |
| 17. <b>I really enjoy talking to people.</b>  | 0 | 1 | 2 | 3 | 4 |
| 18. I believe letting students hear controversial speakers can only confuse and mislead them. | 0 | 1 | 2 | 3 | 4 |
| 19. <b>I would rather cooperate with others than compete with them.</b>                       | 0 | 1 | 2 | 3 | 4 |
| 20. I try to perform all the tasks assigned to me conscientiously.                            | 0 | 1 | 2 | 3 | 4 |



0=Strongly disagree    1=Disagree    2=Neutral    3= Agree    4=Strongly Agree

- |   |          |          |          |          |          |
|---|----------|----------|----------|----------|----------|
| 21. I often feel tense and jittery.   | 0        | 1        | 2        | 3        | 4        |
| <b>22. I like to be where the action is.</b>  | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 23. Poetry has little or no effect on me.   | 0        | 1        | 2        | 3        | 4        |
| <b>24. I tend to be cynical and skeptical of others' intensions.</b>                                      | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 25. I have a clear set of goals and work toward them in an orderly fashion.                               | 0        | 1        | 2        | 3        | 4        |
| 26. Sometimes I feel completely worthless.  | 0        | 1        | 2        | 3        | 4        |
| <b>27. I usually prefer to do things alone.</b>   | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 28. I often try new and foreign foods.  | 0        | 1        | 2        | 3        | 4        |
| <b>29. I believe that most people will take advantage of you if you let them.</b>                         | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 30. I waste a lot of time before settling down to work.   | 0        | 1        | 2        | 3        | 4        |
| 31. I rarely feel fearful or anxious.   | 0        | 1        | 2        | 3        | 4        |
| <b>32. I often feel as if I'm bursting with energy.</b>   | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 33. I seldom notice the moods or feelings that different environments produce.                            | 0        | 1        | 2        | 3        | 4        |
| <b>34. Most people I know like me.</b>  | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 35. I work hard to accomplish my goals.   | 0        | 1        | 2        | 3        | 4        |
| 36. I often get angry at the way people treat me.   | 0        | 1        | 2        | 3        | 4        |
| <b>37. I am a cheerful, high-spirited person.</b>   | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 38. I believe we should look to our religious authorities for decisions on moral issues.                  | 0        | 1        | 2        | 3        | 4        |
| <b>39. Some people think of me as cold and calculating.</b>   | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 40. When I make a commitment, I can always be counted on to follow through.                               | 0        | 1        | 2        | 3        | 4        |
| 41. Too often, when things go wrong, I get discouraged and feel like giving up.                           | 0        | 1        | 2        | 3        | 4        |
| <b>42. I am not a cheerful optimist.</b>  | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 43. Sometimes when I am reading poetry or looking at a work of art, I feel a chill or wave of excitement. | 0        | 1        | 2        | 3        | 4        |
| <b>44. I'm hard-headed and tough-minded in my attitudes.</b>  | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 45. Sometimes I'm not as dependable or reliable as should be.   | 0        | 1        | 2        | 3        | 4        |

0=Strongly disagree    1=Disagree    2=Neutral    3= Agree    4=Strongly Agree

- |   |          |          |          |          |          |
|---|----------|----------|----------|----------|----------|
| 46. I am seldom sad or depressed.   | 0        | 1        | 2        | 3        | 4        |
| <b>47. My life is fast-paced.</b>   | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 48. I have little interest in speculating on the nature of the universe or the human condition. | 0        | 1        | 2        | 3        | 4        |
| <b>49. I generally try to be thoughtful and considerate.</b>                                    | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 50. I am a productive person who always gets the job done.                                      | 0        | 1        | 2        | 3        | 4        |
| 51. I often feel helpless and want someone else to solve my problems.                           | 0        | 1        | 2        | 3        | 4        |
| <b>52. I am a very active person.</b>   | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 53. I have a lot of intellectual curiosity.   | 0        | 1        | 2        | 3        | 4        |
| <b>54. If I don't like people, I let them know it.</b>  | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 55. I never seem to be able to get organized.   | 0        | 1        | 2        | 3        | 4        |
| 56. At times I have been so ashamed I just wanted to hide.                                      | 0        | 1        | 2        | 3        | 4        |
| <b>57. I would rather go my own way than be a leader of others.</b>                             | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 58. I often enjoy playing with theories or abstract ideas.                                      | 0        | 1        | 2        | 3        | 4        |
| <b>59. If necessary, I am willing to manipulate people to get what I want.</b>                  | <b>0</b> | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> |
| 60. I strive for excellence in everything I do.   | 0        | 1        | 2        | 3        | 4        |

**Appendix E**  
**Health Related Hardiness Scale**

Number \_\_\_\_\_

## HEALTH-RELATED HARDINESS SCALE

## Instructions:

This is a questionnaire designed to determine the way in which different people view certain important issues related to their health. Each item is a belief statement with which you may agree or disagree. Beside each statement is a scale which ranges from strongly disagree (1) to strongly agree (6). For each item we would like you to circle the number that represents the extent to which you disagree or agree with the statement. Please make sure that you answer each item and that you circle only one number per item. Thank you for taking the time to complete this questionnaire.

	DISAGREE			AGREE			
	S	M	S	S	M	S	
	T	O	L	L	O	T	
	R	D	I	I	D	R	
	O	E	G	G	E	O	
	N	R	H	H	R	N	
	G	A	T	T	A	G	
	L	T	L	L	T	L	
	Y	E	Y	Y	E	Y	
		L			L		
		Y			Y		
1. Involvement in health promotion activities is stimulating.	1	2	3	4	5	6	_____
2. I can avoid illness if I take care of myself	1	2	3	4	5	6	_____
3. I find it difficult to be enthusiastic about good health.	1	2	3	4	5	6	_____
4. Luck plays a big part in determining how soon I will recover from an illness.	1	2	3	4	5	6	_____
5. No matter how hard I try to maintain my health, my efforts will accomplish very little.	1	2	3	4	5	6	_____
6. I am in control of my health.	1	2	3	4	5	6	_____
7. I admire people who work hard to improve their health.	1	2	3	4	5	6	_____
8. Good health is more important to me than financial security.	1	2	3	4	5	6	_____

DISAGREE      AGREE

S	M	S	S	M	S
T	O	L	L	O	T
R	D	I	I	D	R
O	E	G	G	E	O
N	R	H	H	R	N
G	A	T	T	A	G
L	T	L	L	T	L
Y	E	Y	Y	E	Y
	L			L	
	Y			Y	

- |   |   |   |   |   |   |   |       |
|---|---|---|---|---|---|---|-------|
| 9. My good health is largely a matter of good fortune.                        | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
| 10. No matter what I do, I'm likely to get sick.                              | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
| 11. I find it boring to eat and exercise properly to maintain my health.      | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
| 12. The main thing which affects my health is what I myself do.               | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
| 13. Changes taking place in health care are not exciting to me.               | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
| 14. I find people who are involved in health promotion interesting.           | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
| 15. Setting goals for health is unrealistic.                                  | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
| 16. Most things that affect my health happen to me by accident.               | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
| 17. Changes taking place in health care will have no effect on me.            | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
| 18. If I get sick, it is my own behavior that determines how soon I get well. | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
| 19. I do not find it interesting to learn about health.                       | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
| 20. I will stay healthy if it's meant to be.                                  | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
| 21. I am not interested in exploring new ways to improve my health.           | 1 | 2 | 3 | 4 | 5 | 6 | _____ |

DISAGREE      AGREE

S	M	S	S	M	S
T	O	L	L	O	T
R	D	I	I	D	R
O	E	G	G	E	O
N	R	H	H	R	N
G	A	T	T	A	G
L	T	L	L	T	L
Y	E	Y	Y	E	Y
	L			L	
	Y			Y	

- |  |   |   |   |   |   |   |       |
|--|---|---|---|---|---|---|-------|
| 22. No matter what I do, if I am going to get sick, I will get sick.                                   | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
|  |   |   |   |   |   |   |       |
| 23. I feel no need to try to maintain my health because it makes no difference anyway.                 | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
|  |   |   |   |   |   |   |       |
| 24. The current focus on health promotion is a fad that will probably disappear.                       | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
|  |   |   |   |   |   |   |       |
| 25. No matter how hard I work to promote health for society, it never seems to improve.                | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
|  |   |   |   |   |   |   |       |
| 26. Our society holds no worthwhile goals or values about health.                                      | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
|  |   |   |   |   |   |   |       |
| 27. If I take the right actions, I can stay healthy.   | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
|  |   |   |   |   |   |   |       |
| 28. I get excited about the possibility of improving my health.  | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
|  |   |   |   |   |   |   |       |
| 29. I am determined to be as healthy as I can be.  | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
|  |   |   |   |   |   |   |       |
| 30. When my health is threatened, I view it as a challenge that must be overcome.                      | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
|  |   |   |   |   |   |   |       |
| 31. I read everything I can about health.  | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
|  |   |   |   |   |   |   |       |
| 32. I can be as healthy as I want to be.   | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
|  |   |   |   |   |   |   |       |
| 33. When something goes wrong with my health, I do everything I can to get at the root of the problem. | 1 | 2 | 3 | 4 | 5 | 6 | _____ |
|  |   |   |   |   |   |   |       |
| 34. I have little influence over my health.  | 1 | 2 | 3 | 4 | 5 | 6 | _____ |

## Appendix F

### Family Inventory of Life Events and Changes



Family Stress, Coping and Health Project  
School of Human Ecology  
1300 Linden Drive  
University of Wisconsin-Madison  
Madison, WI 53706

## FILE

### FAMILY INVENTORY OF LIFE EVENTS AND CHANGES<sup>®</sup>

Hamilton I. McCubbin Joan M. Patterson Lance R. Wilson

#### Purpose:

Over their life cycle, all families experience many changes as a result of normal growth and development of members and due to external circumstances. The following list of family life changes can happen in a family at any time. Because family members are connected to each other in some way, a life change for any one member affects all the other persons in the family to some degree.

**"FAMILY"** means a group of two or more persons living together who are related by blood, marriage or adoption. This includes persons who live with you and to whom you have a long term commitment.

#### Directions:

**"Did the change happen in your family?"**

Please read each family life change and decide whether it happened to any member of your family — including you — during the past 12 months and check **Yes** or **No**.

Did the change happen in your family:	During the last 12 months		Score
	Yes	No	
<b>I. Intrafamily Strains</b>			
1. Increase of husband/father's time away from family			16
2. Increase of wife/mother's time away from family			51
3. A member appears to have emotional problems			58
4. A member appears to depend on alcohol or drugs			66
5. Increase in conflict between husband and wife			53
6. Increase in arguments between parent(s) and child(ren)			45
7. Increase in conflict among children in the family			48
8. Increased difficulty in managing teenage child(ren)			55
9. Increased difficulty in managing school age child(ren) (6-12 yrs)			39
10. Increased difficulty in managing preschool age child(ren) (2.5-6 yrs)			36
11. Increased difficulty in managing toddler(s) (1-2.5 yrs.)			36
12. Increased difficulty in managing infant(s) (0-1 yr.)			35
13. Increase in the amount of "outside activities" which the children are involved in			25
14. Increased disagreement about a member's friends or activities			35
15. Increase in the number of problems or issues which don't get resolved			45
16. Increase in the number of tasks or chores which don't get done			35
17. Increased conflict with in-laws or relatives			40



Did the change happen in your family:	During the last 12 months		
	Yes	No	Score
<b>II. Marital Strains</b>			
18. Spouse/parent was separated or divorced			79
19. Spouse/parent had an "affair"			68
20. Increased difficulty in resolving issues with a "former" or separated spouse			47
21. Increased difficulty with sexual relationship between husband and wife			58
<b>III. Pregnancy and Childbearing Strains</b>			
22. Spouse had unwanted or difficult pregnancy			45
23. An unmarried member became pregnant			65
24. A member had an abortion			50
25. A member gave birth to or adopted a child			60
<b>IV. Finance and Business Strains</b>			
26. Took out a loan or refinanced a loan to cover increased expenses			29
27. Went on welfare			55
28. Change in conditions (economic, political, weather) which hurts the family investments			41
29. Change in agriculture market, stock market, or land values which hurts family investments and/or income			43
30. A member started a new business			50
31. Purchased or built a home			41
32. A member purchased a car or other major item			19
33. Increased financial debts due to over-use of credit cards			31
34. Increased strain on family "money" for medical/dental expenses			23
35. Increased strain on family "money" for food, clothing, energy, home care			21
36. Increased strain on family "money" for child(ren)'s education			22
37. Delay in receiving child support or alimony payments			41
<b>V. Work-Family Transitions and Strains</b>			
38. A member changed to a new job/career			40
39. A member lost or quit a job			55
40. A member retired from work			48
41. A member started or returned to work			41
42. A member stopped working for extended period (e.g., laid off, leave of absence, strike)			51
43. Decrease in satisfaction with job/career			45
44. A member had increased difficulty with people at work			32
45. A member was promoted at work or given more responsibilities			40
46. Family moved to a new home/apartment			43

Appendix G  
Family Hardiness Index

## Appendix H

### Family Problem-Solving Communication



Family Stress, Coping and Health Project  
 School of Human Ecology  
 1300 Linden Drive  
 University of Wisconsin-Madison  
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## FPSC

### FAMILY PROBLEM SOLVING COMMUNICATIONS®

Marilyn A. McCubbin   Hamilton I. McCubbin   Anne I. Thompson

*When our family struggles with problems or conflicts which upset us, I would describe my family in the following way:*

	False	Mostly False	Mostly True	True
1. We yell and scream at each other.	0	1	2	3
2. We are respectful of each others' feelings.	0	1	2	3
3. We talk things through till we reach a solution.	0	1	2	3
4. We work hard to be sure family members were not hurt, emotionally or physically.	0	1	2	3
5. We walk away from conflicts without much satisfaction.	0	1	2	3
6. We share with each other how much we care for one another.	0	1	2	3
7. We make matters more difficult by fighting and bring up old matters.	0	1	2	3
8. We take the time to hear what each other has to say or feel.	0	1	2	3
9. We work to be calm and talk things through.	0	1	2	3
10. We get upset, but we try to end our conflicts on a positive note.	0	1	2	3

Appendix J  
Quality of Life Scale

## QUALITY OF LIFE SCALE (QOLS)

Please read each item and circle the number that best describes how satisfied you are at this time. Please answer each item even if you do not currently participate in an activity or have a relationship. You can be satisfied or dissatisfied with not doing the activity or having the relationship.

	Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
1. Material comforts home, food, conveniences, financial security . . . . .	7	6	5	4	3	2	1
2. Health - being physically fit and vigorous . . .	7	6	5	4	3	2	1
3. Relationships with parents, siblings & other relatives- communicating, visiting, helping . . .	7	6	5	4	3	2	1
4. Having and rearing children . . . . .	7	6	5	4	3	2	1
5. Close relationships with spouse or significant other . . . . .	7	6	5	4	3	2	1
6. Close friends . . . . .	7	6	5	4	3	2	1
7. Helping and encouraging others, volunteering, giving advice . . . . .	7	6	5	4	3	2	1
8. Participating in organizations and public affairs . . . . .	7	6	5	4	3	2	1
9. Learning- attending school, improving understanding, getting additional knowledge . .	7	6	5	4	3	2	1
10. Understanding yourself - knowing your assets and limitations - knowing what life is about . .	7	6	5	4	3	2	1
11. Work - job or in home . . . . .	7	6	5	4	3	2	1
12. Expressing yourself creatively . . . . .	7	6	5	4	3	2	1
13. Socializing - meeting other people, doing things, parties, etc . . . . .	7	6	5	4	3	2	1
14. Reading, listening to music, or observing entertainment . . . . .	7	6	5	4	3	2	1
15. Participating in active recreation . . . . .	7	6	5	4	3	2	1
16. Independence, doing for yourself . . . . .	7	6	5	4	3	2	1