

# Women's Experiences of Discontinuing Hormone Therapy

A Dissertation Presented

By

MARY A. FISCHER

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By

Mary A. Fischer MSN WHNP-BC NCMP

August 31, 2011

Approved as to style and content by:

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Susan Sullivan-Bolyai

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Rosemary Theroux

---

Julie Buring

---

Date

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Paulette Seymour PhD RN  
Dean  
University of Massachusetts/ Worcester  
Graduate School of Nursing

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## **Dedication**

This dissertation is dedicated to the memory of four extraordinary whose love, compassion and strength have been a source of inspiration throughout so many facets of my life: my dear aunts Mary Jennings Wessels and Merlyn Jennings Dutra, my wonderful mother-in-law Mabel Albert Canty and especially my mother Catherine Jennings Fischer. Mom, I know you have been with me throughout this journey, watching over me from a place of peace and freedom from the Alzheimer's Disease that took you from us long before we said our final goodbyes. I love you and still miss you every day.

## **Abstract**

### **Women's Experiences Discontinuing Hormone Therapy for Menopause**

Although many women find relief from menopause through hormone therapy (HT), current guidelines recommend that HT be used only for short-term relief of symptoms. Women who attempt to stop HT often encounter troublesome recurrent symptoms leading to a diminished quality of life (QoL); 25% of women who discontinue eventually resume HT. Unfortunately, there is little information for women and their health care providers as to the best way to discontinue HT or how to prepare and guide women through this process. An in-depth description of women's experiences during HT discontinuation and the factors influencing recurrent symptoms, QoL and discontinuation outcome would provide knowledge to develop much needed counseling and support interventions. The purpose of this study was to explore women's experiences discontinuing hormone therapy for menopause.

This Internet-based mixed-methods study used a dominant Qualitative Descriptive design with embedded quantitative QoL measurements. Participants completed the quantitative questionnaires online while open-ended questions were completed either online or by telephone. Interview data were analyzed through Qualitative Content Analysis; descriptive statistics were used to explore the quantitative measures. Participants were stratified by discontinuation status for comparison of variations in discontinuation experiences, QoL and influencing factors.

Thirty-four women (20 stopped, 9 resumed, 4 tapering) were enrolled. One overarching theme--'a solitary journey'--emerged: although all women embarked on this journey, each woman traveled her own path. Two subthemes--'burden and interference' and 'appraising risk'--encompassed the symptom factors (severity, interference and sensitivity) that influenced women's experiences and the manner in which women evaluated their options. Other influencing factors included: readiness

and reasons for stopping HT, beliefs about menopause and roles. QoL was strongly connected to symptoms for many but not all women. Information from health care providers was inconsistent; women desired more support from providers and other women.

The rich description of women's experiences stopping HT highlights the need for providers to assess women's sensitivity to symptoms and readiness to discontinue to determine which women might benefit from more support. Greater health literacy would enhance women's understanding of HT risks. More research is needed on symptom clusters and interference and strategies for minimizing their impact.

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## CHAPTER I

### STATE OF THE SCIENCE

Menopause is both universal and unique: all women who live long enough will experience menopause yet each woman's journey through menopause will be unique. Some women will navigate this transition with ease while others will be beset by much turbulence along the way. For women buffeted by distressing symptoms during their menopause voyage, hormone therapy (HT) can offer a haven of symptom relief and improved quality of life (QoL).

Despite the reduction in symptoms afforded by HT, many women eventually stop taking this medication: some discontinue on their own because of side effects while others do so based on recommendations by health care providers. However, women who attempt to stop HT often encounter troublesome symptoms that may thwart their efforts and cause them much suffering. There is little to guide these women, or their health care providers, as to the best ways to prepare for and navigate this passage.

In order to develop better educational and support interventions, further information is needed about the HT discontinuation phenomenon. An in-depth description of women's experiences of HT discontinuation and the factors that may influence this experience either positively or negatively would provide this information. Therefore, the purpose of this mixed methods study was to describe the experience of discontinuing HT. The specific aims were to:

- 1) explore women's experiences of HT discontinuation;
- 2) describe the personal characteristics and sociocultural contexts that influence symptom perception, evaluation and response among women who have attempted to discontinue HT;
- 3) explore the impact of HT discontinuation on women's quality of life; and

4) discuss women's preferences for counseling and support during HT discontinuation. This chapter will provide a review of the literature relevant to hormone therapy discontinuation and the development of the study purpose and specific aims.

### **Background and Significance**

In order to appreciate the challenges inherent to discontinuing HT, it is essential to understand why women experiencing menopause may choose to begin HT. Accordingly, the Background and Significance section will describe menopause and its associated symptoms as well as provide an overview of the history of HT and the critical event leading to the revelation of the gap in the literature of menopause discontinuation.

### **Overview of Menopause**

Approximately 2 million women experience menopause every year (North American Menopause Society [NAMS], 2007). Defined as a woman's final menstrual period (Glossary—Appendix 1), menopause usually occurs due to the decrease in ovarian function that accompanies aging, although for some women it may be a result of surgery, chemotherapy or radiation. The average age of natural menopause is 51.4 years; the normal range is 40-58 years. This relatively wide range reflects variability in the aging trajectory of the female reproductive system due to the impact of factors such as genetics, environmental exposures, and lifestyles and illnesses (Burger, Hale, Dennerstein & Robertson, 2008; NAMS, 2007; Santoro, 2005).

Because of this variability, chronological age cannot be used to define or predict menopause status. In order to better identify a woman's location in the menopause transition and to promote the adoption of a standard nomenclature, a model of reproductive aging was developed by the Stages of Reproductive Aging Workshop (STRAW) (Appendix 2) (Sherman, 2005; Soules et al., 2001).

**Menopause Symptoms.** The late reproductive and menopausal transition stages, as defined by this model, often herald the onset of physical and emotional changes and symptoms (Table 1). The prevalence of menopause symptoms is difficult to determine precisely as it varies by symptom, population characteristics, individual perceptions and methodological issues such as definitions of symptoms or measurement strategies (Crawford, 2000). While over 85% of women report more than one symptom (Woods & Mitchell, 2005), the experience of these symptoms is variable and subjective and influenced by factors such as ethnicity, genetics and environment (Table 2) (Obermeyer, 2000; Soules et al., 2001). For some women, these symptoms are extremely distressing or troublesome. An estimated 10-20% of women will ultimately seek health care advice or treatment to help manage their uncomfortable menopause symptoms and improve their QoL (Gass, 2006; Woods & Mitchell, 2005).

Some menopause symptoms are clearly associated with changes in the production of reproductive hormones (estrogen and progesterone) resulting from the gradual diminishing of ovarian function (Burger et al., 2008). These symptoms include menstrual cycle changes (irregular or heavy menstrual bleeding), urogenital symptoms (vaginal atrophy and perhaps urinary incontinence) and vasomotor symptoms (hot flashes and night sweats) (NAMS, 2007; National Institutes of Health [NIH], 2005). There is also new evidence suggesting that fluctuating hormone levels may be in part responsible for the onset or worsening of affective disorders (Ryan et al., 2009) although other factors such as life hassles (Smith-DiJulio, Woods & Mitchell, 2008) or a past history of behavioral health concerns may also be operational here (Freeman et al., 2004; Freeman, Sammel, Lin & Nelson, 2006).

Vasomotor symptoms (VMS) in particular have received much attention due to the frequency with which they are reported and their capacity to be disruptive and uncomfortable



(Warren, 2007). During the period of time just prior to and after the final menstrual period (FMP), approximately 35-85% (Utian, 2005) of women, and possibly more (Avis & Crawford, 2006), experience VMS: sensations of warmth, especially in the upper body, often accompanied by flushing, sweating, palpitations, dizziness, and/or feelings of anxiety or panic (Kronenberg, 1999; NAMS, 2007; Voda, 1997). VMS are thought to be due to a shrinking of the thermoneutral zone (TMZ) in the brain due to an increase in norepinephrine. When this TMZ is narrowed, even very small changes in core temperature can trigger VMS (Freedman, 2001).

Although women describe a myriad of other symptoms during their midlife years (Table 1), there is less evidence for a causal link between these symptoms and menopause. Some symptoms may be due to normal age-related changes or illnesses that develop during midlife. Others could be the result of menopause-related hormonal changes superimposed on the changes associated with aging (NAMS, 2007; Woods & Mitchell, 2005). Whatever the cause, non-vasomotor symptoms may also be distressing and burdensome, particularly as they occur at a time when women may be trying to cope with stressors related to other life transitions such as aging parents, children leaving home, changes in employment status, loss of a spouse/life partner or even growing older in a youth-oriented society.

Table 1.  
*Menopause-associated symptoms & changes*

<b>Cognitive Symptoms</b>	Decreased memory Diminished concentration		
<b>Affective Symptoms</b>	Mood swings Irritability	Anxiety Depression	
<b>Somatic Symptoms</b>	Fatigue Joint stiffness/pain Muscle aches Hair loss Dry skin and hair	Acne Brittle nails Headaches Hearing loss Breast pain	Sexual dysfunction Dizziness Changes in balance Weight gain Weight distribution changes

**Menopause Symptom Burden & Quality of Life.** The unpredictability and inconvenience of these symptoms can lead to embarrassment, frustration, changes in body image, stress and anxiety. Health care costs may be incurred for medications, testing, procedures, and consultations with specialists as well as for over-the-counter medications or complementary or alternative medicine (CAM) (Utian, 2005). Symptoms may also have a detrimental effect on workplace productivity (Burton, Pransky, Conti, Chen & Edington, 2004; Kronenberg, 1999; Utian, 2005) and family, social (Kronenberg, 1999; McVeigh, 2005; Utian, 2005) and sexual (Kingsberg, 2006; Kronenberg, 1999) relationships. Hygiene and laundry products, plus a greater consumption of energy resources for laundry and climate control, can add to the financial impact (Utian, 2005). Overall, the burden associated with menopause symptoms—fear, uncertainty, disruptions in professional and personal lives, and costly, uncomfortable and time-consuming tests and treatments—may be quite high (Kronenberg, 1999; Utian, 2005).

This symptom burden may have a deleterious effect on a woman's quality of life (QoL) (Utian, 2005; Woods & Mitchell, 2005) which is worrisome as low QoL has been implicated in increased mortality among midlife women (Kroenke, Kubzansky, Adler & Kawachi, 2008). However, results of studies on the association between menopause symptoms and QoL have been conflicting. Women who have more frequent or intense vasomotor and other symptoms have indeed described low QoL (Leddesert, Ringa & Breart, 1995; Oldenhaave et al., 1993; Williams, Levine, Kalilani, Lewis & Clark, 2008). However, other authors suggest that menopause has little impact on overall QoL (Avis et al., 2009; Li, Holm, Gulanick & Lanuza, 2000). Instead, life hassles and events, or personal characteristics such as education or attitudes toward menopause and aging, exert a greater impact on well-being and life satisfaction (positive

facets of QoL) than does menopause or accompanying symptoms (Dennerstein, Dudley, Guthrie & Barrett-Connor, 2000; Dennerstein, Leherter & Guthrie, 2002; Smith-DiJulio et al., 2008).

Findings from QoL studies in other disciplines have also demonstrated a lack of congruency between symptom reports or tallies and overall QoL ratings (Ferrans, 2007). This discrepancy may be due in part to the reliance on symptom checklists to measure QoL: the presence of symptoms does not necessarily correspond to a diminished QoL (Dennerstein & Helmes, 2001). Because QoL has multiple dimensions (symptoms, functional capacity, health, overall QoL) (Wilson & Cleary, 1995), measuring only one dimension does not provide a complete representation of QoL and limits comparisons between studies. This raises questions about the adequacy of using either menopause-symptom lists or an overall QoL question as the sole method of assessing QoL in women at menopause (Adler, 2002; Matthews & Bromberger, 2005; Wiklund, 1998). Overall QoL questions may minimize the impact of uncomfortable symptoms (Twiss et al., 2007; Wiklund, 1998). Conversely, responses on symptom checklists may reflect differences in interpretations, judgments, memory or symptom sensitivity which may, in turn, be due to variations in contexts such as culture or ethnicity (Crawford, 2007).

**Factors Influencing Menopause Symptoms.** All symptoms are influenced by the context in which they occur. Symptom experience (perception, evaluation and response) is influenced not only by the symptoms themselves (e.g., frequency, intensity, duration) but also by an individual's personal characteristics (e.g., genetics, weight) and sociocultural environment (e.g., ethnicity, social support) (Dodd et al., 2001; Lenz, Pugh, Milligan, Gift & Suppe, 1997; Woods & Mitchell, 2005). Although much of the literature has focused on biomedical factors, menopause occurs within a sociocultural context that greatly influences the meaning a woman attaches to menopause as well as her decisions about symptom management (Kaufert, 1996;

Sievert, 2006). Thus personal and sociocultural factors unique to each woman (see Table 2) impact on the degree to which menopause-related symptoms are perceived as troublesome or disruptive (Avis, Crawford & McKinlay, 1997; Dodd et al., 2001; Kafanelis, Kostanski, Komesaroff & Stojanovska, 2009; Lenz et al., 1997; Woods & Mitchell, 2005).

**Table 2.**  
*Factors associated with menopause symptom tolerance*

<i><b>More Symptoms and/or Less symptom tolerance</b></i>	
High frequency & severity of symptoms	Depression/Anxiety
Symptom duration/chronicity	Higher BMI
Symptom sensitivity/distress	Physical inactivity
Genetic polymorphisms	Childhood abuse
Age	Late perimenopause
Smoking	Surgical menopause
Stress/higher cortisol levels	Overall health/other illnesses
Severe PMS symptoms	Less social support
Low self-esteem/self-image	Lower socioeconomic status
Negative self-appraisal	African-American race
Type A personality	Negative attitudes toward coping strategies
Sensitivity to public perception	Negative attitudes toward aging &/or
Negative affect	menopause
<i><b>Greater symptom tolerance</b></i>	
Asian-American race (fewer symptoms)	Lower BMI
Positive attitudes toward menopause	Physical activity
Higher self-esteem	Fewer symptoms

**Symptom Management.** Numerous strategies exist for managing menopause symptoms. Treatment options include: lifestyle modification (e.g. dressing in layers), relaxation practices (paced respirations (Freedman, 2005) or Mindfulness-Based Stress Reduction (Carmody, Crawford & Churchill, 2006)), CAM (such as herbal supplements or Traditional Chinese Medicine) or Western-medicine prescription medications (including antidepressants or anti-seizure medications). However, the ‘gold standard’ for relief of menopause symptoms is HT containing either estrogen with progesterone (EPT) or estrogen alone (NAMS, 2007).

## Hormone Therapy

An estimated 15% of the almost 40 million women in the United States aged 50-74 (U.S. Census Bureau, 2000) use HT, primarily for relief of troublesome menopause symptoms (Wysowski & Governale, 2004). HT is popular because it effectively mitigates or alleviates many menopause-related symptoms such as VMS, sleep disruptions, mood and memory disturbances, joint pains, urogenital problems and even skin and hair changes (Barrett-Connor, Grady & Stefanick, 2005; NAMS, 2007).

**History of HT.** The first attempts to ‘treat’ menopause with hormone derivatives occurred in the 1920s and 1930s (See HT Timeline—Appendix 3) (Houck, 2006; Krieger et al., 2005; Schulkin, 2008; Watkins, 2007). In 1942, Premarin was introduced to the public for the treatment of uncomfortable symptoms due to estrogen ‘loss’ (Houck, 2006). It became popular in part due to books such as *Feminine Forever* (Wilson, 1966) which touted estrogen as the best treatment for the ‘deficiency disease’ of menopause (MacPherson, 1981; McCrea, 1983) and the means by which women could retain their femininity and youthful appearance for as long as they lived (Houck, 2006; Schulkin, 2008; Watkins, 2007). Although feminists and other grassroots women’s health activists decried HT as contributing to the medicalization of menopause (MacPherson, 1981; McCrea, 1983), many women opted to use HT because their perceptions of how they felt and how they looked were improved.

As findings from numerous observational studies pointed to cardiovascular and bone health benefits for women using estrogen, HT became a standard health-promotion prescription for mid-life women (Barrett-Connor et al., 2005). Negative sequelae of estrogen use—endometrial cancer, blood clots, irregular vaginal bleeding, gall bladder disease and even breast cancer—were also identified over the years however the perceived reductions in bone,

cardiovascular and other health concerns were believed to outweigh any risks (Barrett-Connor et al., 2005; Krieger et al., 2005). Women were encouraged to take HT indefinitely to maintain good health, relieve symptoms and decrease the risks of illnesses associated with aging. By the mid-1990s it had become the number one dispensed drug product in the United States.

Critics, however, argued that the observed health benefits were related more to a healthy woman effect (observational study participants tended to be in better overall health) (Johannes, Crawford, Posner & McKinlay, 1994; Scalley & Henrich, 1993) and that there was no good evidence in the form of randomized controlled trials (RCTs) to support the use of HT for health benefits. In response, several large RCTs were initiated in the 1990s to assess the level of benefit and safety of HT as a primary prevention strategy for cardiovascular disease (Stefanick, Cochrane, Hsia, Barad, Liu & Johnson, 2003). The most noteworthy of these studies, because of its eventual impact on the use of HT, was the Women's Health Initiative (WHI) (Watkins, 2007).

**Women's Health Initiative.** The WHI was a multicenter prospective study consisting of several clinical trials plus an observational study (Matthews et al., 1997). Over 27,000 postmenopausal women between the ages of 50-79 (median = 63) were enrolled in the hormone therapy (EPT) arm. Women were randomized to receive either placebo or conjugated equine estrogen (CEE) with medroxyprogesterone (MPA). (Women without a uterus received only CEE and were part of another study arm.) The primary benefit endpoint was decreased CVD while breast cancer was the primary adverse outcome (Barrett-Connor et al., 2005; Reed, Newton & LaCroix, 2004).

In July 2002, the EPT arm of the WHI was terminated three years early due to evidence indicating increased health risks among women taking CEE and progesterone. These risks included increases in: cardiac events,  $p = .05$  (particularly in the first year but remaining elevated

throughout five years), invasive breast cancer (after 4-5 years HT use), venous thromboembolism (increase during the first one-to-two years of use and remaining elevated afterwards) and stroke (beginning after year one) (Table 3) (Reed et al., 2004; Writing Group for the WHI Investigators, 2002). While the risks of breast cancer, stroke and thromboembolism were already known, the increase in cardiovascular events was surprising as HT had for so long been promoted for its cardioprotective effect.

***Reactions to the WHI.*** The early halt of the WHI and the findings of potential harms from HT were widely heralded in the news media, often gracing the headlines of newspapers and national television news (Canales, Breslau, Nelson & Ballard-Barbash, 2008; Foreman, 2002; Haas et al., 2006; Kolata, 2002). Focusing on the relative risks, some pundits exhorted women to stop taking hormones immediately. Frightened, women turned to their health care providers for support and answers.

However, most providers learned of the study's premature halt at the same time and through the same lay news sources as their patients and were just as surprised and puzzled (Kolata & Peterson, 2002). Without advance knowledge of the findings or new recommendations for practice, they were ill equipped to interpret the information and provide appropriate decision-making support (Canales et al., 2008; Watkins, 2007). Angry, confused and worried, many women discontinued HT, either on their own volition or at the urging of family, friends or health care providers.

Table 3.

*Summary of Results of WHI EPT Trial**N = 16,608 Ages = 50-79 Mean duration of HT use = 5.2 years*

ENDPOINT	NUMBER (annualized %)		RELATIVE RISK	95% CONFIDENCE INTERVAL	ABSOLUTE RISK (per 10,000 women/year)	ABSOLUTE BENEFIT (per 10,000 women/year)
	EPT (n = 8506)	PLACEBO (n = 8102)				
<b>Coronary Heart</b>	164 (0.37)	122 (0.30)	1.29	[1.02, 1.63]	7	
<b>Disease Stroke</b>	127 (0.29)	85 (0.21)	1.41	[1.07, 1.85]	8	
<b>Pulmonary Embolism</b>	70 (0.16)	31 (0.08)	2.13	[1.39, 3.25]	8	
<b>Breast Cancer</b>	166 (0.38)	124 (0.30)	1.26	[1.00, 1.59]	18	
<b>Colorectal Cancer</b>	45 (0.10)	67 (0.16)	0.63	[0.43, 0.92]		6
<b>Hip Fracture</b>	44 (0.10)	62 (0.15)	0.66	[0.45, 0.98]		5
<b>Total Mortality</b>	231 (0.52)	218 (0.53)	0.98	[0.82, 1.18]		
<b>Global Index</b>	751 (1.70)	623 (1.51)	1.15	[1.03, 1.28]	19-20 extra adverse advents	

*Sources:**Manson, 2008**Writing Group for the WHI Investigators, 2002*

*Changes in HT use and prescription patterns.* Using information obtained from health questionnaires completed by women having mammograms at facilities providing data to the San Francisco Mammography Registry, Haas and colleagues (2004) looked at HT use before and after WHI through May 2003. They found a sharp decline—18% per quarter, 95% CI [-21%, -16%]—in reported HT use after the WHI results were released (Haas, Kaplan, Gerstenberger & Kerlikowske, 2004).



Researchers from the Sloane Survey (a random-digit-dial national survey exploring medication use) conducted telephone interviews of 3853 female subjects over the age of 50 between January 2001 and June 2004. Pre-WHI the HT prevalence rate was 29%. However, the rate began to drop in early 2003 to a low of 12% by June 2004, representing a 57% post-WHI decrease. The most rapid decline occurred in the first half of 2003 after the FDA's release of new guideline for HT use (Kelly et al., 2005).

Prescription rates plummeted. There was a 38% decrease, 95% CI [37%, 39%] (Hersh, Stefanick and Stafford, 2004) in HT prescriptions dispensed by outpatient pharmacies from approximately 90 million prescriptions before July 2002 to only 60 million prescriptions between July 2002 and 2003 (Hersh et al., 2004; Wysoski & Governale, 2005). Visits to health care providers for HT prescriptions decreased from 32.7%, SE 2.6, in 2002 to 26%, SE 3.2,  $X^2 p = .002$ , in 2003 (Hing & Brett, 2006). Most of the decreases in HT prescriptions occurred primarily during the first three (Bestul, McCollum, Hansen & Saseen, 2004; Kim et al., 2005) to six (Kelly et al., 2005) months after July 2002, stabilizing after six to nine months.

The largest declines in prescriptions (66%, 95% CI [65, 67%]) were those for the specific HT formulation (PremPro) used in the WHI although prescriptions for other types of HT products decreased as well (Wysoski & Governale, 2005). There was also a 33% (95% CI [32, 34%]) drop in estrogen-only hormone (ET) prescriptions even though the 2002 WHI findings only applied to EPT and there were no recommendations for women to stop taking estrogen-only hormone preparations (Hersh et al., 2004).

Drug company promotional spending for HT, especially samples and direct-to-consumer advertising, also decreased, paralleling the decrease in HT prescription rates. In the second quarter of 2002, \$71 million dollars was spent on HT promotion whereas only \$55 million was

spent in the fourth quarter of 2003, a 37% decrease in the year after the WHI findings. The greatest reductions in promotional activities were for PremPro (Majumdar et al., 2004).

The declines in HT use were reported to be quite similar across socioeconomic and ethnic subgroups (Haas et al., 2004; Kelly et al., 2005). Wei et al. (2005) found no significant differences in decreases in HT prevalence among African-American (-41.6%), Asian (-38.4%) and White (-44.1%) women, between women with a college education (-43.4%) and those without (-42.4%), and between women above (-43.7%) and below (-41%) poverty level. A sampling of the literature from countries outside the USA reveals similar declines in HT use: Canada 28% (Guay et al., 2006), Germany 26% (Heitmann, Greiser and Doren, 2005), Hong Kong 43.5% (Leung, Ling & Tang, 2005), Australia 37.8% (Main & Robinson, 2008) and the United Kingdom 65%,  $p < 0.001$  (Menon et al., 2007). These results suggest that WHI findings were disseminated comparably among diverse groups both nationally and internationally.

***Symptom Recurrence & HT Resumption.*** While many women who attempted to stop HT after the release of the WHI findings encountered only mild or no symptoms (Grady, Ettinger, Tosteson, Pressman & Macer, 2003), some women, especially those symptomatic prior to initiating HT, did experience recurrent symptoms that proved quite troublesome and distressing (Grady et al., 2003; Ockene et al., 2005). Because of these symptoms, approximately 25% of women who discontinued HT after the WHI chose to resume hormones (Grady et al., 2003; Helenius, Korenstein & Halm, 2007).

Some women returned to their prior HT regimen. Others requested lower doses or different formulations such as transdermal HT (French, Smith, Holtrop & Holmes-Rovner, 2006; Newton et al., 2004), hoping that these might be safer than PremPro. As providers began using different HT preparations (Rolnick, Jackson, Kopher & DeFor, 2007), there was a corresponding

increase in prescription rates and promotional expenditures for lower dose Premarin and other non-Premarin HT products (Majumdar et al., 2004). It was not possible to determine how many of these lower dose prescriptions were for women resuming versus tapering HT. There is also no data detailing quantitatively how many times women attempted discontinuation or qualitatively what is the experience of repeated discontinuation and resumption.

**Current HT Recommendations.** Further analyses of the WHI data suggest that the cardiovascular risks may be specific to older women initiating HT over 10 years post-menopause (10-19 years: RR = 1.22; 20-plus years: RR = 1.71;  $p = 0.036$ ) while younger women appear to be at less risk (RR = 0.89) (Manson, Hsia, Johnson, Rossouw et al., 2003). There is renewed speculation that HT may be cardioprotective when initiated within a ‘window of opportunity’ soon after a woman’s FMP and prior to the age of 60 (Grodstein, Manson & Stampfer, 2006; Roussouw et al., 2007). Nevertheless, due to these risks, the current recommendations for HT are that it be used for symptom relief only and at the lowest dose for the shortest period of time (ideally five years or less) (American College of Obstetrics & Gynecology [ACOG], 2008; Ettinger, Barrett-Connor, Hoq, Vader & Dubois, 2006; NAMS, 2008; U.S. Preventive Services Task Force [USPSTF], 2005).

However, the experiences of the women who stopped HT after the WHI revealed a gap in the knowledge about HT discontinuation: menopause symptoms do recur after women discontinue HT and may be quite troublesome and distressing. Unfortunately, there is little information for health care providers as to the best way(s) to prepare, support and guide women stopping HT (Grady, 2006). Thus, women who attempt to discontinue HT may do so without adequate information about HT benefits and risks, discontinuation methods, or symptom management and health promotion strategies.

In 2005, an NIH State-of-the-Science Conference Statement on Management of Menopause-Related Symptoms called for further research to better describe the personal characteristics and self-care strategies associated with fewer symptoms, better symptom tolerance and higher QOL during menopause (NIH, 2005). This knowledge would provide much-needed information for counseling and supporting women through the menopause transition (Simon & Mack, 2003). Similar information is needed about and for women discontinuing HT (NAMS, 2008). The post-WHI exodus from HT has provided researchers with an opportunity to better understand what happens when women discontinue but this knowledge is far from complete and is primarily quantitative. There is little qualitative evidence describing women's experiences of HT discontinuation: their symptoms, management strategies, QoL as well as the overall experience of stopping or stopping and resuming HT.

### **Literature Review**

Some women choose to discontinue HT because of side effects, perceived risks or philosophical beliefs about medications or menopause that may be rooted in ethnic or cultural values (Horne et al., 2004; Pachter, 1994; Rice, 2005). Others attempt to discontinue because of advice from health care providers or family and friends. Until recently, their discontinuation experiences have been mostly invisible. Information has begun to emerge about the experiences of these women who discontinue HT, as the following review of the literature will demonstrate. However, there are still many unanswered questions about this phenomenon.

#### **HT Discontinuation Experience (Specific Aim 1)**

**HT Discontinuation before WHI.** Rooted in the context that HT was beneficial, pre-WHI researchers exploring why women initiated or discontinued HT often did so in an attempt to identify 'barriers' to HT use, not to assist those stopping their medications. It was not unusual

to find the terms ‘compliance’ or ‘adherence’ in the titles or objectives of the articles describing these studies (Bjorn & Backstrom, 1999; den Tonkelaar & Oddens, 2000; Ettinger, Li & Klein, 1996; Faulkner, Young, Hutchins & McCollam, 1998; NAMS, 1998; Regan, Emond, Attardo, Parker & Greenspan, 2001). Most ‘noncompliant’ women stopped HT within 1-2 years after initiation primarily because of side effects such as irregular bleeding or breast tenderness (Ettinger, Li & Klein, 1996). During 2001, for example, 53% of over 37,000 female members of a pharmacy benefits management company discontinued HT within one year of receiving their initial prescription (Kim et al., 2005). Little is recorded, however, as to whether or not they encountered any difficulties during discontinuation because most never contacted their health care providers for support or assistance (Grady, 2006) and very few studies reported recurrent symptoms among participants who were ‘noncompliant’.

In a study exploring whether abrupt declines in estrogen levels could induce VMS in previously asymptomatic women (N = 40), women without symptoms at baseline did not experience VMS after abrupt withdrawal of estrogen (Hammar et al., 1999). While this information may be helpful for women who started HT for reasons other than symptom control, it is not relevant to the population of women who initiate HT for symptom relief.

In stark contrast to the above findings, the results of a qualitative study exploring women’s reasons for discontinuing HT (Bond & Bywaters, 1999) served as a harbinger of what was to be revealed in the aftermath of the WHI. Participants in this study (N = 16) described both the recurrence of VMS and the appearance of new symptoms such as joint pain. Several women reported patterns of stopping and resuming HT as they struggled through the experience with minimal information, monitoring or support from their health care providers. Some felt isolated in their struggles; others expressed disappointment that they were not seen as partners in the

decision-making. However, because the focus of this study was also on how to increase compliance with HT, no recommendations were made for supporting women trying to discontinue HT. It was not until a large percentage of women stopped HT after the WHI that researchers began to explore this phenomenon to gain a better understanding of the aftermath of HT cessation.

**HT Discontinuation after WHI: Symptom Recurrence.** Approximately 30% of women who stop HT can expect to experience recurrent symptoms, both VMS and non-VMS, that may be quite troublesome (Grady et al., 2003). In one of the first studies to examine symptom recurrence, investigators interviewed 670 women in a large northern California HMO soon after the release of the WHI findings. All participants were between the ages of 50-69 and had taken HT for more than one year. Over half (56%;  $n = 377$ ) had attempted to stop HT and 70% of these women had no or only mild symptoms. However, the remaining 30% described symptoms that were very troublesome with flushes (88%) and sweating (76%) being the most common (Grady et al., 2003).

VMS are the most frequently reported recurrent symptom. However, they are not the only symptom women experience and women may have more than one symptom (Grady et al., 2003; Ness, Aronow & Beck, 2006; Shrader & Ragucci, 2006). Investigators surveyed 8405 participants from the WHI EPT arm who had been on EPT study pills as of July 2002. Among these women, the most commonly reported symptoms were joint pain and stiffness (36.8%); VMS were actually third (21%) in overall symptom reports. Over 54%, OR = 3.21, 95% CI [2.9, 3.56] of women who had joint symptoms prior to the study noted these symptoms recurred after stopping study medication, implying aging changes were not the causative factor. Although a

causal link between joint discomfort and hormone changes has not been definitively established, estrogen seems to have a mitigating effect on joint pain (Ockene et al., 2005).

Urogenital symptoms are also reported by 25% to 36% of women (Grady et al., 2003; Helenius et al., 2007; Ness et al., 2006; Rolnick, Kopher, DeFor & Kelley, 2005). These symptoms tend to be more common among older women: in a retrospective chart review (N = 205), researchers noted women over 65 years old reported urogenital symptoms (24%) more often than VMS (5%) (Ness et al., 2006). This is not unexpected as urogenital symptoms tend to worsen with time post menopause while VMS ease. Libido changes are less well documented in the literature: only one study reported a decrease in libido (25%; N = 101) among the participants (Helenius et al., 2007).

Other recurrent symptoms can include insomnia and fatigue (French et al., 2006; Grady et al., 2003; Helenius et al., 2007; Ockene et al., 2005), memory loss and difficulty concentrating (Ockene et al., 2005) and miscellaneous somatic symptoms such as weight gain, headaches, breast tenderness, skin and hair changes, edema and gastrointestinal symptoms (appetite changes, bloating or gas) (Ockene et al., 2005). The gastrointestinal symptoms are particularly noteworthy as there is limited information about the effect of HT cessation on the gut although women do report changes in gastrointestinal function with hormonal fluctuations (Jacobson, Moy, Colditz & Fuchs, 2008).

Although non-VMS greatly influence the overall symptom experience, QoL and the outcome of women's attempts to discontinue (Grady et al., 2003), they have not been studied to the same extent as VMS (Warren, 2007). Thus, further exploration of these non-vasomotor symptoms, their severity and trajectory and the strategies women employ to manage them, would also inform the development of symptom management interventions. More information is also

needed as to whether certain symptom clusters, combinations, or interactions may be more distressing or troublesome.

Most of the information about recurrent symptoms comes from quantitative studies that used symptom checklists to identify symptoms. There is little describing the day-to-day experiences of women who discontinue or the impact on their lives, including relationships and work. Only one post-WHI study has explored HT discontinuation from a qualitative perspective. In this study, 127 women attending a family practice responded to a written questionnaire consisting of both structured and open-ended questions related to their post-WHI attitudes and HT decision-making. Over half (50/78) of the women who had been taking HT in July 2002 stopped after the WHI results were released. These women described being very symptomatic with moderate to severe hot flashes similar to those experienced before initiating HT (French et al., 2006).

***Symptom Similarities and Differences.*** It has occasionally been assumed that discontinuation symptoms will mimic symptoms experienced prior to initiating HT and will hopefully be short-lived and less intense (Aslan et al., 2007; Ockene et al., 2005). For many women this may be true. The majority (n = 92; 64.3%) of women in a recent Swedish study who had been symptomatic before beginning HT (n = 143) reported that recurrent VMS were less distressing than their initial symptoms. However, for a few (n = 9; 6.3%) of the women, recurrent symptoms were actually worse and more distressing than symptoms prior to HT (Lindh-Astrand, Brynhildsen, Hoffman & Hammar, 2009).

Similarly, three of the nine women participating in a phenomenological study exploring the experience of cessation of menses described recurrent symptoms that were more intense and debilitating than their initial menopause symptoms. They even referred to these symptoms as



‘withdrawal’ or rebound symptoms and were especially worried about the possible duration of these symptoms (Matarese, 2005).

Although the majority of women who experience uncomfortable discontinuation symptoms also have uncomfortable symptoms before initiating HT, for some these symptoms may be a new experience. In the aforementioned study by Grady et al. (2003), most of the women with troublesome recurrent symptoms also had symptoms prior to initiating HT. However, 20% of women with severe symptoms had not been symptomatic at baseline (Grady & Sawaya, 2005) unlike the women in the pre-WHI study by Hammar et al. (1999). This difference may be a product of the short duration of estrogen in the latter study. However, the findings from Grady & Sawaya (2005) underscore the need to prepare all women stopping HT, even those asymptomatic beforehand, for the possible onset of uncomfortable symptoms.

Similarities and differences in symptom experiences before and after HT use have not been explored in depth. Further knowledge of these differences and their impact on the outcome would be helpful for preparing women for discontinuing HT.

***Symptom Duration.*** After HT is discontinued, symptoms often recur quickly, within 4-6 weeks of discontinuance (Gordon et al., 2004). Some women actually report symptoms beginning as early as one week (median, interquartile range = 0-4 weeks) after stopping (Grady et al., 2003). However, because many of the post-WHI discontinuation studies are cross-sectional and were conducted within the first year after the WHI (Grady et al., 2003), there is little information about the actual duration of recurrent symptoms. In one recent study, women who had been off HT for almost a year still reported some symptoms (Haskell et al., 2009). Recent study findings indicate that the trajectory of menopause symptoms in general may be longer than previously thought. Among 205 women in a longitudinal Australian study, the average duration

of hot flashes was 5.5 years, whether or not HT was used (Col, Guthrie, Politti & Dennerstein, 2009). It would be helpful to know whether discontinuation symptoms persist in a similar manner in order to more effectively prepare and support women.

***Symptom Management Strategies.*** Women experiencing a recurrence of troublesome symptoms may employ a variety of both medication and non-medication symptom management strategies. Among WHI-EPT participants (n = 6503) who were queried after the cessation of the study (Ockene et al., 2005), almost 46 % tried non-medication strategies; women taking EPT study pills used these techniques more than women taking placebo pills (49% versus 41%,  $p < .001$ ). Strategies reported as most helpful included: using fans or air conditioners (95%), incorporating yoga, meditation and breathing techniques (94%), wearing cotton or layered clothing (93%), socializing more (93%) and drinking more fluids (88%).

Medication-related strategies include prescription medications such as antidepressants (for VMS as well as mood) (Haskell, 2004; Helenius et al., 2007; Kupferer, Dormire & Becker, 2009; Ness et al., 2006; Ockene et al., 2005; Vegter, Kolling, Toben, Visser & de Jong-van den Berg, 2009), antihypertensives and antiseizure medications (Kupferer et al., 2009) and sleep medications (Ockene et al., 2005). Prescription vaginal estrogen products were used by women experiencing urogenital symptoms (Helenius et al., 2007; Ness et al., 2006). Pharmacy databases corroborated a trend toward an increase in prescriptions for vaginal estrogen preparations (Premarin cream 118% and Estrace cream 300%) after the WHI (Wegienka, Havstad & Kelsey, 2006). However, there is little in the literature about therapies women used for recurrent or new-onset sexual dysfunction concerns (e. g. diminished libido or anorgasmia).

Approximately 20-30% of women in the post-WHI studies tried CAM products including over-the-counter herbal or nutritional supplements such as Black Cohosh, Evening Primrose Oil,

soy and Vitamin E (Kupferer et al., 2009; Ness et al., 2006; Ockene et al., 2005; Rolnick et al., 2005; Shrader & Ragucci, 2006). A few women tried alternative medical systems such as homeopathy, Traditional Chinese Medicine (TCM) or ayurvedic medicine (Kupferer et al., 2009). Findings regarding the efficacy of these strategies and modalities to relieve symptoms are mixed: some women noted little relief from alternative methods (Rolnick et al., 2005) while others found them helpful (Helenius et al., 2007; Kupferer et al., 2009; Shrader & Ragucci, 2006). Often multiple CAM therapies were used simultaneously making it difficult to determine the efficacy of any one method.

Women turned to CAM because it was perceived as a safe alternative to HT, however there are questions and concerns about safety, quality, dosage consistency and side effects with many of these therapies. In addition, because women may not report using CAM, and providers don't always ask, CAM use may not be documented in the medical record (Ness et al., 2006; Shrader & Ragucci, 2006) increasing the potential for drug interactions between CAM and prescription medications.

Some women may have opted to try so-called 'natural' hormone preparations: over-the-counter hormone creams or custom-compounded 'designer' hormones similar to those promoted by celebrities (Somers, 2004). Unfortunately, there is no good evidence that these products are effective and/or have a better safety profile for breast or endometrial cancer and stroke than does FDA-approved HT. Quality and dose consistency are also of concern with these products (Patsner, 2009; Pinkerton, 2009).

***HT Resumption.*** As previously noted, approximately 25% of women chose to resume HT to manage troublesome recurrent symptoms. Women resuming HT often do so quite soon—within three to six months—after discontinuing (Newton et al., 2008; Wegienka et al., 2006)

although more delayed resumptions (9-12 months or more) have also been documented (Grady et al., 2003; Haimov-Kochman et al., 2006b; Haskell et al., 2009). Delays in resuming HT may be related to symptom duration and/or discontinuing HT by tapering. In the first instance, women hoping to remain off HT may not decide to resume until troublesome symptoms are prolonged. Women also tend to resume HT when recurrent symptoms are at their peak which occurs later for those attempting to taper (Haimov-Kochman et al., 2006b). Some women actually describe making more than one attempt to stop HT (Bond & Bywaters, 1999; Helenius et al., 2007) underscoring the need for long-term monitoring and support for women discontinuing HT as well as further research that will help set expectations of the experience to guide women and their health care providers.

Of the 50 women who had stopped HT in the qualitative study by French et al. (2006), 12 had already resumed HT at the time of the interviews because of recurrent symptoms, feeling that they were not quite ready to quit. Nonetheless, they expressed fears and worries about continued use of HT as did the women who had chosen not to discontinue. Five of those who resumed stated they were using lower doses in an attempt to taper. Some women who had stopped HT were considering resuming. Clearly recurrence of distressing symptoms is a factor in HT resumption.

### **Factors Influencing the Experience of HT Discontinuation (Specific Aim 2)**

Many factors influencing women's decisions to begin or continue HT were noted in the pre-WHI literature. Some of these are similar to the factors associated with either positive or negative experiences of menopause (Johannes, Crawford, Posner & McKinlay, 1994; Reynolds, Obermeyer, Walker & Guilbert, 2001 & 2002) (see Table 4). Factors associated with more symptom burden may predispose a woman to initiate HT whereas women with greater symptom

tolerance or fewer symptoms are less inclined to initiate or continue HT. More recently, characteristics associated with both discontinuation and resumption of HT are being explored.

Table 4.

*Factors associated with menopause symptoms and HT use*

<b>Factors Associated with Symptoms</b>		<b>Factors Associated with HT Use</b>
<b><i>More Symptoms &amp;/or Less symptom tolerance</i></b>		<b><i>Use of HT</i></b>
High frequency & severity of symptoms	Depression/Anxiety	Uncomfortable VMS and other symptoms
Symptom duration/chronicity	Negative affect	Improved QOL on HT
Symptom sensitivity/distress	Age	Higher education
Genetic polymorphisms	Smoking	Higher SES
Stress/higher cortisol levels	Higher BMI	Better health
Severe PMS symptoms	Physical inactivity	Caucasian ethnicity
Low self-esteem/self-image	Childhood abuse	Greater self-efficacy
Negative self-appraisal	Late perimenopause	Surgical menopause
Type A personality	Surgical menopause	Belief that HT will decrease bone and heart health risks
Sensitivity to public perception	Overall health/other illnesses	
Negative attitudes toward aging and/or menopause	Less social support	
Negative attitudes toward coping strategies	Lower socioeconomic status	
	African-American race	
<b><i>Greater symptom tolerance</i></b>		<b><i>Not using HT</i></b>
Asian-American race (fewer symptoms)		Unpleasant side effects
Positive attitudes toward menopause		Fear of cancer
Higher self-esteem		Worry about hormones
Lower BMI		Positive attitude toward menopause
Physical activity		Negative attitude toward medications
Fewer symptoms		Non-USA countries
		Non-Caucasian ethnicity

**Recurrent Symptoms and HT Resumption.** Some post-WHI researchers have sought to identify factors predictive of unsuccessful discontinuation in order to target women needing closer monitoring and support when stopping HT. Their findings indicate that troublesome or severe recurrent symptoms are the most common reason women resume HT (French et al., 2006; Grady et al., 2003; Helenius et al., 2007; Ockene et al., 2005). But what factors are associated with these symptoms? One common denominator is the presence of symptoms prior to initiating HT. In numerous studies (French et al., 2006; Grady et al., 2003; Haimov-Kochman et al., 2006;

Helenius et al., 2007; Ockene et al., 2005), women who were symptomatic at baseline were more likely to experience uncomfortable symptoms upon discontinuation.

In the previously discussed study by Grady et al. (2003), troublesome symptoms were more likely to reoccur among women who initially started HT for symptom relief than among women who began for other reasons (37% versus 26%, *t*-test  $p = .01$ ). Within the WHI-EPT cohort ( $N = 8405$ ), the rate of recurrence of moderate or severe VMS was over 50% ( $n = 503$ ,  $p < .001$ ) when women taking EPT study pills also had VMS prior to entering the study ( $n = 950$ ) (Ockene et al., 2005).

Other factors typically associated with more troublesome symptoms at baseline have also been linked to HT resumption. These include: surgical menopause (Grady et al., 2003; Lawton, Rose, McLeod & Dowell, 2003), using ET only (Poisson regression,  $RR = 2.91$ , 95% CI [2.77, 3.06]) (Buist et al., 2004), younger age (Buist et al., 2004; Taylor, MacLennan & Avery, 2006; Ockene et al., 2005; Wegineka et al., 2006), starting HT less than three years after the FMP (logistic regression,  $OR = 5.0$ , 95% CI [1.4, 18]) (Barber, Margolis, Luepker & Arnett, 2004) and beginning HT for non-health promotion reasons (Grady et al., 2003). Women who have a surgical menopause experience more intense symptoms and most women using ET-only have had a surgical menopause (Brett & Madans, 1997). Women who started HT primarily for non-health promotion reasons often did so primarily for relief of uncomfortable symptoms. Women starting HT close to their FMP would have been more likely to be symptomatic at baseline as would younger women. Thus, women with any of these characteristics could expect to experience more distressing symptoms after stopping HT.

Age may also impact on the experience of recurrent non-VMS. For example, changes in memory and concentration are more common in younger women (Ness, Aronow & Beck, 2005;

Ockene et al, 2005). These women are more likely to still be employed and as a result the discomfort, embarrassment and stress associated with recurrent symptoms may impact on their work productivity. They also need to rely on memory and concentration skills on the job and even small changes in these skills would present challenges and cause distress.

Symptom combinations may herald particular challenges for some women. Affective symptoms—irritability, mood swings, anxiety, panic attacks and even depression—recur more often in younger age groups (Helenius et al., 2007; Ness et al., 2006; Ockene et al, 2005; Stewart, Rolfe & Robertson, 2004) who are more likely to also be having recurrent VMS. Severe VMS have been associated with worse depression symptoms in menopausal women (Reed et al., 2009). As noted earlier, the fluctuating hormonal milieu accompanying menopause may increase the risk of mood disorders or depression, especially among women with pre-existing emotional issues (Cohen, Soares, Vitonis, Otto & Harlow, 2006; Freeman et al., 2004; Freeman et al., 2006; Ryan et al., 2009). These women may be more vulnerable to recurrence of mood-related conditions when estrogen levels drop upon discontinuing HT. Therefore it is critical that providers screen women for pre-existing mood disorders prior to HT discontinuation and monitor them closely through discontinuation.

The severity of recurrent symptoms may be influenced by a woman's ethnicity. African-American women have more frequent menopause symptoms than do European-Caucasian women (Appling, Paez & Allen, 2007; Avis et al., 2001; Gold et al., 2000). However, only one post-WHI study examined HT discontinuation in a non-European American population. Among 101 African-American and Hispanic HT discontinuers from an inner city internal medicine practice, 75% reported recurrent VMS and 42% rated them as severe. Those with more severe

symptoms were more likely to have had troublesome symptoms pre-HT and thus more likely to resume (Helenius et al., 2007).

As previously noted, symptom duration may be a factor in HT resumption. In one study of 91 Israeli women who stopped taking HT, those whose severe symptoms lasted longer were more likely to resume HT (HR 1.22, CI 95%: 1.02-1.46). Women who have severe symptoms for a prolonged time may become less tolerant of these symptoms and thus more likely to reinitiate HT (Haimov-Kochman et al., 2006b).

Despite the reoccurrence of troublesome symptoms, some women do not resume HT. In the Grady et al. study (2003), approximately 20% of the women who successfully discontinued HT also reported having severe recurrent symptoms but it is not clear what factors may have promoted greater symptom tolerance among these women. A qualitative approach may help to identify some of these important factors.

**Other Factors Influencing HT Resumption.** Non-symptom related factors may also influence HT resumption. Beliefs about HT risks can impact whether or not women resume. Women using HT for many years without complications and women using non-Premarin HT perceive themselves to be at lower risk and are more likely to resume (French et al., 2006; Grady et al., 2003). The absence of comorbidities (Bosworth et al., 2005) such as cardiovascular disease (Haskell et al., 2008; Heller et al., 2005; Newton et al., 2005), hyperlipidemia and diabetes (Newton et al., 2005) and/or the perception of a higher fracture risk (Grady et al., 2003; Newton et al., 2005) are also associated with an increased likelihood of reinitiating HT. In contrast, women who perceive barriers to long-term HT use (risks, expense, side effects, fears of breast cancer or having to take medication continuously) are more likely to discontinue (logistic regression,  $n=157$ ,  $B = 0.150$ ,  $p < 0.05$ ) (Gerend, Aiken, Erchull & Lapin, 2006).



A woman's choice of health care provider may play a role in whether she resumes HT. Gynecologists are more skeptical of the WHI results (Power, Anderson & Schulkin, 2009). They are better able to interpret the findings in terms of relative versus absolute risk and are more favorable to HT than internal medicine or family practice physicians (Brett, Carney & McKeown, 2004; Power et al., 2009; Williams, Christie & Siström, 2005). More experienced providers also tend to be wary of the WHI findings (Power et al., 2009; Power, Zinberg & Schulkin, 2006) and are more likely to advise women not to discontinue or to resume if necessary for recurrent symptoms (Guay et al., 2006).

As part of their analysis of the data collected from telephone interviews (N = 377), Grady et al. (2003) used multivariable logistic regression to develop a set of predictor characteristics to better identify women who may encounter more difficulty in stopping HT. The three critical factors that emerged were: having a hysterectomy (OR 1.9, 95% CI [1.1, 3.6]), using HT for more than ten years (OR 1.2, 95% CI [0.6, 2.4]) and starting HT for non-health promotion reasons (OR 2.0, 95% CI [0.8, 4.6]). Among women for whom all three factors were present, 44.3% resumed HT—a seven-fold increased likelihood. When only one or two characteristics were noted, the rate of resumption dropped to 25% and when women had none of these characteristics, only 9% resumed HT. The primary predictor however was development of troublesome or severe symptoms (OR 8.8; 95% CI [1.1, 3.6]) which increased the resumption rate fourfold, even when none of the predictor characteristics were present.

**Discontinuation Method.** Believing that the method of HT discontinuation can influence both symptom recurrence and HT resumption, many physicians advise women to discontinue HT by gradual tapering (Bush et al., 2007). However, there is little evidence in the literature to support this recommendation. Most studies to date have not reported the method of

discontinuation and most of those that have were not randomized: women selected their own method of discontinuing and there was no consistency in type and duration of tapering (Haskell, 2004; Rolnick et al., 2005).

Few post-WHI studies have specifically attempted to determine whether discontinuation method is associated with variations in symptoms and HT resumption; only two were randomized. Aslan et al. (2007) randomized 70 women on HT to either an immediate discontinuation group or a two-week taper group ( $n = 35$  in both groups). After four weeks, there were no differences in either group with respect to frequency and severity of symptoms. The lack of significant findings was most likely related to the rapidity of the taper as well as assessing symptoms so soon after discontinuation.

In another randomized controlled trial (RCT), 91 women were randomized to either abrupt cessation ( $n = 50$ ) or a six-month gradual cessation ( $n = 41$ ) (Haimov-Kochman et al., 2006a). Discontinuation method did not impact on the overall severity of symptoms or rate of resumption. However it did influence the time of symptom onset, peak symptom severity and HT resumption. Women who stopped abruptly encountered severe symptoms very soon after discontinuing, much worse than the gradually discontinuers ( $p < 0.0001$ ), and those who resumed did so within three months. In contrast, among those who stopped gradually, symptom severity worsened dramatically as tapering progressed and by six months these women had VMS severity scores surpassing the month 3 symptom scores of those who stopped abruptly ( $p = .001$ ). Most taperers who resumed did so between three to six months (Haimov-Kochman et al., 2006a).

The results of this study showed a trend ( $p = 0.67$ ) toward lower resumption rates among women who taper (Haimov-Kochman et al., 2006a). In contrast, in the study by Grady et al. (2003) women who stopped abruptly ( $n = 269$ ) were less likely to resume (24%;  $n = 65$ ) than

those who tapered (29%; 32/107) but these findings also did not achieve statistical significance ( $p = .27$ ).

A recent retrospective observational study (Haskell, Bean-Mayberry & Gordon, 2009) produced several surprising findings about the impact of tapering on symptom recurrence and discontinuation success. Among 836 postmenopausal female veterans who had discontinued HT post-WHI, 75% stopped abruptly while the remainder tapered. Multivariate analyses showed that tapering was associated with younger age (OR 0.97, 95% CI 0.94-0.99), initiating HT for menopause symptoms (OR 1.79, 95% CI 1.12-2.87) and longer use of HT (OR 1.65, 95% CI 1.08-2.51)—all factors associated with more troublesome symptom recurrence and resumption of HT. Surprisingly, however, in a multiple logistic regression model these women had lower menopause symptom scores (estimates = -0.58, SE = 0.21,  $p = 0.01$ ) after discontinuation than those who stopped abruptly. It is possible that the retrospective study design may have affected recall of troublesome symptoms because of the time between discontinuation of symptoms and completing the study survey.

Of particular interest however is the significant association between tapering and later HT resumption (OR 2.06, 95% CI 1.20-3.52): even though women who tapered HT tended to have fewer symptoms, they were more likely to resume. It is possible that some women may not be able to tolerate *any* degree of symptom recurrence (Haskell et al., 2009) suggesting that there may be other factors influencing this experience.

Table 5.

*Factors associated with menopause symptoms, HT use and HT resumption*

<b>Factors Associated with Symptoms</b>	<b>Factors Associated with HT Use</b>	<b>Factors Associated with HT Resumption</b>
<i>More Symptoms &amp;/or Less symptom tolerance</i>	<i>Use of HT</i>	<i>Resuming HT</i>
High frequency & severity of symptoms Symptom duration/chronicity Symptom sensitivity/distress Genetic polymorphisms Age Stress/higher cortisol levels Severe PMS symptoms Low self-esteem/self-image Negative self-appraisal Type A personality Sensitivity to public perception Depression/Anxiety Negative affect Higher BMI Smoking Physical inactivity Childhood abuse Late perimenopause Surgical menopause Overall health/other illnesses Less social support Lower socioeconomic status African-American race Negative attitudes toward aging and/or menopause Negative attitudes toward coping strategies	Uncomfortable VMS and other symptoms Improved QOL on HT Higher education Higher SES Better health Caucasian ethnicity Greater self-efficacy Surgical menopause Belief that HT would decrease bone and heart health risks	*Troublesome recurrent symptoms *Symptoms at baseline *Starting HT for non-health promotion *Surgical menopause *Estrogen therapy only *Younger age *Tapering HT *Gynecology provider *Using non-Premarin HT
<i>Greater symptom tolerance</i>	<i>Not using HT</i>	<i>Not resuming HT</i>
Asian-American race (fewer symptoms) Positive attitudes toward menopause Higher self-esteem Lower BMI Physical activity Fewer symptoms	Unpleasant side effects Fear of cancer Worry about hormones Positive attitude toward menopause Negative attitude toward medications Non-USA countries Non-Caucasian ethnicity	*Older age *Comorbidities *Non-caucasian ethnicity

Although some characteristics predictive of worse symptom experiences and HT resumption have been identified, this list is certainly not exhaustive when compared to characteristics known to impact on initial menopause symptoms and HT initiation (see Table 5). While some of these previously-known factors may still be salient in the discontinuation setting there may be other less well-known factors that also influence the experience and outcome of HT discontinuation. One possible factor is life transitions: women discontinuing HT after long-term use may have sustained life changes or transitions (retirement, loss of partner, illness) that could reduce their capacity to cope with hormone withdrawal symptoms (Voda & Ashton, 2006).

In order to understand why some women are more tolerant of recurrent symptoms, further research was needed to identify other factors that may influence the experience and the outcome of women's discontinuation efforts. A qualitative approach would provide an in-depth description of the experience of discontinuing HT and help to uncover other factors influencing symptom tolerance and QoL.

### **HT Discontinuation and Quality of Life (Specific Aim 3)**

Quality of life is often used as an outcome measure in research exploring the impact of HT on menopause symptoms. In clinical practice, women frequently use this criterion when weighing benefits and risks of various treatment options. But here too, findings have been mixed. While some studies show great symptom reduction and improvement in menopause-related QoL with HT, women's overall QoL often shows no significant improvement (Brunner et al., 2005; Hays et al., 2003; Hess et al., 2008; Hlatky, Boothroyd, Vittinghoff, Sharp & Whooley, 2002; Welton et al., 2008). This may be related to the aforementioned variability in defining and measuring QoL. It may also be due to mixed-age study samples: women further from their FMP often report greater QoL than perimenopausal or recently post-menopausal women .

**QoL after HT Discontinuation.** Despite the increasing popularity of measuring QoL in menopause research, there is limited information from post-WHI studies as to the impact of discontinuing HT on QoL and, in turn, the influence of QoL on HT resumption. Specific QoL measurements are notably absent from the HT discontinuation literature. Many studies measured symptoms only, using checklists (Haimov-Kochman et al., 2006a; Ockene et al., 2005) or chart review (Ness et al., 2006). When overall health was measured, no significant relationships were found between health status and HT discontinuance or resumption (Grady et al., 2003, Helenius et al., 2007).

As part of the WISDOM (Women's International Study of long Duration Oestrogen after Menopause) trial, a UK study similar to the WHI, focus groups were conducted to explore women's HT decisions post-WHI. Although the researchers did not specifically focus on HT discontinuation, some participants did discuss their decision regarding HT resumption. The key factors in their decision were recurrent symptoms and diminished QoL. For women choosing to resume or continue HT, enhancement of QoL (described as feeling or looking better) was a benefit that outweighed any risks highlighting the need for further investigation of how women themselves define and evaluate QoL in relation to menopause and HT (Welton et al., 2003).

In the qualitative study by French et al. (2006), women also cited a desire to look or feel better' as a rationale for resuming or continuing HT. A recent qualitative study of attitudes toward HT provides further insight: here participants also reported that HT made them feel better but described this in terms encompassing more than symptom relief. They saw HT as helping them to perform better in their daily activities, maintain balance and integrity, and preserve their self-image, youthful appearance and physical well-being (Kolip, Hoefling-Engels & Schmacke, 2008). These in-depth descriptions reflect multiple dimensions of QoL and are more closely

aligned with the concept of overall QoL, suggesting that women evaluate more than just symptoms when assessing QoL. This again implies that measuring symptoms alone is not a sufficient measure of QoL (Dennerstein & Helmes, 2001). These findings also demonstrate the benefits of a qualitative approach to elicit dimensions of QoL not captured solely through quantitative instruments.

Further research is necessary to assess the impact of HT discontinuation on QoL. The question remains however as to how best to measure QoL. A comprehensive approach could include both menopause-specific and overall QoL measures combined with qualitative interviews to elicit women's subjective definitions and descriptions of their QoL during and after discontinuing HT (Crawford, 2007). However, no post-WHI studies have used this approach.

#### **Education and Counseling for HT Discontinuation (Specific Aim 4)**

Quality of life is one of many factors women consider when making decisions regarding HT (Schied, Coleman & Hamm, 2003; Theroux, 2009). These decisions are based on an elaborate risk-benefit analysis which includes other factors such as personal and family health history and experiences, attitudes toward menopause, aging, and medications and perceived advantages and harms of HT (Bravata, Rastegar & Horwitz, 2002; Hunter, O'Dea & Britten, 1997; Marmoreo, Brown, Batty, Cummings & Powell, 1997; Theroux, 2009; Walter & Britten, 2002). Thus, in order to make informed decisions about discontinuing or resuming HT as well as symptom management strategies, women need accurate information about HT benefits and risks and what to expect when stopping.

In addition to facilitating decision-making, being better informed may also help improve women's tolerance of menopause symptoms: among breast cancer survivors with chemotherapy-induced menopause (N = 31), those who were better prepared and more knowledgeable

experienced less symptom distress and uncertainty than women with less preparation (Knobf, 2008). These findings suggest that women's experience of HT discontinuation and the eventual outcome may be dependent in part on the information they receive prior to stopping their hormone medications. Unfortunately, women's knowledge of HT is all too often fraught with misperceptions and misinformation and many women overestimate HT's possible harms while underestimating the benefits (Deeks, Zoungas & Teede, 2008; Johnson, Ozdemir, Hauber & Kauf, 2007; Levens & Williams, 2004; Schied et al., 2003).

Information sources may be responsible for some of women's misperceptions. After the release of the WHI results, women who stopped HT most often turned to the media (Ettinger, Grady, Tosteson, Pressman & Macer, 2003; Haskell, 2004) or their health care providers (Barber, Margolis, Luepker & Arnett, 2004; Ettinger et al., 2003; Haskell, 2004) for information and advice. However, reports in the lay press often framed the WHI findings negatively, focused on breast cancer while downplaying the cardiovascular risks, and presented only relative risk of adverse events rather than absolute risk (Canales et al., 2008; Haas et al., 2006). As a result, women attributed the risks of HT improperly as they contemplated whether to discontinue or resume (Main & Robinson, 2008; McIntosh & Blalock, 2005; Parker-Pope, 2007; Welton et al., 2003). In addition, few reports distinguished between EPT and ET, which may have contributed to the vast numbers of women who stopped ET even though the 2002 results did not apply to them (McIntosh & Blalock, 2005).

Women who turned to health care providers did not fare much better. Because the initial WHI reports refuted findings from prior observational studies, calling into question the practice of recommending HT for cardiovascular health, providers felt less confident in their understanding of the findings (Bush et al., 2007). Some providers also confused relative and



absolute risk, resulting in an overestimation of HT-associated risks (Williams et al., 2005). It is not surprising therefore that many women expressed dissatisfaction with the level of support and advice presented to them. They described the amount of counseling they received from their providers as less than adequate (Ettinger et al., 2003; Flanagan, Serrato, Altschuler, Tallam & Thomas, 2005) and verbalized a desire for more consistent information (Breslau et al., 2003).

Of particular concern is the lack of counseling regarding health promotion behaviors. Symptoms are not the only sequelae of discontinuing HT: women may experience other physiologic changes that are less obvious but which have profound implications for long-term health. It is well known that bone health deteriorates when HT is stopped (Simon, Wehren, Ascott-Evans, Omizo, Silfren & Lombardi, 2006). Women may also develop higher lipid levels thus increasing cardiovascular risks (Petee et al., 2007). Furthermore, new evidence suggests that women with worse VMS, such as women who begin HT for non-health promotion reasons, may be at greater risk of cardiovascular events (Gast et al., 2008; Huang, Sawaya, Vittinghoff, Lin & Grady, 2009; Thurston, Sutton-Tyrell, Everson-Rose, Hess & Matthews, 2008). Therefore it is critical that women stopping HT initiate lifestyle modifications and/or different medications to minimize bone loss (Simon & Mack, 2003) and cardiovascular risk (Petee et al., 2007).

Unfortunately, only a smattering of post-WHI studies described whether study participants attempted to modify their risks by lifestyle or medication changes, e. g. taking calcium and/or bisphosphonates for bone health (Ness et al., 2006; Rolnick et al., 2005; Shrader & Ragucci, 2006) or increasing cardiovascular exercise (Ockene et al., 2005; Rolnick et al., 2005). In fact, less than half of the 142 women in a primary care practice reported discussing disease prevention or health promotion with their providers after the WHI. In this study, only 34% of women at risk for osteoporosis (39 of 114) and 26% of women with cardiovascular risk

factors (32 of 122) recalled having conversations with their providers about their risks (Schonberg & Wee, 2005).

Furthermore, as a consequence of the lack of adequate and accurate information, women became less trusting of their health care providers (McIntosh & Blalock, 2005; Schonberg, Davis & Wee, 2005). This lack of trust extended beyond menopause and HT concerns: 34% of the participants in the study by Schonberg et al. (2005) stated they were less willing to take new medications to prevent cardiovascular disease. Nonwhite women, who are often at greater cardiac risk, were less willing than white women to accept new medications, putting them at even greater risk of cardiac events (Schonberg et al., 2005).

Other negative emotions were also evoked by the fallout of the WHI. In the few qualitative studies that mentioned women's experiences stopping HT, feelings of grief, guilt, fear, isolation and anger also surfaced. Women grieved the loss of their symptom-free life and the higher energy and positive attitude they enjoyed on HT (French et al., 2006; Welton et al., 2003). Those who reinitiated or never stopped expressed worry and fear that they had made the wrong decision (Kolip et al., 2009; Welton et al., 2003). Some experienced guilt, as though using HT was a secret vice and a few women even voiced anger at HT manufacturers (French et al., 2006). These powerful emotions have not been described in other studies and speak to the usefulness of a qualitative approach to elicit information not yet known or fully understood about HT discontinuance (French et al., 2006; Kolip et al., 2009). A deeper understanding of these reactions as well as what information women consider critical to know about discontinuing HT would help providers to better counsel and support women, ultimately improving their trust, minimizing negative reactions and decreasing the health risks for women stopping HT.

Table 6.

*Gaps in the knowledge of HT discontinuation*

<b>What is known about HT discontinuation</b>	<b>What is not known about HT discontinuation</b>
Both VMS and non-VMS can recur	Does HT merely postpone the menopause transition? How similar is the discontinuation symptom experience to the pre-HT symptom experience? How long do recurrent symptoms last? Are there any symptom combinations that cause more distress than others?
Some predictors of more troublesome symptoms have been identified	What other factors influence the symptom experience and outcome (e.g. coping strategies, life transitions, symptom interactions, personal characteristic, sociocultural influences)?
Some women resume HT because recurrent symptoms are very troublesome	What women might be better off not discontinuing HT?
QOL influences resumption of HT	How does discontinuation impact on both menopause-specific and overall QoL?
Discontinuation may result in reversals in bone and cardiac health	What do women know & do about changing health risks after stopping HT?
Women are unhappy with the amount of counseling they receive	What are women's preferences for counseling and education? What is the best way to prepare women for this experience? What is the best way to discontinue HT?

**Summary**

Women stopping HT, either of their own volition or on the recommendations of their health care providers, need to be thoroughly prepared with information about how best to discontinue, what symptoms to expect, how to manage symptoms, and how to maintain or initiate healthy lifestyle behaviors to offset bone and cardiovascular disease risks. Better counseling,

symptom management and health promotion strategies are needed to prepare and support women through this experience and beyond. Researchers have begun to explore this phenomenon but there is still much to be learned (Table 6). An in-depth description of women's experiences with HT discontinuance, including personal characteristics and strategies associated with greater symptom tolerance, quality of life (National Institutes of Health, 2005) and successful discontinuation, would provide information for developing education and support interventions for assisting women through this experience. Therefore, the purpose of this exploratory descriptive study was to describe the experience of discontinuing HT.

## CHAPTER II

### PURPOSE, PARADIGMS AND FRAMEWORK

This study was designed to develop an in-depth understanding of the experience of discontinuing HT in order to determine how to better prepare and support women attempting to cease HT. During the design process, a conceptual framework based on a model developed by Woods and Mitchell (2004) was used to undergird this study. This chapter will provide a review of the study purpose and aims followed by a discussion of the use of conceptual models in research, culminating with a description of the Woods and Mitchell framework.

#### **Purpose and Specific Aims**

Although HT may provide welcome relief from the troublesome symptoms that may accompany menopause, it is only recommended for short-term (five years) use because of risks such as stroke, breast cancer, and thromboembolism (NAMS, 2008). Many women will eventually attempt to discontinue HT, however recurrent symptoms can make this experience a difficult one (Ockene et al., 2005). Unfortunately, there is minimal information as to how best to counsel and support women during this experience (Grady, 2006).

Therefore, the purpose of this mixed methods study was to describe the experience of discontinuing HT. It was hoped that through an in-depth description of women's experiences of discontinuing HT, the study findings would provide information critical for fostering the development of much-needed counseling, symptom management and health promotion strategies. The specific aims were to:

- 5) explore women's experiences of HT discontinuation;

- 6) describe the personal characteristics and sociocultural contexts that influence symptom perception, evaluation and response among women who have attempted to discontinue HT;
- 7) explore the impact of HT discontinuation on women's quality of life; and
- 8) discuss women's preferences for counseling and support during HT discontinuation.

### **Philosophical Paradigm and Conceptual Framework**

Menopause has often been dichotomized into either a biomedical or sociocultural phenomenon and research has reflected that polarized view with investigators approaching menopause through an either-or lens. The biomedical tradition is tied to an overarching depiction of menopause as a deficiency state: a *disease* or endocrinopathy best *treated* by replacing what is lost—estrogen (Andrist & MacPherson, 2002; Dickson, 1989; MacPherson, 1981; Rothfield, 1997; Voda, 1997; Wilson, 1966). In contrast, the sociocultural approach focuses on menopause as a normal developmental process that has been culturally defined. In this view, each woman's unique psychological, social and cultural characteristics are the primary influences on how she navigates this passage (Andrist & MacPherson, 2001; Dickson, 1989; Voda, 1997).

In truth, both views are reductionistic with neither view alone capturing the totality of women's experiences through menopause. Women have been confused, angered and silenced either by being told that they should take medication for what they perceive as a natural, normal process or by having their health concerns or troublesome symptoms dismissed as products of social and cultural roles and attitudes (Goldstein, 2000; Voda, 1997). In order to bridge this gap, investigators conducting research on women's health through menopause must work within paradigms and frameworks that give support and structure to explorations of women's complex, multifaceted lives.

## **Philosophical Paradigm**

The philosophical paradigm of pragmatist feminism served as the foundation for the proposed study. Pragmatist feminism may be viewed as an intersection of two distinct paradigms: feminism and pragmatism (Duran, 1993). Feminist epistemology focuses on issues of gender and how gender influences knowledge and inquiry, rejecting the traditional androcentric view of women as products of their reproductive biology and therefore inferior and incapable of knowing. This view renders women's knowledge and experience invisible (Andrist & MacPherson, 2001; Im, 2007; Sullivan, 2007).

In contrast, a feminist worldview seeks to deconstruct categories that are dichotomous, absolute and exclusive and instead to understand how experiences are connected and interrelated in order to reveal the complex reality of women's lives (Campbell & Bunting, 1999; Rodgers, 2005). Research rooted within a feminist paradigm is situated within women's lived experiences and perspectives (Harding, 1987) and thus is subjective and contextual. Feminist-based research is nonhierarchical with the researcher always in-relation to the subject-knower as a partner in the process of inquiry and knowledge creation. The researcher's reflexive sharing of her/his experiences with the research and the validation of findings with participants provide further insight and understanding of the phenomena (Anderson, 2007; Andrist & MacPherson, 2001; Campbell & Bunting, 1999; Harding, 1995; Im, 2007). Feminist scholarship strives to be *for* women (MacPherson, 1983; Hesse-Biber & Leckenby, 2004), integrating knowledge with action in order to improve women's lives (Andrist & MacPherson, 2001, Campbell & Bunting, 1999; Im, 2007). Thus knowledge generated within a feminist epistemology, irrespective of the methods used to obtain data, is embodied, reciprocal, intersubjective and relevant.

While early feminist researchers and writers favored qualitative research methods in order to avoid transforming women's experiences into exclusive categories, this reliance on one method is reductionistic in itself (Campbell & Wasco, 2000). Quantitative methods are also used by feminist researchers who often formulate their questions and hypotheses so that their findings will uncover women's situated knowledge and influence social change (Harding, 1995; Miner-Rubino, Jayaratne, & Konik, 2007). In fact, the use of multiple methods of exploration could be considered commensurate with women's multiple ways of knowing (Leckenby & Hesse-Biber, 2007; Reinharz, 1992; Stewart & Cole, 2007).

The philosophical tradition of pragmatism was developed in the United States in the late nineteenth century in an effort to find alternative meanings of the nature of knowledge and inquiry and, through this new knowledge, bring about social change (Maxcy, 2003). Pragmatism rejects Cartesian dualisms and reductionism and seeks to integrate theory and practice, subject and object, the natural-physical world and the social-psychological world, mind and body, in order to ultimately transform the human condition (Johnson & Onwugbuzie, 2004; Morgan, 2007; Sullivan, 2007). Traditional assumptions of a fixed Truth are replaced by a belief in multiple truths that are contextual, provisional and dynamic (Creswell, 2009; Creswell & Clark, 2007; Johnson & Onwugbuzie, 2004). Concepts, hypotheses and theories are understood through their practical consequences (Hookway, 2008). Knowledge is transactional, rooted in and emerging through the interaction of the body-mind of the knower with the objective real world (Greene, 2007; Seigfried, 1991; Sullivan, 2001). Of particular relevance to nursing and nursing research is that patterns of caring knowledge are developed and strengthened through embodied interactions with others (Hamington, 2004).



Research from a world view of pragmatism focuses on the experiences and problems of living organisms situated within their social, political, and cultural environment (Johnson & Onwugbuzie, 2004; Sullivan, 2007). Research consequences or findings become tools for social action or change. The research question takes primacy and any research method which can answer the question and ultimately transform lives is deemed appropriate (Bryman, 2006; Tashakkori & Teddlie, 2003). Pragmatic research is eclectic, holistic and pluralistic. Pragmatic researchers are able to look at issues through both macro and micro lens, thus integrating empirical and descriptive precision (Onwugbuzie & Leech, 2005). Not surprisingly, some proponents of mixed methods research invoke pragmatism as the philosophical paradigm that underpins their efforts to understand the complex realities of human lives (Johnson & Onwugbuzie, 2004; Onwugbuzie & Leech, 2005; Tashakkori & Teddlie, 2003).

The intersections of pragmatism and feminism are fairly obvious. Both reject dualism, the concept of a fixed reality or absolute truth, and the superiority of thinking over doing. Both stress the importance of embodied experiences, relationships, connections and transactions in the creation and emergence of knowledge. Finally, both endorse pluralistic methods for knowledge development with the improvement of living conditions or the enactment of social change as the ultimate goal (Duran, 1993; Sullivan, 2007; Whipps, 2004). Thus a conjoined pragmatist feminist epistemology would replace the dichotomy of the biomedical and sociocultural approaches to menopause research with a holistic perspective that reconnects the many facets of women's experiences. An emphasis on the primacy of women's experiences serves as the basis for developing knowledge to improve women's lives through menopause and beyond. Therefore, pragmatist feminism formed the foundation on which was set the conceptual framework that

provided structure to the mixed methods study on women's experiences with HT discontinuation.

### **Conceptual Framework**

The conceptual framework that supported this mixed methods study is based upon a model developed by Woods & Mitchell (2005) for studying perimenopausal symptoms. According to Miles & Huberman (1994), a conceptual framework explains "...either graphically or in narrative form...the key factors, constructs or variables—and the presumed relationships among them" (p.18). Conceptual frameworks or theories inform every aspect of a study, beginning with the choice of a research topic, question and purpose through the selection of a design and measurements, and ultimately to the data analysis and re-presentation of the findings (Burns & Grove, 2005; Maxwell, 2005; Sandelowski, 1993). Theories or frameworks may also be refined through their use within a study as their strengths and weaknesses become more readily apparent (Fowler, 2006; Anfara & Mertz, 2006).

Because this study used a mixed methods approach, the framework had to be applicable to both the qualitative and quantitative components (Maxwell & Loomis, 2003). It is important, therefore, to understand the role of conceptual frameworks in different types of research, particularly in qualitative research which is the dominant approach of the proposed study.

**Conceptual Frameworks in Quantitative Research.** In quantitative research, theories or frameworks play a critical role in the development of causal or predictive hypotheses derived from the research questions. Variables to be studied are operationalized from the concepts of the theory and the data are analyzed and discussed in terms of whether they verify or refute the theoretically-driven hypotheses (Anafara & Mertz, 2006; Burns & Grove, 2005; Seibold, 2002). Because theories or frameworks in quantitative research are typically used in the exploration of

differences among variables, they are sometimes referred to as variance theories (Maxwell & Loomis, 2003).

**Conceptual Frameworks in Qualitative Research.** The role of models or frameworks in qualitative inquiry is not dissimilar. As in quantitative research, frameworks help the researcher to remain focused during the development of specific aims and research questions and more clearly develop interview questions or observational strategies (Ayres, 2007; Fowler, 2006; Anafara & Mertz, 2006). A framework helps the researcher to ‘make sense’ of the data, guiding the initial data review and providing a means to organize emerging patterns and even identify relationships not previously known or understood (Kearney & Hyle, 2006; Maxwell, 2005; Seibold, 2002). Because qualitative research often asks questions about the process, context and/or meaning of an event or phenomenon, theories used in this type of research are sometimes termed process theories (Maxwell & Loomis, 2003).

Although the role of frameworks is similar in both types of research, in qualitative research the framework may be less rigid and more open and emergent. The amount of structure provided by frameworks or theories falls along a continuum from very loose to very tight (Miles & Huberman, 1994). For beginning researchers, tighter designs provide more focus, direction and manageability (Merriam, 2006), prevent overload and promote generalizability (Miles & Huberman, 1994).

At the same time, frameworks should not be deterministic. While a framework may provide direction and guidance, care must be taken to prevent it from becoming prophetic or constraining, leading to premature closure (Harris, 2006; Mills & Bettis, 2006). Instead, it is the obligation of the researcher to maintain a degree of skepticism and, during continued and prolonged engagement with the data, seek out alternative interpretations and explanations. This

pattern of continued engagement with and withdrawal from the framework becomes a part of the iterative process of qualitative research (Mills & Bettis, 2006), reinforcing the role of the researcher as the primary instrument through which the research comes to life (Harris, 2006).

Rigor or trustworthiness is enhanced through the use of a framework or theory (Henstrand, 2006; Kearney & Hyle, 2006). The inherent concepts and relationships provide a vernacular for the development of a rich description of the findings (Kearney & Hyle, 2006; Anafara & Mertz, 2006). Thus the framework serves to: assist the reader in determining the transferability of the findings (Kearney & Hyle, 2006), link the study to the existent scholarly literature within the discipline (Ayres, 2007; Fowler, 2006; Harris, 2006), and point the way toward future research (Mills & Bettis, 2006).

**Conceptual Frameworks in Mixed Methods Research.** In mixed methods research, theories or frameworks also link the question with the chosen methods but must be able to support both qualitative and quantitative designs. Some mixed methods research studies use two or more separate theories for distinct facets of a study: a variance theory for the quantitative component and a different process theory for the qualitative inquiry (Maxwell & Loomis, 2003).

Mixed methods studies may also be informed by a single framework or model that combines or integrates both process and variance components. An integrated framework allows for the open, inductive process that generates a rich, detailed description of meaning or process. It also supports the use of discrete, quantitative measures to explore differences or relationships between the theoretically-driven variables. Data derived from the qualitative and quantitative components of the research may then be directly compared to provide within-case analysis, further interweaving the study findings (Maxwell & Loomis, 2003). The Woods & Mitchell (2005) framework served as an integrated model which encompassed both facets of this study.

**Conceptual Framework.** Theoretical or conceptual frameworks informing a study may be chosen from existing models or constructed during the development of the study. Frameworks are derived from both the literature of the discipline or topic of interest as well as the beliefs, experiences, values and goals that the researcher brings to the research process (Maxwell, 2005; Merriam, 2009; Miles & Huberman, 1994; Sandelowski, 1991). Concepts, contexts and conditions pertinent to the phenomenon are included in the framework (Ayres, 2007). The decision to situate the proposed inquiry within a symptom framework was based on the centrality of recurrent symptoms in both the literature on HT discontinuation as well as in the narratives told by the women seen in the researcher's practice.

The level of discomfort experienced with any symptom is often associated with elements of the symptom itself: frequency, intensity, location, and duration/chronicity. This is no less applicable to menopause-related symptoms: for example, women describe VMS in terms of how often they occur, how severe they are and when they began. However, symptoms are subjective experiences and symptom assessment and management models stress the contextual nature of symptom experience, perception, evaluation and response (Dodd, Janson, Facione, Faucett, Froelicher, Humphreys, et al. 2001; Lenz, Pugh, Milligan, Gift, & Suppe, 1997). Thus a symptom model supported the study goals to explore both the symptom experience and the influencing factors related to discontinuing HT.

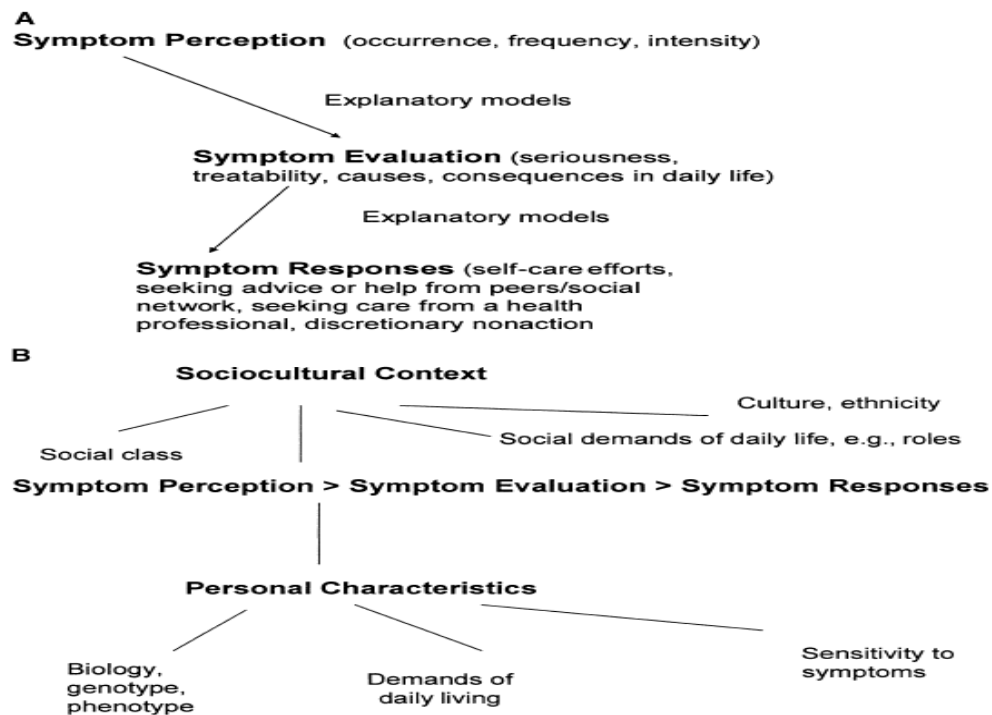
Several well-established symptom frameworks, including the Theory of Unpleasant Symptoms (Lenz, Pugh, Milligan, Gift, & Suppe, 1997) and the University of California/San Francisco Symptom Management model (Dodd et al., 2001), were considered for this proposed research. They were ultimately rejected because their primary use has been with symptoms related to disease conditions. In keeping with the initial premise of this study that menopause is a

normal developmental transition, a model was needed that would not portray menopause within the context of illness or disease.

The Woods & Mitchell (2005) framework chosen for this study was developed to specifically address the experience of perimenopausal symptoms. As a situation-specific model, it attempts to downplay the view of menopause as a disease or deficiency state. Instead, it seeks to bridge the biomedical-sociocultural chasm that exists in menopause research by viewing symptoms as influenced by both personal characteristics and sociocultural contexts.

The components of the framework as proposed by Woods & Mitchell (2005) include three central symptom-related elements—symptom perception, symptom evaluation and symptom responses—which are influenced by explanatory models. In addition, the overall symptom process is also influenced by both personal characteristics and sociocultural context.

Figure 1. Woods & Mitchell Conceptual Framework for Understanding Perimenopausal Symptoms



(Used with permission from N. F. Woods from —Symptoms during the perimenopause: Prevalence, severity, trajectory, and significance in women's lives” by N. F. Woods and E.S. Mitchell, 2005, *American Journal of Medicine*, 118 (Suppl 12B), 14-24.)

***Symptom Perception.*** Symptoms are defined in this model, as in many other symptom models, as sensations that are different from those ordinarily perceived. Symptom perception occurs when a different sensation is noticed. However, perception involves more than just observing the occurrence or presence of a sensation: characteristics of the symptom such as frequency and severity are also noted as part of perceiving a symptom (Woods & Mitchell, 2005). Women discontinuing HT often remarked on the intensity of their symptoms (Helenius et al., 2007; Matarese, 2005).

***Symptom Evaluation.*** The evaluation of a symptom refers to the judgements made about the meaning a symptom holds for the person experiencing the symptom. Individuals seek to know or understand what the cause of the symptom is, whether it is serious and how amenable it is to treatment, what consequences may be associated with the symptom, and what the presence of the symptom means in their life (Woods & Mitchell, 2005). Women discontinuing HT may be uncertain as to whether to attribute symptoms to menopause or aging (NAMS, 2007).

In addition, women attempting to stop HT may also perceive a decrease in QoL as a result of their recurrent symptoms. As previously noted, there is a discrepancy in results of QoL research among menopausal women which may be due in part to the multifaceted nature of QoL. Components of QoL include not only symptoms, but also other elements such as functional status, well-being and health (Bowling, 2005; Wilson & Cleary, 1995). Physical issues, such as symptoms or functional status, impact on health while emotional well-being has more impact on overall QoL (Ferrans, 2007).

QoL is also very subjective, based on each person's perceptions and evaluations of all these dimensions and strongly influenced by sociocultural and environmental contexts (Padilla, Frank-Stromberg, & Koresawa, 2004). The multidimensionality of QoL argues for the use of

multiple measures to explore the different dimensions (Ferrans, 2007; Padilla et al., 2004). Furthermore, because QoL is highly contextual, the most comprehensive measure of QoL may be a combination of both qualitative and quantitative methods to obtain both subjective and objective data. This approach would help to determine the facet(s) of QoL most influenced by HT discontinuation.

***Symptom Responses.*** In this model, responses may include the person's thoughts and feelings that have been evoked by the occurrence of the symptom or symptoms. Responses may also be manifested externally by an individual's behaviors: engaging in self-care techniques or symptom management strategies (e.g., lifestyle modifications, over-the-counter nutritional or herbal supplements), turning to family, friends or even media sources for advice, seeking information or assistance (e.g., medications, counseling, CAM) from health care providers, or choosing not to pursue any course of action to address the symptoms (Woods & Mitchell, 2005). Some women stopping HT reported being dissatisfied with information from health care providers (Ettinger et al., 2003; Schonberg et al., 2005) underscoring the importance of determining what information women discontinuing HT want and need to guide and assist them.

***Explanatory Models.*** Symptom perception, evaluation and response are inextricably linked by explanatory models: culturally derived beliefs about what is wrong, how to get care and how best to manage symptoms. These explanatory models are responsible for much of the variation in how people perceive and define symptoms, the strategies and interventions chosen, and the outcomes of the symptoms (Mechanic, 1962; Mechanic, 1986). They are rooted in an elaborate cultural system consisting of three distinct but intersecting sources of knowledge about health: popular (family and social/community networks), folk (lay or ethnic healers) and professional (complex professional health care services). These understandings of health impact



are embedded within the individual from infancy and influence how individuals monitor their physical states, perceive deviations from normal, and apply meaning to the new sensations and experiences (Chrisman & Kleinman, 1983; Mechanic, 1962; Mechanic, 1986).

The application of the culturally mediated definition and meaning drives the choices for treatment or symptom management strategies, what to do or not do about any given symptom. An individual's social network provides options for treatment as well as additional resources such as reassurance, social support, or financial assistance. In determining which treatment to choose, an individual must weigh the symptom or illness burden against the available resources (Chrisman and Kleinman, 1983; Mechanic, 1962; Mechanic, 1986).

Once this process is initiated, it may continue to cycle as the individual evaluates how symptoms respond and change with treatment and whether the treatment recommendations should continue to be followed. Evaluation and adherence are greatly influenced by trust in the commitment of the helper (Chrisman & Kleinman, 1983).

Findings from the menopause literature confirm the existence of this socially patterned process. There are clear differences in the way menopause symptoms are perceived, defined and managed among women from diverse cultures and ethnicities (Gold, Block, Crawford, Lachance, FitzGerald, Miracle, et al., 2004; Kaufert, 1996; Lock, 2002).

***Personal Characteristics.*** The process of symptom perception, evaluation and response is postulated to be influenced by physiological factors unique to the individual experiencing the symptom(s). These personal characteristics are thought to contribute to the occurrence of symptoms and include factors such as genetics (e.g., genetic polymorphisms), biology (high BMI), symptom sensitivity (narrowed thermoneutral zone) and demands of daily living (stress) (Woods & Mitchell, 2005). From the HT discontinuation literature, characteristics such as age

and surgical menopause, both associated with worse symptom recurrence, could be added to this component of the model (Grady et al., 2003).

***Sociocultural Context.*** The model developed by Woods & Mitchell (2005) seeks to provide a balanced view by also including the sociocultural context in which women experiencing symptoms are situated. Here can be found factors such as social class, culture, ethnicity, and social demands of daily living, such as the multiple roles taken on by or imposed on many women today. These sociocultural contextual factors may influence the meanings that women ascribe to their symptoms as well as their subsequent responses to the symptoms. Post-WHI studies on HT discontinuation have yielded mixed results as to the influence of sociocultural factors on symptom recurrence.

**Relevance to the proposed study.** The conceptual model developed by Woods & Mitchell (2005) served as an organizing framework for the proposed study. The framework helped to the researcher to develop the specific aims and research questions in order to best address the study purpose (see Table 7). In addition, the framework assisted in both developing the semistructured interview questions and choosing the quantitative measurements that answered the research questions. The analysis of the data and discussion of the findings were guided by the framework.

Table 7.

*Relationship of Research Questions, Specific Aims, Conceptual Framework & Conceptual Definitions*

RESEARCH QUESTIONS	SPECIFIC AIMS	CONCEPTUAL FRAMEWORK		CONCEPTUAL DEFINITION
What is the experience of discontinuing HT?	Explore women's experiences of HT discontinuation	Symptom experience	Symptom perception	Awareness of symptom frequency & intensity
			Symptom evaluation	Judgements about symptoms' seriousness, treatability, causes & consequences
			Symptom response	Feelings, thoughts or behaviors that occur as a result of the symptoms
What factors do women identify as making this experience more or less manageable?	Describe the personal characteristics and sociocultural contexts that influence symptom perception, evaluation and response among women who have attempted to discontinue HT	Personal characteristics		Genetic, molecular & physiologic factors that may contribute to symptoms
		Sociocultural context		Ethnic, cultural & social factors that may contribute to symptoms
How does HT discontinuation impact on women's QoL? Do the reports of QoL among women who have attempted to discontinue HT differ depending on which dimension of QoL is being measured?	Explore the impact of HT discontinuation on women's quality of life	Symptom evaluation: quality of life		Global sense of life satisfaction or well-being encompassing physical, social, psychological and spiritual domains
What information do women need to help them manage symptoms and maintain health during and after HT discontinuation?	Discuss women's preferences for counseling and support during HT discontinuation	Symptom response: seeking information		Sources and adequacy of health-related information

There are several limitations to the Woods & Mitchell framework. One limitation is that there are no connections between personal characteristics and sociocultural context. Because

some personal characteristics may be influenced by the sociocultural environment and vice versa, the framework might be improved by showing connections or linkages between the two components. This would better reflect the pragmatist feminist paradigm which stresses that knowledge and caring are built and strengthened through the experiences of human organisms transacting with the real world (Hamington, 2004; Seigfried, 1996; Sullivan, 2001).

Another limitation is that the framework has not been used to date to support any other research or generate any decision-making theories. Because it is still in an early stage of development, more elements may need to be added to the model. The exploratory nature of the study helped to uncover additional characteristics or contexts that could be added to the model to further develop this framework (Fowler, 2006; Maxwell, 2005).

### **Summary**

Women who discontinue HT may be beset by troublesome symptoms that could negatively impact on their QOL and ultimately drive them to resume HT despite the risks or their desires. This experience of recurrent symptoms may be influenced, not only by women's perceptions, evaluation and responses to these symptoms, but also by their personal characteristics and sociocultural contexts. The purpose of the study was to describe the experience of discontinuing HT in order to better understand the experience of recurrent symptoms and the influencing personal and sociocultural factors.

The Woods & Mitchell's (2005) conceptual framework for studying perimenopausal symptoms, undergirded by a pragmatist feminist paradigmatic stance, supported the use of a mixed methods approach to allow women's perspectives and experiences of HT discontinuation to be elicited. It is hoped that the findings will provide the foundation for developing better counseling and support guidelines and recommendations for women discontinuing HT.

## CHAPTER III

### METHODS

The purpose of the study was to describe women's experiences of HT discontinuation. A mixed methods approach was used to develop an in-depth description of this phenomenon. A qualitative research method known as Qualitative Description comprised the primary portion of the study, that is, the exploration of women's experiences during discontinuation, factors influencing the experience and needs for counseling and support before, during and after discontinuation. In addition, an embedded quantitative component addressed multiple dimensions of QoL for women discontinuing HT. This chapter will discuss the methodological details for the study: design, sampling, measures, procedures, data analysis and ethical considerations including protection of human subjects.

#### **Design**

##### **Mixed Methods Design**

A mixed methods design was used to address the questions and specific aims of the proposed study. Mixed methods research combines and integrates both quantitative and qualitative methods within either a single study (in this instance) or a larger program of research. Using different methods within the same study allows multiple facets of a research problem or question to be explored in a comprehensive fashion. Quantitative and qualitative data are ultimately compared, contrasted and converged in order to develop inferences that are well-substantiated and valid (Erzberger & Kelle, 2003; Teddlie & Tashakkori, 2003). (See Table 8 for a comparison of the three primary research traditions.)

Table 8.

*Comparison of Three Research Traditions*

<b>CHARACTERISTIC</b>	<b>RESEARCH TRADITION</b>		
	<b>QUANTITATIVE</b>	<b>QUALITATIVE</b>	<b>MIXED METHODS</b>
<b>Philosophical origin</b>	Logical Positivism, Empiricism	Naturalism, interpretivism	Pragmatism
<b>Ontology</b>	Single reality or Truth exists	Multiple realities or truths	Single & multiple realities; provisional truths
<b>Epistemology</b>	Distance, impartiality, independence between researcher and subjects	Interaction, collaboration, intersubjectivity between researcher & participants	Practicality
<b>Axiology</b>	Control of biases & values, objectivity	Values inevitable & desired; intersubjectivity	Multiple & variable perspectives on the role of values
<b>Focus</b>	Concise, objective, reductionistic	Broad, subjective, holistic	Comprehensive
<b>Reasoning</b>	Logistic, deductive	Dialectic, inductive	Inductive $\leftrightarrow$ Deductive; Abductive
<b>Basis of Knowing</b>	Explanation, prediction Cause & effect	Meaning, understanding	Discovery & verification; Confirmation & exploration
<b>Theoretical Focus</b>	Tests theory	Develops theory	Develops & tests theory
<b>Methods of Measurement</b>	Questionnaires, scales, physiological instruments	Unstructured interviews, observations; researcher as instrument	Qual & Quan; Sequence, priority
<b>Data</b>	Numbers	Words	Narratives & numerals
<b>Analysis</b>	Statistical analysis	Individual interpretation	Integration
<b>Findings</b>	Generalization, universal; outcomes	Context specific; unique; focus on process	Transferability Comparison, convergence (divergence) & corroboration
<b>Rigor</b>	Reliability, validity	Trustworthiness	Inference quality

Adapted from: Burns &amp; Grove (2005)

Creswell &amp; Plano-Clark, 2007

Johnson &amp; Onwuegbuzie (2004)

Morgan (2007)

Teddlie &amp; Tashakkori (2003)

A mixed methods approach is well suited for research that seeks to more fully understand complex and multifaceted aspects of human behavior. Mixed methods designs are especially useful when different questions about a phenomenon need to be answered, or different dimensions of a concept need to be explored, and a single data type is not enough to capture the multiple facets of the phenomenon under investigation (Creswell & Plano-Clark, 2007; Greene, 2007; Johnson, Onwuegbuzie, & Turner, 2007; Teddlie & Tashakkori, 2003). Thus, mixed methods is particularly useful for nursing researchers seeking to understand the complicated and multidimensional components of the human experience of health and illness (Carper, 1978; Sandelowski, 2003; Twinn, 2003).

There are many typologies of mixed methods research designs (Creswell & Plano-Clark, 2007; Greene, 2007; Kroll & Neri, 2009; Morgan, 1998; Morse, 1991; Teddlie & Tashakkori, 2003). The choice of design is dependent on the purpose for using a mixed methods approach. Greene (2007) describes five different purposes for mixing methods: triangulation, complementarity, development, initiation and expansion. For the proposed study, *complementarity* serves as the purpose for the design. Complementarity refers to the use of multiple methods for measuring different facets or dimensions of the same phenomenon. The goal is to develop a deeper, broader and more expansive understanding of the phenomenon or concept being explored. In this study, influencing factors and QoL of women discontinuing HT were explored using both qualitative and quantitative inquiry.

Ideally, when complementarity is the purpose of the study, the qualitative and quantitative findings will overlap to produce a comprehensive description of the topic. In some instances, however, the results may instead converge (triangulation) or diverge (initiation). This shift in purpose, albeit accidental, may occur through insights gleaned during data analysis and

can lead to new interpretations and understandings of the phenomenon. Unanticipated patterns in the results may highlight the need for modifications of the qualitative interview guide or point toward further explorations of the topic or framework (Greene, 2007).

The researcher's purpose for choosing mixed methods directs the choice of design including decisions regarding the sequence (order), weight (priority or dominance) and integration (mixing) of the qualitative and quantitative components (Creswell & Plano-Clark, 2007; Greene, 2007; Morgan, 1998; Morse, 1991). Mixed methods studies with complementarity as the purpose may be implemented through either blending or nesting designs (Greene, 2007; Happ, Dabbs, Tate, Hrick & Erlen, 2006). The proposed study used a nested design.

In a nested or embedded design, one component takes primacy (weight) while the other is less dominant and plays a supportive or secondary role (Creswell & Plano-Clark, 2007; Greene, 2007) or addresses a specific subtopic of the research question (Kroll & Neri, 2009). Data are typically collected concurrently (sequence) and the different data sets are connected during the process of analysis (integration) (Creswell & Plano-Clark, 2007; Greene, 2007). An important consideration with this design is that the nested component adheres to the methodological procedures (for example, sampling, rigor) of the primary method (Greene, 2007; Happ et al., 2006). For this study, a smaller set of quantitative measures was embedded within the larger Qualitative Descriptive study therefore decisions about the design and process of the proposed study were guided primarily by the qualitative research tradition.

Because the researcher collects all the data in one phase, this design saves time and is more manageable for graduate students or novice researchers whose resources are limited (Creswell & Plano-Clark, 2007). In addition, if the different data sets produce convergent or divergent findings, as noted above, this actually enhances the inferences that can be drawn from



the analysis (Greene, 2007). Challenges to this design include difficulty integrating or interpreting results because of different research questions and unequal weighting of the methods as well as limited available guidance for resolving discrepancies or divergent findings in the data sets (Creswell & Clark, 2007).

**Qualitative Description.** Qualitative research seeks to discover or describe knowledge related to meaning, process or experience. Often, but not always, words comprise the data to be analyzed and are obtained through observations and/or interviews. Qualitative questioning allows participants' voices and views to be heard in order to gain in-depth understanding of a particular phenomenon (Creswell & Plano-Clark, 2007).

For this study, the specific qualitative method that was used was Qualitative Description (QD). QD is a type of naturalistic inquiry that looks at everyday experiences or events and is especially useful when these phenomena have not been fully described, as is the case with HT discontinuation. Unlike other qualitative approaches that interpret findings through abstract philosophical or theoretical lenses, QD uses a low-inference interpretation that remains closer to the actual data in order to identify patterns and themes. This results in a rich and comprehensive summary of an event or an experience that is rooted in the point of view of the participant and expressed in their everyday language (Sandelowski, 2000b; Sullivan-Bolyai, Bova, & Harper, 2005). Although QD may appropriate the tone or characteristics of other types of qualitative approaches by seeking to describe lived experiences (phenomenology) or developing theories (grounded theory), it differs by holding the data and analysis close to the actual experiences of the participants (Sandelowski, 2000; Sullivan-Bolyai et al., 2005).

The analytic strategy best suited for QD is content analysis, a systematic coding and summarizing of data in order to achieve an accurate and straightforward rendition of the

meanings associated with an experience or an event. Findings are re-presented in a manner that best reflects the data and will be most easily understood and relevant for the intended audience (Sandelowski, 2000).

QD may be quite beneficial for helping to improve health outcomes, particularly with vulnerable populations. Because QD can provide detailed information about health issues that is rooted in the participants' sociocultural contexts and reported in their vernacular, it may be more culturally congruent than other types of research. Thus it lends itself well to health care disparities research, such as conducting needs assessments or developing interventions to transform the lives of underserved populations (Sullivan-Bolyai et al., 2005).

This approach also blends easily with quantitative inquiry to inform mixed methods research where the entire study may be undergirded by pragmatism (Greene & Caracelli, 2003; Teddlie & Tashakkori, 2003) or a transformative-emancipatory paradigm (Mertens, 2003). QD may also reflect frameworks such as feminism (Sandelowski, 2000) or critical theory (Sullivan-Bolyai et al., 2005). It was particularly appropriate for this study which was built upon a foundation of pragmatist feminism, a world view that stresses the importance of allowing women's voices to be heard. In so doing, their experiences were better understood and will ultimately support the development of knowledge for transforming the lives of women discontinuing HT (HesseBiber & Leavy, 2007; Leckenby & Hesse-Biber, 2007). To achieve this goal, semi-structured interviews were used to explore women's overall experiences with discontinuing HT, identify contextual factors influencing the experience, develop a better understanding of QoL during discontinuation and elicit suggestions for improving the preparation and counseling they require for this experience.

**Embedded Quantitative Component.** In quantitative research, numerical data are obtained in order to describe various elements of a phenomenon, determine associations among these elements or variables or identify a cause-and-effect relationship among specific variables (Table 8.) (Burns & Grove, 2005). However, when quantitative measures are embedded within a larger qualitative study, their purpose is to obtain data that may complement or expand upon specific dimensions of the phenomenon of interest. Quantitative data collection methods can quickly and efficiently measure personal characteristics, attitudes and other social, behavioral and cognitive constructs (Johnson & Turner, 2003; Tashakkori & Teddlie, 1998) that can then be compared and contrasted with related qualitative findings. Comparison may occur both across and within cases (Ayres, Kavanagh & Knafl, 2003).

For this study, several quantitative measures were nested within the QD component. First, demographic information was collected to both describe the sample and obtain personal data relevant to women's personal characteristics and sociocultural contexts in accordance with the organizational framework (Woods, 2005). In addition, several instruments were used to obtain information about dimensions of QoL for comparison within and across-cases (Ayres et al., 2003) and across strata (Cohen & Crabtree, 2006; Patton, 2002) thus deepening understanding of the phenomenon of QoL during HT discontinuance.

## **Sample**

### **Sampling Strategy**

In order to be congruent with the purpose and design of the proposed inquiry, the sampling method was appropriate for a primarily qualitative study (Greene, 2007; Happ et al., 2006). In qualitative research, participants are chosen because they hold information pertinent to the specific experience, culture or process under investigation (Speziale & Carpenter, 2007).

Qualitative sampling strategies are thus labeled ‘purposeful’ or ‘purposive’ in that they are clearly linked to the *purpose* of the study. The researcher seeks to identify people who will be good sources of the information needed for developing an in-depth description of a particular phenomenon (Merriam, 2009; Patton, 2002; Sandelowski, 1995).

The qualitative researcher has a wide assortment of purposeful sampling strategies from which to choose. As noted above, the choice of strategy is greatly dependent upon the study purpose and the types of cases or participants needed to obtain sufficient data for answering the research question. The researcher must also consider whether the sampling procedure is adequate to ensure the credibility and transferability of inferences drawn from the data as well as whether the strategy is feasible, practical and ethical (Kemper, Stringfield & Teddlie, 2003).

Maximum variation sampling is a sampling procedure commonly used by researchers conducting QD studies. With this sampling method, participants or cases exhibiting a wide range of variation of the phenomenon, or specific aspects of the phenomenon, of interest are purposefully selected (Polit & Beck, 2008; Sandelowski, 1995). The characteristics to be maximized are typically determined a priori in order to achieve adequate representation of those dimensions (Sandelowski, 1995). The resulting diversity of the dimension of interest within the sample allows for detailed descriptions of both unique cases and common experiences and patterns (Patton, 2002).

This study sought to employ maximum variation sampling to obtain a sample of women with diverse HT discontinuation experiences, particularly with regard to type of HT used, discontinuation method, recurrent symptoms and outcome. Because there may be local or regional patterns of HT use (Keating, Cleary, Rossi, Zaslavsky & Ayanian, 1999; Kim et al., 2005), it was hoped that using the Internet to recruit participants from multiple locales would

promote maximum variation sampling. Efforts were also made to recruit women from diverse sociocultural and ethnic backgrounds which also enhances maximum variation. Ultimately the lack of ethnic diversity may have precluded true maximum variation within the sample although variability of experiences was still achieved.

It is not uncommon for multiple sampling strategies to be used within one study. For example, an attempt was also made to use snowball sampling to identify potential participants. Chain or snowball sampling is another technique for identifying potential participants through key informants in the community or other study participants (Kemper et al., 2003; Patton, 2002). In addition, the purposefully selected sample may be further subdivided into subgroups or strata, which are also prespecified, in order to compare and contrast the groups along different levels of a specific characteristic (Kemper et al., 2003; Patton, 2002; Sandelowski, 2000). The purpose of stratification is to illuminate variations rather than commonalities among the subgroups (Patton, 2002). Therefore, participants were stratified into groups based on HT discontinuation status (stopped, tapering and resumed HT) in order to compare influencing factors and QoL. However, as there were more women in the discontinued subgroup (20) than in the resumed subgroup (9) and only a small number (5) of women who were tapering, the unequal size of the strata limited some comparisons.

Because the goal of purposeful sampling is to obtain a sample that will ultimately yield findings rich or significant from an informational perspective as opposed to a statistical perspective (Sandelowski, 2000), there are no definitive rules or mathematical calculations for predetermining the requisite number of participants. Rather, sample size is based on the research question and purpose, the participant selection criteria (Merriam, 2009), the rationale behind the

sampling strategy chosen (Sandelowski, 1995), the resources available to the researcher (Miles & Huberman, 1994; Patton, 2002) and the achievement of data saturation.

Data saturation or redundancy is the term that indicates no new information relevant to the study phenomenon is emerging from the data. The researcher determines saturation has been reached when knowledge elicited from new informants is repetitive of what has already been discovered and serves to confirm rather than expand upon the findings (Lincoln & Guba, 1985; Morse, 1989; Patton, 2002; Speziale & Carpenter, 2007). Sampling continues until data saturation or redundancy is attained therefore the final sample size for a qualitative study cannot be determined a priori.

While this perspective is in keeping with the open and evolving nature of qualitative inquiry, practicality, guised in the form of grants, budgets or even thesis committees, may demand a more definitive projection of the number of participants necessary for answering the research question. Patton (2002) recommends both specifying a minimum sample size and clearly stating the rationale for choosing that number, with the understanding that the sample—and sampling plan—may be changed based on emerging information. Furthermore, the researcher should describe the criteria that would indicate the need to adjust the sample size either up or down. However, because data saturation is situational—new or different information could be obtained given another sample, time or context (Morse, 1989)—the researcher should discuss in the dissertation how the chosen sample, sample size and/or sampling techniques may have impacted on the findings (Patton, 2002).

QD studies typically have moderate sized samples, often between 20-50 participants (Sullivan-Bolyai et al., 2005). This is primarily due to the use of maximum variation sampling which requires more cases to maximize the variations of the phenomenon found in the data

(Sandelowski, 1995). Based on this guide, this study sought to enroll 30-40 women (meeting the eligibility criteria noted in Table 9) who had attempted to discontinue HT as it was thought that this number would achieve variation between participants. Saturation of information about the HT discontinuation experience was the primary criteria for determining whether more participants need to be recruited. If new themes had continued to emerge from the data once this number were enrolled, more participants would have been recruited until only repetitive and confirmatory information was being found in the data, however this was not necessary.

Table 9.

*Inclusion/Exclusion Criteria*

<b>Women eligible for this study:</b>	<b>Women not eligible for this study:</b>
1) are 45 years of age or older;	1) are younger than 45 years of age;
2) are in good health;	2) have health issues such as cancer or cardiovascular disease,
3) are in either the late menopause transition or postmenopause stage as defined by STRAW;	3) have not reached the late menopause transition or postmenopause stage as defined by STRAW;
4) have used HT for a minimum of 3-4 months;	4) have used HT for less than 3-4 months;
5) have attempted to discontinue HT (by any method of discontinuation) within the past 2 years, regardless of outcome;	5) have not attempted to discontinue HT;
6) are able to read, speak and write English; and,	6) are not able to read, speak and write English; and,
7) have Internet or telephone access.	7) do not have Internet or telephone access.

The minimum age requirement was set at 45 years old to decrease the possibility that any participants may have recently experienced premature menopause (menopause prior to the age of 40) or Premature Ovarian Failure (POF)—ovarian insufficiency prior to age 40 which leads to amenorrhea. These women are at greater risk for early onset of CVD and osteoporosis because of earlier withdrawal of ovarian hormones. The current recommendations for discontinuation after 5 years may not apply to these women when they are early in this process thus they may comprise

a different population than was addressed through this study. Currently, there are no clinical trial data establishing a maximal length of HT use for these women. However, clinical guidelines recommend keeping these women on HT until age 50 and then consider discontinuation (NAMS, 2010). Based on these guidelines, women who had transitioned through menopause prior to age 40 but who were now past the age of 50 were deemed appropriate candidates for participation.

Women in the early menopause transition may still have occasional ovulatory cycles therefore any increases or decreases in symptoms may reflect hormonal fluctuations related to ovulation not HT discontinuation; this could confound the description of symptom duration. Also, because HT may take several months to reach maximum effect, women stopping during this timeframe may not have achieved maximum relief of symptoms which could limit comparison to recurrent symptoms.

As the focus of this study was on women's experiences with discontinuation, all participants must have attempted discontinuation. For the purpose of maximum variation sampling, the sample included women who used different discontinuation methods, who made multiple attempts to discontinue, who were tapering HT, or who had chosen to resume HT. Diversity in symptom experience among participants was also sought.

As noted in Chapter 1, the duration of recurrent symptoms is unknown as most studies were done within a year after the WHI. In order to capture the experiences of women who may be symptomatic for longer than a year, and yet still decrease the risk of recall bias, the time range was limited to discontinuation within the past two years.

Because the majority of women in this study were located in areas distant from the researcher, the interviews were conducted either online or via the telephone. Therefore all participants had to have access to one of these means of communication. In addition, participants



were recruited from several menopause-related Internet sites at which all postings are in English therefore only participants who can understand and communicate in English were recruited.

### **Setting**

Through the qualitative lens, understanding the meaning that people ascribe to their experiences is a critical component of understanding the experiences themselves (Marshall & Rossman, 1998). Meaning is derived in part through the setting or context in which an experience occurs, thus the setting cannot be overlooked as a powerful influence on the inferences that emerge from a study (Illingworth, 2006).

The most common interpretation of setting is the location or physical environment wherein the participant completes study procedures such as questionnaires, interviews or laboratory testing (Burns & Grove, 2005; Speziale & Carpenter, 2007). With qualitative interviews, the setting is typically the location where the participant and researcher meet face-to-face, ideally representing the real-world where the participant experiences and gives meaning to the phenomenon being explored. Thus setting includes not only the physical structure(s) where the interview occurs but also other aspects of the environment including the community, weather, time of day, indigenous language, even the presence of other people in the immediate surroundings (Patton, 2002). All of these contexts may impact on the way in which the participant experiences or describes the phenomenon, the quality of the interview and the feasibility of obtaining an adequate sample size. Therefore it is inherent upon the researcher to describe the setting in as much detail as possible (Patton, 2002; Polit & Beck, 2007).

However, in this study the interviews were conducted either online or via telephone and not face-to-face, therefore the researcher did not have access to information about the environment of the participants at the time of their responses. Accordingly, the researcher asked

participants to describe their setting: location, time of day, weather and so on. In addition, the Internet itself, particularly the group or site from which the participant is recruited, became a separate and significant context of communication and interaction between participant and researcher (Illingworth, 2006).

### **Internet as Research Setting**

**Internet Community.** Since the fledging efforts to establish computer-mediated communication 40 years ago, the use of computers for communication has grown phenomenally into a world-wide network for social, business, scientific and academic interaction (Mann & Stewart, 2000). Currently, 79% of the United States population (over 147 million adults) uses the Internet for both personal and professional purposes (Madden, 2009).

Internet usage varies by both ethnicity and gender. While initially the Internet was used primarily by white males, individuals from other ethnic backgrounds have been gaining ground and women have essentially caught up with men online. Internet penetration among Asian Americans is higher than among any other ethnic group (Im, Shin & Chee, 2008) while half of Hispanic Americans and about a third of African Americans are Internet users. Among African Americans, more women (60%) than men (50%) are online (Fallows, 2005).

Although almost equal numbers of women and men now use the Internet, online activities vary by gender. Men are more likely to use the Internet to obtain information and perform transactions. Women, on the other hand, go online more for personal enrichment: building social contacts and staying connected through emails or other forms of cyber-social networking, looking up health/medical information for themselves or others, soliciting support for personal and health problems and seeking religious information (as well as getting maps and directions!) (Fallows, 2005; Fox, 2007).

Through their Internet interactions and conversations, women may form connections and networks that are equally as important as their non-Internet relationships. For example, support group participants at two online websites, one for women at high risk for hereditary breast and ovarian cancers (Kenen, Shapiro, Friedman & Coyne, 2007) and another for breast cancer survivors (Radin, 2006), developed tightly-knit bonds and a deep sense of solidarity. Self-disclosures and shared confidences reduced their feelings of isolation and promoted the development of virtual social communities. Frustrated by health care providers' insensitivity and limited and conflicting information, women shared knowledge, advice and support, essentially creating cyber-families and sisterhoods rooted in an abiding trust. These online communities have become part of the networks that serve as sources for the development of culturally derived beliefs about symptom perception, evaluation and response (Chrisman & Kleinman, 1983; Mechanic, 1962; Mechanic, 1986). Because of the powerful interpersonal online networks that many women develop, the Internet has become an important setting or context that must be considered by researchers looking at women's health experiences.

**Internet Research.** The use of the Internet for research has been broken into three distinct categories: locating resources, completing demographic surveys and conducting empirical investigations (Senior & Smith, 1999). This study falls under the third heading. Within this category, the Internet may be used as a recruitment resource and/or the repository for the actual study materials (Ahern, 2005).

**Internet Recruitment.** Investigators looking to recruit participants through the Internet may develop their own website. However, a study website will still need to be advertised in some manner as waiting for potential participants to find the site on their own may yield a low recruitment rate (Birnbaum, 2004). Therefore, many researchers looking to conduct Internet-

mediated research often avail themselves of the many types of pre-existing online groups to recruit participants.

The most basic type of group is a *listserv*: a mailing or discussion list that can be used to send email messages to a group of subscribers (Read, 2004). *Chat group* systems allow real-time (synchronous) connections via lines of text sent between members of the group whereas *bulletin boards* or *newsgroups* are a form of asynchronous communication. In these latter groups, members post series of messages related to an overarching theme or topic (Im & Chee, 2001; Mann & Stewart, 2000).

Another type of asynchronous interaction can be found at *discussion boards* or *forums*. These groups are typically located on larger websites targeted toward specific populations and serve as a place where individuals can post messages related to a particular topic. There are usually multiple topics, started either by group administrators or group members. Individuals belonging to the group post messages and responses under each topic, thus forming a thread or continuous string of messages related to the same topic. The various designs found at different websites add another contextual layer to the discussions that take place there and may influence the type of participant available for recruitment at each site (Im & Chee, 2001). Therefore, in order to determine the feasibility of obtaining an adequate sample size, the researcher should explore each potential recruitment site to understand the characteristics of group members and the dynamics of the group interactions.

A variant of the site-based discussion forum is a *networking group*. These are large websites specifically designed for fostering connections and communication among members. Some are primarily for social interactions while others may have a more professional purpose. Members of these groups typically have individual pages displaying personal or business

information, however there may also be special interest groups within these larger groups. Individual members may join or link to these subgroups for further networking opportunities, thus forming communities within communities (Golder, Wilkinson, & Huberman, 2007).

Recruitment through any of these groups most often involves posting a message about and/or a link to the study (Hamilton & Bowers, 2006; Walther, 2002). Interested group members would then seek out the researcher or study site for further information. It is important to understand however that some groups may have an administrator or moderator that has oversight of messages posted in the group. Therefore, prior to posting study information, researchers need to determine whether there is a group moderator and request permission from that individual to place recruitment information at that site.

Messages and postings advertising the study should conform to Netiquette, guidelines for courteous online interactions and behaviors, as well as any rules and regulations specific to each group (Mann & Stewart, 2000; Sharf, 1999). Because some of these group-based rules may not be expressly documented, it would again behoove the researcher to spend time *‘observing’* the posting behaviors of group members to ascertain the interaction nuances of each group. Knowledge of group *‘rules’* as well as the language and hierarchy of communication contributes to developing an understanding of the group’s culture and therefore the setting (Murray & Sixsmith, 2002).

***Internet Research.*** There are various ways by which a research project may actually be conducted via the Internet. As previously noted, an investigator may develop a website specifically for the study or instead may use a pre-existing site, such as a university website (which may be more convenient for investigators with limited website-building resources). In either instance, participants log onto this site to complete the research procedures (Birnbaum,

2001). This option may be particularly advantageous for online focus groups where participants may post synchronous or asynchronous responses to interview questions posed to the group (Selwyn & Robson, 1998).

Another option for Internet-based research is to send the qualitative and/or quantitative questionnaires electronically either as an email attachment or through an online survey program (Selwyn & Robson, 1998). In addition, qualitative researchers may choose to use established discussion boards as the setting for their research. One method is to copy text from ongoing discussions and posted messages which then become the database for an observational project. However, ethical concerns may arise if consent is not obtained from the forum participants as this may be seen as a violation of confidentiality (Cotton, 2003a; Eysenbech & Till, 2001; Murray & Sixsmith, 2002; Pittenger, 2003; Whitehead, 2007). Alternatives include either obtaining permission from the group to use their posts in the study or to begin a new thread or topic specifically for the study. This would necessitate approval from the moderator, if there is one, as well as a clear statement that by posting in that thread, members are consenting to the possible use of their statements for research purposes.

**Issues in Internet Research.** While the Internet offers many attractive options for conducting research, it also presents some challenges that need to be considered or addressed when deciding whether or not to use this setting for a research project. One advantage is that the Internet is more cost efficient in terms of time, money and effort: response time is faster, there is no need to wait for recordings to be transcribed, traveling to interviews and associated costs are eliminated, and asynchronous data collection reduces time constraints (Im & Chee, 2003). It is easier to maintain an audit trail and conduct member checks. Because there is less need to use office supplies, online research may also be more environmentally friendly. However, the

researcher must be very computer literate with access to additional resources for troubleshooting technical problems (Im & Chee, 2003).

Internet recruitment initiatives may help to target participants that are well-suited to provide answers to the specific research questions (Truell, 2003). However, this may also decrease the heterogeneity of the sample. While the Internet has penetrated more and more into United States culture, over a quarter of the population, primarily individuals from lower socioeconomic levels, are still not regular users (Fallows, 2005). These groups, often most in need of health services, are all too often under-represented in research samples thereby limiting knowledge of their health issues and health care needs. Women often comprise a large proportion of these groups. Internet-mediated research, therefore, has the potential to perpetuate women's marginalization (Im & Chee, 2001) and disparities in health research and health care.

Sample diversity may also be limited (coverage error) because people who have limited computer literacy skills, who don't express themselves well through writing or who prefer greater interaction between the researcher and participant may exclude themselves (Dillman, 2007). On the other hand, for people too shy to consider face-to-face interviews or focus groups, online interviews provide a means for their voices to be heard, an issue especially pertinent for women (Illingworth, 2006). The Internet also confers a sense of anonymity not present with research conducted in person. It is actually possible that anonymity may promote freedom of expression and deeper revelation, even around sensitive topics (Murray & Sixsmith, 1998), and thus enhance the richness of the data (Illingworth, 2006). This actually proved to be the case in this study: women were very open in their narratives about topics often deemed 'sensitive' in nature such as sexual and behavioral health issues.

In addition to allowing women to discuss very personal issues, the Internet affords the researcher an opportunity to recruit potential participants who otherwise would be beyond their reach: those with limited transportation, for example, or even individuals from other countries (Eysenbech & Till, 2001; Liehr, Takahashi, Liu, Nishimura & Summers, 2004; Mann & Stewart, 2000). Thus, while sample heterogeneity is a potential concern, this may be counteracted in part through the Internet's world-wide expanse allowing people, formerly ineligible because of personal or geographical constraints, to participate in the discovery of new knowledge.

Sampling issues are not the only concerns of the investigator developing an Internet-based study: s/he will also need to decide on whether data collection will be through email, a website or a hybrid. Emails may have an advantage in that the participant can download the questions and respond at their own pace, allowing ample time for reflection (Hamilton & Bowers, 2006). However with email, consideration must be given to minimizing privacy risks. One option is to ask the participant to password protect the completed study materials if possible when returning them to the investigator (Hamilton & Bowers, 2006). Secure survey websites may provide better privacy and confidentiality protection but participants may not be able to complete the questionnaires in stages over time.

With online questionnaires, quantitative measurements may need to be reformatted to accommodate the online setting and instructions may need to be modified to align with the changes in format (Dillman, 2007). Depending on the extent of required revisions, the potential exists for these changes to impact on an instrument's psychometric properties (Whitehead, 2007). Also, because of differences between computers—such as resolution and speed—the format the researcher sees may differ from what the participant sees (measurement error)



(Dillman, 2007). Pilot testing may be warranted for quantitative-dominant studies to evaluate reliability and validity of any instrument reformatted for Internet use.

The researcher collecting qualitative data must also decide whether to do so synchronously or asynchronously. Synchronous interviews or focus groups offer the advantage of ‘live’ conversations occurring within close temporal proximity so that the flow of interactions is smoother. However, synchronous interactions may be more social and superficial (Hewson, 2008) and more difficult to arrange when participants and researchers are located in different countries and time zones (as in this study). Time differences are not an issue with asynchronous data collection, however, and interruptions are also less likely to be of concern (Beck, 2005). By providing both participant and researcher more time to ponder and process their questions and responses, asynchronous interviewing may actually promote greater reflexivity and consequently enhance the rigor and trustworthiness of the study (Illingworth, 2006).

While some Internet research challenges, such as missing data, maturation and participant retention are common to all types of survey research, the way in which they are addressed may be different for Internet-mediated inquiry. For example, forced responses can minimize the potential for missing data (Dillman, 2007) while progress indicators may promote retention (Truell, 2003). In fact, because of the use of the above strategies, Internet surveys and questionnaires are known to have greater response completeness (Truell, 2003). Embedded equivalency questions, follow-up checks and critical appraisal of the informant’s knowledge of the topic are strategies for establishing the authenticity of the participant (Mann & Stewart, 2000). The potential for multiple submissions may be reduced by techniques such as sending the consent to the participant’s address, only allowing access to the study site through a password and not allowing the participant to return to the survey site once the questionnaire is completed.

Closely evaluating participant responses, knowledge of the subject matter, and inconsistencies in writing style or narrative may help flush out an imposter or multiple authors (Dillman, 2007; Mann & Stewart, 2004; Murray & Sixsmith, 2002). The current study employed some of these strategies such as mailing the consent form to participants and restricting password access.

Lack of response is always a concern in conducting research. When using the Internet for recruitment, the interval for sending out follow-up invitations to join the study or other recruitment materials should be shorter: 4-7 days is considered appropriate. This short time span has been reported to almost double the response rate (Truell, 2003).

Unfortunately, it may be difficult to determine actual response rates with online research, unless the investigator is recruiting through a very specialized group or sending study invitations only to specific individuals. Because some people listed as group members may no longer be active in the group, or may misrepresent themselves, numbers of potential recruits may be lower than presumed. However, website groups may also be frequented by ‘lurkers’—individuals who read posts and messages but are not yet group members—who may potentially be recruited by seeing a study advertisement (Im & Chee, 2001). Because the total pool of potential participants may not be able to be accurately determined, some studies report the number of inquiries as an alternative.

Another challenge facing the online qualitative investigator concerns the nature of the interactions. With face-to-face and even telephone interviews, the participant’s responses—facial expressions, gestures, sounds, tone of voice, pauses and displays of emotion—are easy to recognize and record within the field notes. Emotional expression is more difficult to gauge when interviews occur online. The researcher must look for cues in the writing such as repetition, underlining, the use of strong language or symbols such as emoticons (Illingworth,

2006; Mann & Stewart, 2000). If these are not present, the researcher may need to resort to the use of probes such as —How did you feel when you wrote that statement?”

Qualitative research is intersubjective in that the researcher’s perspective or voice is an essential component of all facets of the research process, influencing data collection, analysis and representation. The reflexive thoughts of the researcher actually become part of the data to be analyzed and the knowledge to be created. Trustworthiness or rigor of qualitative research is enhanced through the interaction of the researcher with the participants and the study data. While Internet-based research may facilitate data management and immersion, participant-researcher interaction may be less because of the lack of a physical or embodied presence (Illingworth, 2006; Im & Chee, 2001). This is a particularly critical issue in feminist research which strives for reciprocal relationships between researcher and participants (Im & Chee, 2001). Practices such as frequently checking in, sending encouraging emails, and sharing personal insights or information can -- and did -- demonstrate the researcher’s virtual presence and accessibility and maintained the participant-researcher connection (Mann & Stewart, 2000).

Researchers working from a feminist paradigm strive to decrease power inequities not only through their findings but also throughout the research process as well. Using the Internet for research on women’s issues may promote a more equitable relationship between the participant and researcher (Im & Chee, 2001). For some people the Internet is more than a tool or a place to be with other people. Instead, it constitutes a primary and inseparable part of their being in the world, a virtual embodiment that becomes part of their authenticated selves. By choosing when, where and how they appear to others, women gain more power in the research relationship. They also have a greater sense of control over what they share as online communication affords them an opportunity to examine and edit their responses (Illingworth,

2006). Rather than restricting the depth of their responses however, the relative anonymity and of the Internet allows women to escape the isolation and restrictions of the non-virtual world, fostering a sense of freedom and comfort that empowers them to express themselves openly and passionately (Cotton, 2003; Illingworth, 2006). In addition to enhancing the richness of the data, this freedom of expression may potentially be cathartic and therapeutic as women allow their voices and emotions to be heard and validated (Illingworth, 2006).

The ability of the researcher to validate women's stories, conduct member checks and share study findings is enhanced through online research giving women a greater sense of ownership of the knowledge resulting from the research (Im & Chee, 2001). This mutual or co-creation of knowledge is important in balancing the distribution of power between subject and researcher and it also provides women with a sense of purpose (Beck, 2005; Im & Chee, 2001). The women in Beck's Internet study on birth trauma (2005) reported that their desire to help other women was a key reason that they chose to tell their stories. This was also true of the women in this study. The belief that one is contributing to the development of knowledge that may help other women is especially salient for women considering whether or not to enroll in a research study. Women opt to participate in research when they possess both an awareness of the importance of their involvement and adequate resources for accessing the study, including considerations of time constraints (Brown, Long, Gould et al., 2000), which may be facilitated when recruitment and study procedures are online.

**Relevance of the Internet for this Study.** As noted earlier, the primary component of the proposed study was conducted via the Internet and incorporated both recruitment and data collection procedures. First, participants were recruited from a variety of women's social and/or menopause-focused websites including a listserv, website-based discussion boards and groups at

several professional and social networking sites (Appendic D). Using these pre-existing virtual communities increased the potential for obtaining a sample appropriate for the study purposes.

Secondly, the study incorporated both web-based and email data collection procedures. The study instruments were located on the University of Massachusetts Medical School (UMMS) Intranet website. The UMMS Survey Tool was an application developed over 10 years ago through the Information Services department for the purpose of conducting university-based surveys. It has also been used occasionally to conduct off-campus research including previous doctoral dissertation research. The researcher completed training in the use of this Survey Tool.

The Tool used a web language known as Cold Fusion for the actual survey questions as well as HyperText Markup Language (HTML) for additional comments or instructions. Both open-ended and preset response questions could be created and questions could be designated as required (forced response). All surveys were given an address or URL. Access to the survey could be designated as global or open to anyone on the Internet, however this carried the potential for a hacker to view participants' email addresses. Therefore the scope of the survey for this study was done by authentication, that is, a user ID and password created by the researcher was required to access this website in order to enhance security and decrease the potential for multiple entries. This user information, as well as the Survey Tool URL, was emailed to participants (Chabot, 2009, personal communication). Finally, follow-up (asynchronous) emails were used for clarification, additional questioning and member checks.

These online procedures offered more than just a convenient means for collecting data. By providing a setting for reflection and interaction (Illingworth, 2006), the Internet was in essence a unique virtual context that fostered intersubjectivity, reflexivity and the emergence of a rich description of the HT discontinuation experience.

## **Procedures**

### **Recruitment**

Three strategies were used to recruit participants for this study. The primary recruitment efforts were through the Internet but were supplemented by traditional methods of community recruitment and snowball sampling. All recruitment initiatives continued until data saturation was attained.

**Internet Recruitment.** In addition to fostering social communities that can serve as the research setting, the Internet offers another advantage for researchers seeking to explore women's health issues in that women may be more likely to be recruited for research studies through the Internet than are men (Im et al., 2008). Because women need to believe that their participation provides some benefits (Brown et al., 2000) recruitment literature stressed the study purpose of obtaining information to ultimately develop methods to help other women through HT discontinuation.

The advertisements (Appendix E) describing the study and the inclusion criteria were posted on topic threads in the discussion boards and forums at several menopause-related websites (Appendix D). The researcher's contact information (phone number and UMMS email) was provided in the posting. The study was also posted at several professional (advanced practice clinicians and women's health) networking sites.

Although it is impossible to determine exactly how many members are at each site, it was estimated that the combined membership may be over 15,000, although as previously noted this number could vary up or down because of lurkers, inactive members, or women being members at multiple sites. Because of the large potential population, the postings were staggered to

decrease the possibility that the researcher would acquire too many inquiries to permit responding in a timely fashion.

Women interested in participating contacted the researcher to obtain details about the study. Responders were screened by inclusion criteria. If eligible and willing to participate, they were mailed a fact sheet (Appendix F) with information about the study, two copies of the consent form (one to be signed and returned to the researcher and the other for their personal records), and a stamped self-addressed envelope for returning the signed consent. Once the signed consent was received, the participant was emailed the directions for accessing the UMMS survey website as well as a user name and password in order to open and respond to the interview and survey questions.

Recognizing that not everyone would wish to participate online, the researcher also offered the option of participation via telephone. The consent packet was mailed to potential telephone participants and when the researcher received the signed consent, the participant was called to arrange a mutual time for a telephone interview. The majority of the women who opted to participate in a phone interview first completed the quantitative component at the Survey Tool and then arrangements were made for the telephone component.

If a woman did not return the consent within seven to ten days (Dillman, 2007; Truell, 2003), she was contacted by email or telephone to confirm continued interest in participating. If there was no response, the woman's name was removed from the list of potential participants.

**Traditional Recruitment.** In addition to posting advertisements on Internet sites, the researcher also used more traditional recruitments efforts as needed. For example, flyers (Appendices G & H) announcing the study were placed in community venues within Metrowest Massachusetts, an ethnically and socioculturally diverse area comprising communities west of

Boston, MA. Letters and fact sheets (Appendix I) describing the study were also mailed to: health care providers (MDs, APCs, and CAM providers) in private practices in these and other communities and to Obstetric/Gynecology and/or Behavioral Health providers at UMass Memorial Medical Center (Worcester, MA) and Mount Auburn Hospital (Cambridge, MA).

**Snowball Sampling.** Snowball or chain sampling (Kemper et al., 2003) constituted the third form of recruitment. Participants were asked to refer other women to the study by giving the researcher's information to family members, colleagues or friends. In order to make this request, however, it was essential that the researcher garner the trust of the participant (Atkinson & Flint, 2001) through processes such as openness about the research process and purpose, listening to cues and changes in tone, delicacy when dealing with sensitive topics, and reflexive self-disclosure (Mann & Stewart, 2000).

**Participant Recruitment Summary.** A total of 39 women were enrolled in this study. Four women were consented but did not complete the study: three were lost to follow-up after signing the consent and one withdrew because of a personal life crisis. One other woman was excluded from the study when it became apparent from her interview responses that she did not meet eligibility criteria (Figure 2).

Participants were recruited through a variety of the above methods: six heard of the study from their health care providers and one from a professional colleague of the researcher. Two women viewed recruitment cards left by the researcher in community settings. Six participants contacted the researcher after seeing an advertisement on professional websites and listservs for advanced practice clinicians and two participants were recruited through UMass. The remainder were recruited through postings on the Internet (Appendix H), primarily Craig's List (n = 12, 37.5%) although three women heard of the study through postings on websites for menopausal

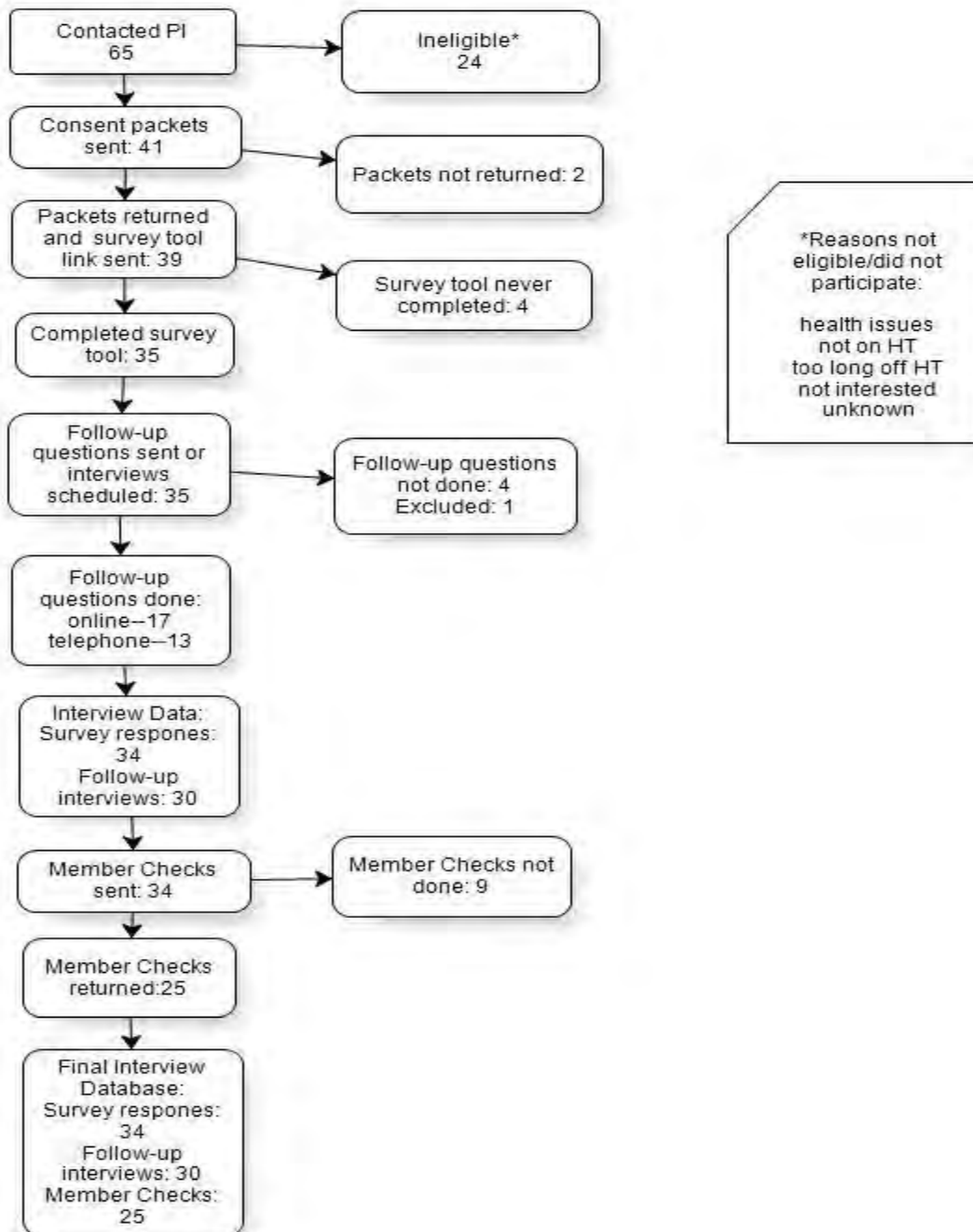


and midlife women and one woman did learn of the study through a Facebook advertisement. Advertising the study online greatly expanded the geographical area from which to recruit potential participants. The final sample consisted of 34 women from eighteen states and Canada (Appendix J) .

Thirty of the 34 participants completed both the online questionnaire and the follow-up questions. Sixteen out of these 30 women completed the follow-up questions online and the remainder chose to participate in a telephone interview to answer the follow-up questions. Twenty-five participants from the entire sample of 34 women also completed the member check. Four participants completed only the questionnaire and were unable to respond to the follow-up questions due to time constraints or health-related issues, although two of them did complete the Member Check (Figure 2).

Figure 2.

*Enrollment Flowchart*



## **Data Collection, Recording and Management**

In qualitative and certain typologies of mixed methods research, data collection, recording and management are done simultaneously with data analysis. However, for the purpose of clarification, each process will be discussed separately.

**Data Collection.** As previously noted, women who consented and chose to participate online were instructed how to access the study at the UMMS Intranet website. The researcher also offered to answer any additional questions prior to the subjects' logging into the website. Each subject first completed the demographic questionnaire, then the interview guide and finally the quantitative instruments (Floyd, 1993). They were also asked if it would be permissible to re-contact them for more information, clarification or member checks, as well as their preferred re-contact medium.

At the time of the scheduled telephone interviews, scheduled after the participant had completed the quantitative questions online, the researcher again offered to answer any questions the participant may have had before beginning the interview. These participants were then queried as to whether and how they could be contacted at a later time for member checks or additional questions.

After each subject completed the questions, either online or by telephone, the researcher reviewed the responses for completion and developed further questions or probes based on the participant's initial responses. The researcher then emailed or phoned participants to clarify responses, elicit further details or examples, or probe for more information. It was anticipated that participants may need to be re-contacted between one to three times (Beck, 2004; McDonough, 2007) in order to achieve a comprehensive understanding of their experiences and this was indeed the case. However, because of the brevity of many women's responses to the

open-ended questions, it was often necessary to send a series of further prompts and probing to the participants to obtain an adequate amount of data. Several of these women chose to participate in a telephone interview in order to respond to the questions in more depth leading to the need to conduct more telephone interviews than was first anticipated.

***Retention.*** One potential concern is retention of participants through the follow-up email/telephone process. In face-to-face interviews, silences or pauses during the conversation may indicate that a participant is processing or reflecting upon a question. Silences also exist with online or telephone studies in the form of non-response to follow-up emails or telephone calls but the reason for these silences may be more difficult to ascertain. Lack of a quick response may not necessarily indicate a lack of interest in continuing with the study but rather competing issues such as busy schedules, technological complications or even the need to take time for deeper reflection. Periodic, reassuring emails or calls to ‘check-in’ may be helpful to both facilitate trust and gently prod toward re-contact (Mann & Stewart, 2000). Participants who did not respond to check-in calls or emails after one-two weeks were sent an email or called to confirm or decline continued participation in the study.

As an additional incentive to enhance retention, participants were informed prior to and as part of the consent process that follow-up questions may be a part of the study process. They indicated whether they were willing to grant permission for the researcher to re-contact them after their initial responses. They were also informed at enrollment that compensation would be provided (\$20 Amazon gift certificate) to participants who completed all components of the survey as well as any follow-up communication.

***Data Recording.*** Unlike studies incorporating face-to-face interviews or focus groups to collect data, this study had less need for recording verbal communication as most of the

interviews were completed online. Telephone interviews or follow-up conversations were digitally recorded; these recordings were then transcribed by a professional transcriptionist.

The researcher also recorded field notes after each interview and maintained a reflexive journal to record decisions made during the course of the research. Field notes contained observations pertinent to each interview and provide additional context for analyzing women's experiences for HT discontinuation. For the telephone interviews, these notes included the date, time and length of each interview (also noted on the digital file) as well as the participant's tone of voice and any significant reactions (such as pauses or crying) to specific questions. Observations relevant to the online interviews were also recorded: the date and time the interview was posted, length of each interview and any cues as to the participant's reactions such as emoticons or words or phrases that are underlined, italicized or capitalized. The researcher's own impressions of reading or listening to each interview were also documented. In addition, the researcher also included information gathered from observations of the websites where participants were recruited, such as a description of the site, its purpose, topics discussed and the relative frequency of activity on the site.

In addition to the field notes, the researcher maintained a reflexive journal throughout the study recording insights, reflections and decisions made about and throughout all facets of the research process. Journal entries included notations relevant to the analysis of the data, modification of the interview guide or codebook or steps taken to prevent premature closure. All memos, notes and journal reflections were maintained in a notebook and will ultimately be transcribed and incorporated into the database.

**Data Management.** The third facet of this interactive data triad is data management, a term that refers to the manner in which the data is prepared for analysis (Knafl & Webster,

1998). Typically, data management consists of devising and adhering to a system of organizing the data and should be developed early in the study (Burns & Grove, 2005; Merriam, 2009). In the past many researchers did this by hand with elaborate index card systems, although now qualitative data management is often enhanced by the use of computer assisted qualitative data analysis systems (CAQDAS) (Burns & Grove, 2005).

For the current study, the NVivo (initially version 8, later replaced by version 9) system was used for qualitative data management as well as to merge the quantitative and qualitative data for the integrated analysis. NVivo is a sophisticated CAQDAS for storing, organizing, analyzing and retrieving data. Documents, such as journal articles, interview data, field notes and even this proposal can be stored in NVivo ‘\_folders’ and grouped according to their eventual utility. In NVivo, ‘\_nodes’ are storage areas that contain data. Two types of nodes, case nodes and tree nodes—were used. Each participant in a study constitute a ‘\_case’ and all materials relevant to that participant, including attribute data such as age and ethnicity are stored in a case node. Tree nodes, on the other hand, are hierarchically structured and are used to organize and structure emerging ideas and relationships; all data pertinent to particular codes can be filed in tree nodes and linked to the source documents which also promotes ease of retrieval of both coded and source materials (Bazeley, 2007). The node structure also provides a visual mechanism for ascertaining data saturation: when no further nodes are being developed, saturation is achieved. Field notes as well as methodological and reflexive memos can also be stored in folders, coded and entered into tree nodes. Furthermore, all documents are date and time stamped (Bazeley, 2007) which results in a chronology of the researcher’s decision-making processes that is transparent and traceable.

Prior to data collection, an NVivo shell or framework was created with nodes for cases as well as folders for field notes and memos. An NVivo codebook (Krippendorff, 2004; Nuendorf, 2002) was developed based on the concepts of the organizational framework (Woods & Mitchell, 2005). The codes from the codebook were entered into the framework as tree nodes. Codes that emerged inductively from the data were added as data analysis progressed. Collected data, transcripts of telephone interviews and narrative text from online interviews were copied into case nodes. Pertinent, field notes and reflexive journal entries were also included in the analysis.

A statistical analysis software program, PASW 18 (Predictive Analytics Software, formerly known as SPSS), was used for the quantitative data. The quantitative variables were also entered into NVivo as case attributes; they were used in the integrated analysis and comparison of qualitative and quantitative findings both within and across cases as well as across strata (Bazeley, 2007).

All electronic data—both quantitative and qualitative—as well as the codebook and the data inventory were saved on a separate hard drive. The hard drive, the digital recorder, consent forms, the field notes and the reflexive journal were kept in a locked file cabinet in the researcher's office.

## **Measurements**

### **Specific Aims and Measures**

This inquiry employed both quantitative and qualitative measurements to address the specific aims of the study although not every aim was addressed by both types of measures (Table 10). The specific aims were to:

- 1) explore women's experiences of HT discontinuation—the qualitative semi-structured interview elicited information about women's lives during and after discontinuing HT

including recurrent symptoms as well as similarities and differences between women's initial menopause experience and that of HT discontinuation;

2) describe the personal characteristics and sociocultural contexts that influence symptom perception, evaluation and response among women who have attempted to discontinue HT—both the interview questions and the demographic/QOL measurements were used to identify factors that may influence women's experiences during discontinuation and whether they stopped or resumed HT;

3) explore the impact of HT discontinuation on women's quality of life—various facets of QOL were explored and compared through the use of both quantitative and qualitative measurements; and

4) discuss women's preferences for counseling and support during HT discontinuation—open-ended interview questions were employed to examine the type and source of counseling or support women received as well as what information and support women desire to prepare them for this experience.

The online survey began with the demographic questionnaire followed by the open-ended interview questions. Upon completion of the narrative responses, participants responded to three short quantitative measures: the Menopause Rating Scale, the Hot Flash Related Daily Interference Scale and the Well-Being Scale. These instruments are described next, beginning with the quantitative measures.



Table 10.

*Relationship of Research Questions, Specific Aims, Conceptual Framework & Operational Definitions*

RESEARCH QUESTIONS	SPECIFIC AIMS	CONCEPTUAL FRAMEWORK		CONCEPTUAL DEFINITION	OPERATIONAL DEFINITION
What is the experience of discontinuing HT?	Explore women's experiences of HT discontinuation	Symptom experience	Symptom perception	Awareness of symptom frequency & intensity	Qualitative Interview  Menopause Rating Scale
			Symptom evaluation	Judgements about symptoms' seriousness, treatability, causes & consequences	
			Symptom response	Feelings, thoughts or behaviors that occur as a result of the symptoms	
What factors do women identify as making this experience more or less manageable?	Describe the personal characteristics and sociocultural contexts that influence symptom perception, evaluation and response among women who have attempted to discontinue HT	Personal characteristics		Genetic, molecular & physiologic factors that may contribute to symptoms	Qualitative Interview  Demographic Questionnaire  Menopause Rating Scale
		Sociocultural context		Ethnic, cultural & social factors that may contribute to symptoms	Hot Flash-Related Daily Interference Scale
How does HT discontinuation impact on women's QoL? Do the reports of QoL among women who have attempted to discontinue HT differ depending on which dimension of QoL is being measured?	Explore the impact of HT discontinuation on women's quality of life	Symptom evaluation: quality of life		Global sense of life satisfaction or well-being encompassing physical, social, psychological and spiritual domains	Qualitative Interview  Menopause Rating Scale  Hot Flash-Related Daily Interference Scale  Well-Being Scale  General Health and QoL Questions
What information do women need to help them manage symptoms and maintain health during and after HT discontinuation?	Discuss women's preferences for counseling and support during HT discontinuation	Symptom response: seeking information		Sources and adequacy of health-related information	Qualitative Interview

## Quantitative Instruments

**Demographic Questionnaire.** A questionnaire was developed to collect demographic/health information from each participant (see Appendix K). Requested information included: age, race/ethnicity, marital status, level of education, occupation, financial strain, gravity and parity, number of children, age at menopause, type of menopause, type(s) of HT, duration of HT use and the type of health care provider seen for menopause-related care. The responses were used to describe the sample however, given that the organizational framework includes constructs such as ethnicity, these data were also included in the analysis of factors influencing HT discontinuance.

**Menopause-Specific QoL Measures: Menopause Rating Scale.** The Menopause Rating Scale (MRS) is an 11-item questionnaire encompassing three domains/subscales (somatic, psychological and urogenital) of menopause-related symptoms (Appendix L) (Schneider, 2002). Each item represents a symptom or complaint and is rated on a five-point Likert scale of severity ranging from 0 (*no symptoms*) to 4 (*very severe symptoms*). The severity point values of items in each subscale are summed to obtain a score for the three separate dimensions. Subscale scores are then added together for the composite or total score (Klaas Heinemann et al., 2004; H. P. Schneider, 2002; H. P. Schneider & Behre, 2003; Zollner, Acquadro, & Schaefer, 2005). Higher scores reflect more severe symptoms and supposedly diminished QoL.

In this study, the MRS served a two-fold purpose. First, it helped to compile a list of women's symptoms and which of those symptoms were most troublesome. While it was anticipated that the open-ended interviews would also extract a list or description of the symptoms each woman experiences, the MRS may have enabled women to recall symptoms not

mentioned in their narratives and occasionally alerted the researcher to probe further about symptoms checked but not described. By enhancing the depth of information obtained, the MRS also promoted rigor.

The second purpose for the MRS was as a QoL measure. Because symptoms are one dimension of QoL, symptom information obtained through the MRS was germane to Specific Aim #3 which sought an understanding of how the different dimensions of QoL are affected by HT discontinuance.

The MRS was developed in Germany in 1992 in response to a growing dissatisfaction with existing menopause symptom/QoL measures (Greene, 2002; H. P. Schneider & Behre, 2003; Zollner, et al., 2005). Items were generated from the developers' expert opinion based on their clinical practice and also through comparisons to existing instruments (Zollner, et al., 2005). Initially designed to be administered by the clinician/researcher, the MRS underwent further testing in 1996 using a sample of 689 German women 40-60 years of age and was adapted into a self-administered format (Heinemann, 2007). It has since undergone extensive psychometric testing.

Factor analysis in a large (over 10,000 women) HT post-marketing study using Varimax rotation yielded a four-factor model—Hot Flushes, Soma, Urogenital and Psyche--explaining 72.2% of the variance (H. P. Schneider, Rosemeier, Schnitker, Gerbsch, & Turck, 2000). Re-evaluation of the four-factor model and follow-up factor analyses in the same sample at three and six month post-treatment intervals led to Hot Flushes and Soma being combined into a Somatic subscale (Potthoff, Heinemann, Schneider, Rosemeier, & Hauser, 2000). The other two dimensions were renamed 'Psychological' and 'Urogenital.' The three-factor model explains 59% of the variance and is more stable (H. P. Schneider, Rosemeier, et al., 2000). This same

factor structure (Principal component analysis, Varimax rotation) was observed in other large multi-nation samples ( $N = 10297$ ) however the subscale correlations are moderate ( $r = 0.4 - 0.7$ ) when compared to subscale scores (0.7-0.9) suggesting that the subscales are not as independent as the factor analyses demonstrate (Heinemann et al., 2004). Thus it may be preferable to use the total and not the subscale scores (Heinemann, 2007).

Internal consistency reliability of the MRS has been good in multiple samples with Cronbach's alpha ranging from 0.55 to 0.9 for subscale and 0.83 to 0.88 for total scores (Heinemann, 2007). Test-retest reliability (Pearson's correlation coefficient) ranges from 0.74 to 0.82 suggesting acceptable consistency of the MRS across time and multiple populations (Heinemann, 2007; Schneider et al., 2000b; Zollner et al., 2005). Domain scores do differ slightly in some regions which implies that cultural factors may influence a woman's perception of symptom severity (Heinemann et al., 2004; Heinemann, 2007).

Concurrent validity was assessed through a comparison of the MRS with both the Kupperman Index (KI), an older menopause symptom scale, and the Short Form-36 (SF-36) a QoL measurement. Both Kendall's *tau* ( $t-b = 0.75$ ; 95% CI [0.71-0.80]) and Pearson coefficients ( $r = 0.91$ ; CI [0.89-0.93]) (DeVellis, 2003) between the MRS and KI were quite acceptable and statistically significant (H. P. Schneider, Heinemann, Rosemeier, Potthoff, & Behre, 2000). Associations between the SF-36 domains most relevant to midlife women, somatic ( $t-b = -0.43$ , 95%CI [-0.52, -0.35];  $r = -0.48$ , 95% CI [-0.58, -0.37]) and psychological ( $t-b = -0.49$ , 95%CI [-0.56, -0.41];  $r = -0.73$ , 95% CI [-0.81, -0.65]), and the MRS were also good although correlations were lower for other SF-36 domains (H. P. Schneider, Heinemann, et al., 2000). The correlations between the SF-36 domains and the MRS prompted the scale developers to describe the MRS as a measure of menopause-related QoL.

The investigators also looked at the predictive ability of the MRS. By comparing ‘successful’ and ‘not successful’ ratings by both the MRS and physicians, sensitivity (correct prediction of a positive assessment) and specificity (correct prediction of a negative assessment) were determined to be moderate at 70.8% and 73.5% respectively (K. Heinemann, Assmann, Mohner, Schneider, & Heinemann, 2002).

The MRS is often used as an outcome measure in studies evaluating the efficacy of treatments to reduce menopause symptoms, for example, in several German clinical trials of alternative herbal remedies, such as Black Cohosh (Frei-Kleiner, Schaffner, Rahlfs, Bodmer, & Birkhauser, 2005; Kowalcek, Rotte, Banz, & Diedrich, 2005; Osmers et al., 2005; Uebelhack et al., 2006; Wuttke, Seidlova-Wuttke, & Gorkow, 2003). It has also been employed in population-based studies assessing menopause symptoms (Kakkar, Kaur, Chopra, Kaur, & Kaur, 2007; Monterossa, Blumel & Chedraui, 2007). The MRS has been successfully translated and culturally-adapted into other languages: English, Spanish, French, Indonesian, Swedish, Turkish, Brazilian, and Mexican/Argentinian. The various language versions of the tool are available on the internet (L. Heinemann, Potthoff, & Schneider, 2003).

The strengths of the MRS include its simplicity and ease of administration and scoring (Zollner, et al., 2005). It can be completed in less than ten minutes thus it does not impose undue participant burden (Heinemann, 2007). Because the MRS is self-administered, possible threats to validity such as investigator-participant interaction and socially desirable responses are reduced. Weaknesses include: lack of items to assess irregular bleeding and inability to distinguish between true and placebo effects (K. Heinemann, et al., 2002). Also potential difficulty differentiating between anxiety and irritability items as well as severe and very-severe ratings and assymetry of responses can result in a negatively skewed depiction of menopause symptoms.

In fact, when the MRS was compared to the KI, menopause symptoms were attributed more often into the moderate and severe range by the MRS (68%) than by the KI (24%) which underscores the need for caution when equating symptom checklists with QoL.

**Menopause-Specific QoL Measures: Hot Flash-Related Daily Interference Scale.** In this study, the Hot Flash-Related Daily Interference Scale (HFRDIS) (Appendix M) was used as another QoL measure assessing interference in function. An essential component of QoL, functional status is defined as a person's ability to perform daily living tasks. Function can be subdivided into four domains—physical, psychological, social and role—although this list is not necessarily exhaustive (Bredow & Peterson, 2004). Symptoms are an important factor in an individual's functional status, but other factors, such as physical environment or family support, may also contribute to the perception of functional ability or disability (Bowling, 2005; Bredow & Peterson, 2004). People who have adjusted to a condition or symptoms may no longer describe them as restrictive or interfering with day-to-day functions. This may help explain why some people with many symptoms still score high on overall QoL measures (Bowling, 2005).

This seemingly paradoxical pattern of experiencing more symptoms yet reporting a good overall QoL has also been observed in the menopause literature. In some studies, the QoL of women with severe symptoms is not significantly worse than that of women whose symptoms are mild (Carpenter et al., 1998) which may be related to the impact of menopause symptoms on a woman's functional capacity. However, while menopause symptom/QoL checklists may catalogue the frequency and severity of symptoms, they typically do not elicit the degree to which symptoms disrupt or interfere with a woman's daily functioning.

The HFRDIS was developed to be a menopause-specific measure of the impact of VMS on both functional ability and QoL (Carpenter, 2001). It is a 10-item scale that measures the

degree to which VMS interfere with nine daily functions—work, social and leisure activities, interpersonal relationships, sleep, mood, concentration, sexuality and enjoyment of life—as well as overall QoL (Carpenter, 2001). Each item is scored on a 11-point Likert scale ranging from 0 (*do not interfere or no VMS*) to 10 (*completely interfere*). Responses are based on symptom experience over the previous two weeks. Scores for each item are summed then the mean score is calculated. A higher overall score (0-3 = *mild*, 4-6 = *moderate*, 7-10 = *severe*; personal communication with Dr. J. Carpenter) is indicative of greater interference on daily life and potentially worse QoL (Carpenter, 2001; Carpenter & Rand, 2008).

Two scales assessing the impact of pain or fatigue on daily activities, the Brief Pain Inventory and the Fatigue Symptom Inventory, were used as models for the development of the HFRDIS (Carpenter, Johnson, Wagner & Andrykowski, 2002). Psychometric testing of this instrument was conducted using a sample of 100 women (54 breast cancer survivors and 46 comparison women) who completed the scale twice (Times 1 and 2) at a six-month interval. Internal consistency reliability was examined at both points. Inter-item correlations ranged from 0.55 to 0.90 (Time 1) and 0.59 to 0.95 (Time 2). Item-total correlations at Time 1 were between 0.77 and 0.93 and at Time 2 the range was 0.82 to 0.93 (all correlations significant at  $p < .01$ ). Cronbach's alpha was the same (0.96) at both measurements points ( $p < .001$  for all). Test-retest reliability was not done because of the great potential of VMS to change over time (Carpenter, 2001).

Convergent validity of the HFRDIS was mixed: correlations ( $p < .01$  for all) with overall VMS severity and bother ratings were high at both time points ( $r = 0.51 - 0.81$ ) and moderate for diary-related frequency and severity ( $r = 0.33 - 0.69$ ). However, there was only weak-to-

moderate correlation with symptom duration ( $r = 0.11 - 0.56$ ) implying that duration is not as much a factor in VMS interference as are frequency, severity and bother (Carpenter, 2001).

At both time points, the HFRDIS scores were higher among women experiencing VMS than those who were asymptomatic when compared by  $t$  tests ( $p < 0.001$  for all) demonstrating known-groups validity. Although interference scores were higher for items pertaining to mood, sleep and concentration, all items were affected to some degree by VMS. In addition, the HFRDIS scores of women whose VMS increased in frequency between time points were higher at Time 2 ( $F = 8.75$ ,  $df = 2$ ,  $p < 0.001$ ) indicating that the scale is sensitive to change in VMS interference over time (Carpenter, 2001).

The Positive and Negative Affect Scale (PANAS) and Profile of Mood States-Short Form (POMS-SF) were used to assess construct validity. As could be expected, women's scores on the HFRDIS at both time points were negatively correlated with positive affect ( $r = -0.14$  to  $-0.40$ ) and vigor ( $r = -0.14$  to  $-0.38$ ) and positively correlated with mood disturbances ( $r = 0.18$  to  $0.52$ ) and negative affect ( $r = 0.28$  to  $0.54$ ) ( $p < .001$  for all correlations). The low-moderate level of these correlations suggest that the construct measured by the HFRDIS—interference—is not collinear with mood or affect (Carpenter, 2001).

A subsequent secondary data analysis using Semantic Equation Modeling (SEM) lent additional support to some of the psychometric properties of the HFRDIS (Cronbach's  $\alpha = 0.94$ ) showing moderate correlations between interference and symptom severity ( $r = 0.52$ ,  $p < 0.01$ ). In the SEM, interference was predicted by symptom severity (0.66) and in turn predicted both positive ( $-0.56$ ) and negative ( $0.75$ ) affect ( $p < 0.01$ ) suggesting that interference as measured by the HFRDIS may be a useful outcome index (Carpenter & Rand, 2008).



Because it is a relatively new instrument, the HFRDIS has not yet been used extensively in the literature although a few recent studies have used the tool to evaluate treatment strategies for menopause symptoms. In a randomized-controlled trial (N = 93) testing the effectiveness of an herbal supplement for relief of VMS, the HFRDIS demonstrated good test-retest reliability ( $r = 0.76, p < 0.05$ , two-tailed). Intraclass correlation coefficients were also calculated ( $r = 0.76, p < 0.01$ ) further supporting the reliability of the HFRDIS (van der Sluijs, Bensoussan, Chang & Baber, 2009). It was also used in a pilot study exploring the effects of yoga on menopausal symptoms (Booth-LaForce, Thurston & Taylor, 2007) however no reliability data were reported.

**Generic QoL Measures.** As previously noted, situation-specific or symptom measures alone may not be sufficient for developing a comprehensive understanding of such a complicated construct as QoL (Utian, 2005; Wiklund, 1998). The addition of generic health and QoL indices complemented the menopause-related QoL measures and provided an opportunity to compare the results of both types of measures for each woman discontinuing HT. The use of generic measures also allowed for direct comparison of health and QoL measures between HT users and non-users (Taylor, MacLennan & Avery, 2006).

**General Well-Being Subscale.** Outcome measures in both research and health care tend to focus on negative experiences, such as complications, symptoms, even morbidity and mortality, or on individuals experiencing deviations from health (Bowling, 2005; Stewart, Ware, Sherbourne & Wells, 1992). This is very much in evidence in the menopause specialty where much research has been done using symptom checklists and conducted on women experiencing troublesome symptoms. As a result, the messages from the literature convey a sense of menopause as a negative and distressful experience (Smith-DiJulio, Woods & Mitchell, 2008).

Yet many women view menopause as either a natural life event or a positive transition suggesting that there is more than one perception of menopause. Indicators of positive experiences and outcomes are necessary for restoring balance to the overall perspective of QoL (Bowling, 2005). In an effort to counteract the negative connotations associated with menopause, some researchers have chosen to measure well-being in women during the menopause transition (Dennerstein, Lehert & Guthrie, 2002; Smith-DiJulio et al., 2008).

Well-being is considered to be a subjective measure of an individual's perceptions of their life. It has two separate but related concepts: subjective well-being (e.g., happiness, life satisfaction, morale) and psychological well-being (e.g., personal growth, mastery, autonomy) (Bowling, 2005). The emphasis of well-being is on positive dimensions of function, not symptoms or illness (Smith-DiJulio et al., 2008), thus a well-being scale will provide a counterbalance to the more symptom-focused measurements.

The four-item subscale to be used in the proposed study is a part of the General Well-Being Schedule (GWB) developed by Dupuy in 1977 for use in the US Health and Nutrition Examination Survey (HANES). The total GWB scale measures both positive and negative feelings, states or affect which reflect six dimensions: positive well-being, self-control, vitality, anxiety, depression and general health. While much of the initial psychometric analyses have not been reported, subsequent studies using the GWB reported high internal consistency reliability alphas, ranging from 0.88 to 0.95 (Bowling, 2005; McDowell, 2006). Data from studies representing 18 countries and 16 languages (N = 8356) was pooled by the International QoL Outcomes Database group; alpha values for all six dimensions of the scale were above 0.7 with inter-item coefficients above 0.4 (McDowell, 2006). Test-retest reliability has been lower, 0.68 to 0.85, perhaps reflecting changes in subjects over time (Monk, 1981).

The GWB has also been shown to have adequate validity with construct validity ranging from 0.47 to 0.78. When measured against various depression and anxiety scales, the average predictive validity correlations were 0.69 and 0.64 respectively (Bowling, 2005; McDowell, 2006). In addition, the correlation between the Affectometer, a scale measuring overall happiness and well-being, and the GWB was 0.74 (Bowling, 2005).

In discriminant validity testing, the correlation between the GWB and somatic and psychological problem indices was 0.73. Symptoms and self-perceptions of health explained 31% of the variance in the scores on the GWB (McDowell, 2006) suggesting symptoms alone cannot be used as a measure of QoL or well-being.

Although the overall GWB is often broken down into six possible subscores based on the initial proposed dimensions, factor analyses have resulted in other GWB models with 3 or 4 factors (Bowling, 2005; McDowell, 2006). Because of inconsistent factor analyses and high ratings of internal consistency, a recent report (Taylor, Poston, Haddock et al., 2003) has suggested that the GWB is unidimensional. Nonetheless, subscales reflecting the six dimensions have been used in the literature to assess any or all of the six dimensions. Correlations between these subscales and various criterion measures have been mostly good, ranging from 0.65 to 0.90. Data pooled from a large ( $n = 8536$ ) international database representing 18 countries and 16 languages shows alpha values of over 0.7 for all six dimensions (McDowell, 2006).

The GWB was modified and incorporated into the RAND Mental Health Inventory as part of the Health Insurance Study and the later Medical Outcomes Study. A factor analysis based on 1209 respondents corroborated the six factor structure (McDowell, 2006). Internal consistency scores for the subscales ranged from 0.72 to 0.88. In particular, the well-being subscale had an internal consistency (Cronbach's alpha) of 0.83 and a one week test-retest

reliability of 0.74 ( $n = 437$ ). Well-being in general was highly correlated with health: 0.83 (Brook et al., 1979). Further testing showed an internal consistency coefficient of 0.92,  $M = 59.2$ ,  $SD = 24.3$ ,  $N = 2862$ ) (Hays, Sherbourne & Mazel, 1995; Stewart et al., 1992).

One of the benefits of this scale is that it does not include references to physical symptoms associated with emotional health issues so there is less likelihood of misinterpretation of findings (Bowling, 2005; McDowell, 2006). In fact, psychometric testing demonstrates low correlations with physical functioning ( $r = .14$ ) (Hays et al., 1995) therefore it provides some counterbalance to the previous instruments which focus on physical symptoms. In keeping with the intent to measure positive aspects of health, the subscale used contains only positively worded items (see Appendix N). Participants are asked to respond based on how they have been in the past month and their responses are made on a scale of 0 – 5 with higher scores indicating higher well-being. A similar well-being scale was used in the Seattle Midlife Women's Health Study ( $N = 334$ ) where, between the years 1990 to 2006, alpha ranged from 0.82 to 0.89 (Smith-DiJulio et al., 2008).

***Measures of Overall QoL and Health.*** In order to provide a comprehensive understanding of QoL through HT discontinuation, overall and health-related QoL (HRQoL) were also measured. In essence, both of these concepts are highly subjective and represent a synthesizing of multiple and interacting dimensions such as symptoms, function, life satisfaction or morale, thus no one clear definition of these concepts has been deemed sufficient or acceptable to all disciplines. Despite this lack of a standardized definition, both are widely used as outcome measures in clinical research.

Simplistically speaking, HRQoL refers to an individual's general health perceptions or assessment of overall health (Bowling, 2005; Ferrans, 2007). It is a valuable adjunct in symptom

research: for example, in intervention studies differences between the symptom responses and HRQoL responses can point toward the presence of some other mediating factor warranting further exploration. The term HRQoL is often used interchangeably with QoL, especially in health care research, however, HRQoL is actually a subdimension of overall QoL. Overall or global QoL is considered the endpoint or summation of all the other dimensions and may also incorporate elements such as material resources and/or spirituality (Bowling, 2005; Ferrans, 2007; McDowell, 2006).

Both QoL and HRQoL are commonly measured by single-item questions that require the respondent to evaluate his/her life or health in order to choose the best response. The benefit of this approach is that it allows participants to respond based on the criteria or dimensions most salient in their lives at that moment, rather than on fixed dimensions important to the scale developer or researcher (Ferrans, 2007; McDowell, 2006). Therefore, in this study, QoL and HRQoL were measured through two global questions drawn from the WHOQOL-BREF Scale (Appendix O).

As implied by the title, the WHOQOL-BREF is an abbreviated form of the WHOQOL, a 100-item scale developed by the World Health Organization to assess overall QoL. Rather than just reporting symptoms or functional ability, the WHOQOL seeks to determine the impact of these dimensions on QoL, taking into account the physical, psychological, spiritual, social, cultural and environmental status of the respondents (McDowell, 2006). It contains four items for each of 24 facets of QoL plus four general items (Bowling, 2005) and over multiple studies has shown good internal consistency reliability (Cronbach's alpha 0.72 – 0.88) and concurrent validity with the SF-36 (0.6 – 0.7) (McDowell, 2006).

The WHOQOL-BREF is a 26-item derivation of the 100-item scale, with one item for each of the 24 QoL facets and two global questions (the two global questions are not incorporated into the scoring of the scale). Psychometric testing of the WHOQOL-BREF shows good internal consistency reliability ranging from 0.66 to 0.85. Four week test-retest reliability alphas ranged between 0.64 to 0.79. The abbreviated scale correlates well with the WHOQOL ( $\alpha = 0.82 - 0.95$ ) and captures 95% of the variance in the total facet score of the longer scale. Factor analyses yielded a four-factor model and mean scores and standard deviations are available as reference standards for 23 countries (McDowell, 2006).

Despite their simplicity and subjectivity, single-item summary ratings in general have a strong correlation with mortality, even when other risk factors are controlled (McDowell, 2006). For example, among women rating their health as poor, the adjusted odds ratio for the prediction of four-year mortality was 3.0 – 3.2 (Idler, Kasl & Limke, 1990) indicating strong predictive validity. Test-retest reliability correlations on various summary self-rating questions indicated kappa coefficients of 0.86 for overall QOL and 0.69 for physical health (McDowell, 2006).

In this study, the first global question asked the individual to rate her overall QoL while the second asked for an assessment of satisfaction with health. Responses are rated along a five-point scale although the answers differ for each question. For the overall QoL item, responses range from *1 = very poor* to *5 = very good* while the health-related question options range from *1 = very dissatisfied* to *5 = very satisfied* (McDowell, 2006).

### **Qualitative Interview Guide**

Semi-structured interviews using open-ended questions sought to elicit an in-depth description of women's experiences of HT discontinuation. Additional prompts were used to probe for personal characteristics, symptom management strategies and other factors influencing

the discontinuation experience and outcome. Women were also asked to describe their QoL and the counseling and support they believed would have been most beneficial for them during this experience. This interview guide was revised as new categories emerged during the course of the investigation (Appendix P).

### ***The Qualitative Researcher***

In qualitative research, the researcher is considered the primary instrument in that her/his questions, interactions and interpretations form the conduit through which the phenomenon is brought to light. Because the researcher actually becomes part of the investigation, her/his knowledge, experiences, beliefs, values and biases influence the research process and product (Dowling, 2006). All aspects of the inquiry may be influenced: the choice of a research topic and question, decisions about methodology and methods, development and adaptation of the interview guide, the process of data analysis and the inferences drawn from the findings (Patton, 2002; Polit & Beck, 2008). In an effort to acknowledge and address these influences, the researcher also contributes information—field notes, memos and reflexive journal entries—for inclusion in the analysis of the data.

As previously described, field notes of observations pertinent to the context of the interviews and memos illuminating the researcher's methodological decisions were maintained throughout the research process and were incorporated into the analytic process. The use of the NVivo CAQDAS facilitated linking this material to the interview transcripts and coding it in conjunction with the text data. In addition to the memos and field notes, pertinent entries from the researcher's journal were also included in the qualitative data analysis. This journal is one of the primary mechanisms for recording and displaying the researcher's reflexivity.

**Reflexivity.** Reflexivity refers to the open, honest, critical and thoughtful reflection by the researcher about any and all aspects of the research experience and process (Hesse-Biber & Leavy, 2006; Polit & Beck, 2008). However, reflexivity is more than introspection and self-appraisal; it is also epistemological—inextricably linked to how knowledge is constructed (Dowling, 2006). The act of reflexivity should be, not only descriptive (relating the researcher's reflections) but also analytical (comparing and evaluating the multiple realities emerging from the participants' narratives and researcher's reflections) (Letherby, 2002). It is this analysis that brings balance between objectivity and subjectivity (Patton, 2002). During reflexive journaling, the researcher acknowledges her/his background, experiences, assumptions, beliefs, values and even attributes such as age and gender which may impact on interactions with participants. The researcher may examine how these biases and preconceptions can impact on the process and quality of the research and describe any strategies used to offset these biases (Beck, 2004; Hesse-Biber & Leavy, 2006; Lincoln & Guba, 1985).

Because of its inherent intersubjectivity (Im & Chee, 2003), qualitative research may also be reciprocal: that is, the researcher not only influences the research process but may also, in turn, be influenced by the experience resulting in a shift in her/his values or perspective. These shifts may further influence the process of inquiry therefore they must also be acknowledged. Thus reflexivity is a dynamic process requiring that the researcher engage in a moment by moment awareness of her/his thoughts and assumptions, what influences them and what they may then influence (Dowling, 2006).

Understanding these reflexive circles (Koch & Harrington, 1998; Patton, 2002) is of particular importance in feminist-based research. The inferences constructed from emerging knowledge in qualitative research arise in part from the insights and interpretations of the



researcher that may lead to the perception that the researcher holds ultimate authority and privilege (Freshwater & Avis, 2004). However, the goal of feminist research is to minimize power differentials and hierarchical positioning and allow women's authentic voices to be heard (Dowling, 2006; Hesse-Biber & Piatelli, 2007; Im & Chee, 2003). Strategies that facilitate the sharing of stories, such as the researcher providing information about her/his similarities and differences from participants (Seibold, 2000), biases and opinions, and even insights from the data, can bring balance to the participant-researcher relationship. The inquiry becomes collaborative and knowledge is co-created (Dowling, 2006; Hesse-Biber & Piatelli, 2007). It is therefore critical that the researcher acknowledge these reciprocal influences, their influence on the research process, the repositioning of both researcher and participant within the reflexive circle, and any tensions arising from this positionality (Hesse-Biber & Piatelli, 2007).

The constant sharing and shifting of perspective and influence means that reflexivity is an ongoing process rather than an end result (Finlay, 2002). It does not seek to eliminate bias or variability or influence, but rather to understand (Maxwell, 2005; Merriam, 2009) and gain new perspectives and fresh insights from these variations (Finlay, 2002; Morse et al., 2002). Thus reflexivity in feminist research provides a means to recognize the contextual nature of the multiple realities and truths of women's lives.

Another advantage of reflexive inquiry is that it can help the fledgling researcher develop a deeper understanding of and appreciation for all facets of the research process and ultimately become a better researcher (Watt, 2007). Reflexive journaling may also foster an ethical research environment by providing a space for recording thoughts about how to address ethical dilemmas, sensitive topics, and participant confidentiality as well as the impact of these ethical decisions on the study process and outcomes.

Patton (2002) suggests a triangulated approach to reflexive journaling by focusing on three different perspectives: self-reflexivity, reflexivity about those studies and reflexivity about the intended audience (see Table 11). Self-reflexivity involves attention to the perspective and voice of the researcher, preferably writing in the first-person to convey a deeper sense of intimacy and authenticity. As already noted, reflexivity allows the voices of participants to become audible, the second component. Finally, through reflexivity the researcher can consider issues such as the influence of stakeholders and how to ensure that findings are presented and disseminated to be of greatest use (Patton, 2002). Accordingly, for this study, the researcher attempted to incorporate these three perspectives into the reflexive writing.

Table 11.

*Triangulation of Reflexivity*

<b>REFLEXIVITY PERSPECTIVE</b>	<b>POTENTIAL QUESTIONS FOR CONSIDERATION</b>
Self-reflexivity	What do I know and how do I know it? What has influenced my perspectives? What voice do I use in sharing my perspective? What steps am I taking to reflect both critical thinking and creativity?
Reflexivity about participants	How do they know what they know? What shapes their experiences & perspectives? How do they perceive me? How do I perceive them? How can I be sure I am accurately representing all participant realities and exploring all alternative perspectives?
Reflexivity about audience	How do they interpret & make sense of the findings? Will readers be able to follow the thread from philosophical underpinnings through discussion of findings? What perspectives do they bring? How do they perceive me and I, them? How will the findings be used?

*Adapted from: Patton (2002) & Polit & Beck (2008)*

In NVivo, a folder with subcategories addressing these themes was developed for reflexive journal entries for data analysis. One of the first entries was the researcher's experiences and beliefs related to HT discontinuation. Of particular relevance to this investigation is the researcher's professional experience as a certified Menopause Clinician

providing care to peri/menopausal women as part of a Menopause Consultation Service. Some of these women have been contemplating or actually experiencing HT discontinuation therefore the researcher has had the opportunity to counsel and provide support to these women. These encounters have obviously influenced the choice of this research topic as well as decisions regarding the research design. They may continue to influence the researcher's interpretations of the data and relationships with participants and therefore must be acknowledged and explored as part of the reflexive process. In addition, the researcher also documented reflections on her own experiences as a mid-life woman transitioning through peri/menopause and how that ongoing experience shapes her perceptions and beliefs about women's choices about HT.

### **Data Analysis**

Data analysis integrated both qualitative and quantitative methods. The degree of integration varied by specific aims will be discussed below. Online and telephone data were initially analyzed separately and compared in order to determine if there were substantive differences in the data obtained through each method. It is important to keep in mind that, although discussed separately, data collection, management and analysis are not linear but actually occurred concurrently, interactively and iteratively.

### **Qualitative Content Analysis**

The primary analytic method of this study was Qualitative Content Analysis. Content analysis is viewed as a technique for making inferences from verbal, visual or written data in order to describe a phenomenon (Downe-Wamboldt, 1992; Krippendorff, 2004; Weber, 1990). The focus of the inferences may include the source of the message, the audience of the message, or the message itself (Weber, 1990). Inferences or findings are discovered through a very explicit and detailed process of coding and abstraction (Elo & Kyngas, 2007).

With content analysis, large sections of text or other data are systematically coded according to a standardized guide or codebook consisting of names and definitions of category codes (Cohen & Crabtree, 2006; Neuendorf, 2002; Zhang & Wildemuth, 2009). These text sections are then condensed into more manageable segments, which are further compressed or grouped into subcategories and finally categories, a process known as abstraction (Elo & Kyngas, 2007; Schilling, 2006). Categories, which may or may not be counted, are ultimately summarized and described in terms of their manifest (frequency) and/or latent (context, meaning, relationship) content (Downe-Wamboldt, 1992; Krippendorff, 2004; Busch et al., 2005; Sandelowski, 2000).

Although the roots of content analysis may date back as far as the Inquisition of the 17<sup>th</sup> century, the first documented analysis of textual data did not occur until the 18<sup>th</sup> century in Sweden. The increase in production of printed material that occurred at the beginning of the 20<sup>th</sup> century spawned numerous quantitative analyses of mass communication materials, often in an effort to identify hidden propaganda. In the second half of the 20<sup>th</sup> century, content analysis spread to other disciplines and other types of data sources, including the Internet. Computers have been a boon to content analysts with software programs that can make the task of retrieval and categorization of data much more efficient (Krippendorff, 2004). The burgeoning qualitative research tradition that began during this period (Greene, 2007) also contributed to the evolution of content analysis (Krippendorff, 2004).

Qualitative content analysis was first proposed in 1953 by Kracauer who believed that the traditional approach to content analysis was so focused on identifying and counting words (manifest content) that the meanings within the text (latent content) were lost (Priest, Roberts & Woods, 2002). The qualitative variation of content analysis stresses the importance of going

beyond the manifest or explicit content to the deeper latent contexts underlying the data. It has been employed in the systematic analysis of ethnographic, narrative, conversational and even interview data and has become increasingly popular, especially in scholarly disciplines such as the social sciences (Krippendorff, 2004) and health care (Cohen & Crabtree, 2006). Content analysis can be useful within feminist or other emancipatory paradigms to highlight what is absent, oppressed or taken for granted in a culture by analyzing messages promulgated from the dominant sector (Leavy, 2007).

However, there is still disagreement about the definitions and techniques that comprise the qualitative content analysis process. Some argue that qualitative content analysis does not exist as a separate entity (Neuendorf, 2002) while others see it as clearly distinct from the quantitative form (Mayring, 2000; Morgan, 1993). It has also been suggested that content analysis is actually a continuum that includes both qualitative and quantitative approaches. Still others contend that all content analysis incorporates both qualitative and quantitative strategies and is thus a type of mixed methods inquiry (Leavy, 2007).

One of the primary distinctions between qualitative and quantitative content analyses is in the amount of data to be analyzed. In comparison to the volumes of textual material analyzed in quantitative content analysis, qualitative content analysis is conducted with smaller amounts of text (Krippendorff, 2004). Another difference lies in the depth of the analysis. Although the focus of quantitative content analysis has expanded to include both manifest (conceptual analysis) and latent (relational analysis) content (Busch et al., 2005), it has been posited that the qualitative approach goes deeper into the contexts and meanings between and beneath the words (Graneheim & Lundman, 2003; Morgan, 1993; Sandelowski, 2000; Weber, 1990).

The manner in which codes are applied and/or categories are summarized is in great part responsible for the deeper understandings that arise via the qualitative approach. In content analysis, data are analyzed based on a consistent coding schema developed by the researcher(s) to identify the concepts within the theoretical framework or research question. With the quantitative-dominant approach, the codebook is designed prior to data collection, categories are mutually exclusive and adherence is mandatory (Neuendorf, 2002; Zhang & Wildemuth, 2009). With qualitative content analysis however, codes are not defined a priori but are generated through initial and continued analysis of the data (Hsieh & Shannon, 2005; Morgan, 1993; Polit & Beck, 2008; Sandelowski, 2000; Sullivan-Bolyai et al., 2005). This inductive approach (Elo & Kyngas, 2007; Mayring, 2000) is more deeply rooted in the contexts of the data and may lead to the development of concepts, models or hypotheses to be tested (Hsieh & Shannon, 2005).

It is also possible to use a hybrid or deductive analytic approach (Elo & Kyngas, 2007; Mayring, 2000) whereby some codes, based on literature, experience or an organizational framework, are designated prior to the analysis (Hsieh & Shannon, 2005; Morgan, 1993). As the analysis progresses, these codes may be revised or even discarded and other codes added to the codebook. A hybrid approach may help to validate or expand upon existing frameworks or theories (Hsieh & Shannon, 2005). It may also be particularly useful in a mixed methods study where the researcher's approach may flow between induction and deduction in her/his efforts to answer the research question.

There are some qualitative content analyses that actually appear to conform to a more traditional quantitative format resulting in frequency counts of the words or concepts being investigated. However, these tallies are not the end of the analysis but are rather an intermediate or transitional step. Moving from description to interpretation, the researcher proceeds to

examine patterns found within the numerical summaries that may point the way toward the latent content awaiting exploration and discovery (Crabtree & Miller, 1999; Hsieh & Shannon, 2005; Morgan, 1993). Even the categories that emerge through the inductive or hybrid approaches may be tabulated in order to detect deeper or different patterns of meaning than those already identified and described (Morgan, 1993; Sandelowski, 2000). The enumeration of categories through qualitative content analysis may also facilitate comparisons both within and across subjects (Ayres, et al., 2003) as well as between groups or strata (Morgan, 1993).

Although qualitative content analysis enables an understanding of the deeper meanings and relationships within the data (Zhang & Wildemuth, 2009), it remains less interpretative than the analytic procedures used in other qualitative research methods such as phenomenology. Because findings are typically re-presented using terminology found within the text of the data and the codebook, qualitative content analysis is especially appropriate for Qualitative Description which results in a rich description couched in the language of the participants (Sandelowski, 2000; Sullivan-Bolyai et al., 2005). Therefore, qualitative content analysis was an appropriate analytic method for the proposed qualitative-dominant study.

### **Data Analysis for this Study**

For this mixed methods study, qualitative content analysis was the primary analytic method. To ensure that the analysis of the data accurately addressed the specific aims of the study, a codebook was developed. A hybrid or directed approach was used in the development of this coding scheme. Codes corresponding to concepts within the organizational framework, as well as standardized information (date, time, length of interview and so on) from the field notes, were identified and defined a priori. Codes arising inductively from the data were added to the codebook as they are identified. The quantitative measures were also described in the codebook.

The texts were first read, however, without applying any codes in order to obtain a sense of the whole experience and to facilitate immersion in the data (Graneheim & Lundman, 2003; Hsieh & Shannon, 2005; Woods, Priest & Roberts, 2002). After the initial reading the texts were reread and coded (Hsieh & Shannon, 2005). Line by line coding, the reduction of data into smaller units of information (Merriam, 2009; Miles & Huberman, 1994), was used to identify similar words, phrases or other segments of text that illustrate concepts relevant to the predetermined coding classifications in the codebook (Sandelowski, 2000; Sullivan-Bolyai et al., 2005). As data analysis continued, segments of text bearing the same codes were then clustered or collated and systematically organized to facilitate easy retrieval of specifically coded sections (Merriam, 2009; Miles & Huberman, 1994). These text segments were coded as free nodes.

Once the initial coding was completed, the text was then re-analyzed to inductively code data not captured with the existing codes. These text segments were then assigned a label or code (Merriam, 2009; Miles & Huberman, 1994) which were derived either from the actual text (descriptive) or may have been metaphorical (interpretive), reflecting the corresponding meaning or context (Miles & Huberman, 1994). Any new codes were added to the codebook (Hsieh & Shannon, 2007). Analysis of each text continued in this iterative fashion until no new codes were found in the data.

As previously noted, codes were condensed or reduced into subcategories and categories (Elo & Kyngas, 2007; Graneheim & Lundman, 2003; Schilling, 2006) and migrated into tree nodes. Frequency counts of these categories supplemented the descriptive re-presentation of the findings (Bazeley, 2003; Sandelowski, 2000). Cross tabulations were also done to assist in comparing categorical themes across strata and against quantitative scores to seek any patterns



that may warrant further exploration (Krippendorff, 2004). Ultimately tree nodes were structurally clustered by specific aim.

Analysis varied by specific aim as described below (Table 12). Although each Specific Aim and relevant analysis are discussed sequentially here, in reality the analyses was interactive and iterative.

**Specific Aim #1: *explore women's experiences of HT discontinuation.*** The content analysis process as described above identified categories related to women's discontinuation experiences and the specific symptoms encountered during and after discontinuation. These categories were then used in the development of a rich description of women's discontinuation experiences. Frequency counts of emergent categories were done to further support the findings. Cross tabulations were also computed to explore variations in the experiences of women who stop or resume HT by comparing the frequencies of the categories by discontinuation status.

**Specific Aim #2: *describe the personal characteristics and sociocultural contexts that influence symptom perception, evaluation and response among women who have attempted to discontinue HT.*** To address this aim, codes related to women's personal and sociocultural characteristics (e.g., ethnicity) and their symptom experience (symptom description, meaning and influencing factors) were applied during the initial analysis of the interview data. Any additional codes related to the concepts that emerged from the data were also incorporated into the analysis. Some of the qualitatively-derived codes were quantitized into categorical variables (e.g., ratings of post-discontinuation symptom severity were quantitized as mild-moderate-severe) to facilitate further descriptive statistical analysis; these were then added to the codebook. Codes were once again enumerated and compared by discontinuation status (strata) to allow for the discovery and further exploration of potential new patterns of meaning and context.

Descriptive statistics (means, frequencies and cross tabulations) were run on the quantitative data using PASW 18. Responses from the demographic questionnaire were used not only to describe the study participants but also as part of the analysis as some of this data was pertinent to concepts within the organizational framework. Categories from the qualitative analysis were then compared against the quantitative data to look for patterns indicative of underlying meanings or relationships in the data.

**Specific Aim #3: *explore the impact of HT discontinuation on different facets of women's quality of life.*** Both within and across subjects' analyses were performed for this specific aim. First, women's QoL with HT discontinuance was described. MRS and HFRDIS scores were collapsed or qualitized into categories (corresponding to the scale choices on the MRS and the aforementioned categories for the HFRDIS). This allowed for identification of groups of women with similar levels or profiles (Sandelowski, 2000) of interference and/or symptom severity for further comparison of experiences. Finally, each woman's MRS and HFRDIS profile as well as her well-being scores were compared to her qualitative description of HT discontinuation-related QoL to identify congruent or divergent results (Erzberger & Kelle, 2003). This direct comparison provided information to understand the best method(s) for assessing QoL in women at menopause. Finally, both qualitative and quantitative results were compared by discontinuation strata.

**Specific Aim #4: *discuss women's preferences for counseling and support during HT discontinuation.*** Emerging and predetermined codes related to menopause information sources were used to categorize and describe both the amount of information and support women desire with HT discontinuation and the information and support they actually received. These were compared to identify any discrepancies between preferred and actual level of support. Any

discrepancies may help point the way toward the development of interventions to help women during this experience.

Table 12.

*Data Analysis*

<b>SPECIFIC AIM</b>	<b>ANALYSIS</b>	<b>RESULT</b>
<b>Specific Aim #1</b>	Coding	Description of discontinuation experience
	Frequencies	Rank order summary of experiences
	Cross tabulations	Comparison of experiences by discontinuation status
<b>Specific Aim #2</b>	Coding	Description of symptoms & influencing factors
	Frequencies	Rank order summary of symptoms & influencing factors
	Descriptive statistics	Summary of scores of MRS, HFRDIS, well-being & QoL
	Cross tabulations	Comparison of symptoms & influencing factors with score results & discontinuation status
<b>Specific Aim #3</b>	Coding	Description of QoL with discontinuation
	Descriptive statistics	Summary of QoL scores & comparison to qualitative description
	Cross tabulations	Comparison of QoL by discontinuation status
<b>Specific Aim #4</b>	Coding	Description & comparison of women's counseling preferences and actual counseling received

### **Rigor and Trustworthiness**

The goal of health research is to produce knowledge of the highest quality in order to benefit society. Rigor, the degree to which study results are reliable and valid and the degree to which the reader can have confidence in the findings, enhances the quality of the study. Characteristics of a rigorous study include a detailed study design that adequately addresses the research question, precision of measurement, adherence to the sampling plan and study protocol, systematic analysis and presentation of results in a manner that may be applicable in other settings (Burns & Grove, 2005). The traditional criteria for achieving rigor—internal and external validity, reliability and objectivity—are rooted in quantitative research (Lincoln & Guba, 1985).

## Validity in Qualitative Research?

Qualitative researchers also strive to produce high quality knowledge but differences in study procedures such as sampling and data analysis render the above criteria difficult to apply in the qualitative setting. In 1985, Lincoln and Guba proposed that *trustworthiness* should guide the evaluation of quality in the naturalistic or qualitative research setting. They described four criteria for establishing trustworthiness: credibility, transferability, dependability and confirmability. Later they would add authenticity (Guba & Lincoln, 2005).

While many qualitative researchers have adopted Lincoln & Guba's criteria to evaluate the quality of their research proposals and findings, some have criticized these standards as still too rooted in the positivist paradigm. Accordingly, numerous other models of trustworthiness have been developed, some specific to distinct research methods such as ethnography or grounded theory while others are more general in scope (Cohen & Crabtree, 2006; Whitemore, Chase & Mandle, 2001). Most of these models incorporate criteria and procedures such as authenticity, reflexivity, and systematic development and implementation of the study design (Cohen & Crabtree, 2006) yet emphasize not sacrificing the creative or interpretive dimension that is the art of qualitative research (Maxwell, 2005; Morse, 2008; Polit & Beck, 2008; Sandelowski, 1993). Mixed methods research has added to the controversy with terms such as inference quality (Teddlie & Tashakkori, 2003) and legitimation (Onwuegbuzie & Teddlie, 2003; Onwuegbuzie & Johnson, 2006) as alternatives for avoiding the quantitative-qualitative validity-trustworthiness dichotomy.

Recently, some qualitative researchers have resumed using the terms rigor, reliability and validity, arguing that this terminology is applicable to both qualitative and quantitative research while the specific criteria or techniques for establishing rigor will differ (Cohen & Crabtree,

2006; Morse, Barrett, Mayan, Olson & Spiers, 2002). Decrying that trustworthiness criteria are all too often applied a posteriori, they assert that ensuring rigor should be the responsibility of the researcher, not the reviewer. Verification strategies, which inform the researcher when to modify, continue or bring an ending to a study, should be ongoing and transparent throughout the entire inquiry process in order to foster rigor (Creswell, 2007; Morse et al., 2002).

**Validity in the Proposed Study.** Because the proposed study is qualitative dominant, rigor was attained by qualitatively-focused validity criteria. Through a synthesis of key validity models, Whittemore and colleagues (2001) developed a framework for establishing rigor that includes primary and secondary criteria as well as specific techniques for actualizing these criteria. This framework guided the researcher in the choice of strategies for ensuring and evaluating quality for this study.

Within the Whittemore framework, the overarching goal is validity and the four primary criteria necessary to achieve this goal are credibility, authenticity, criticality and integrity. A study is *credible* when the researcher has confidence in the accuracy of the data and the inferences drawn from the analysis of the data. In other words, are the findings believable (Lincoln & Guba, 1985; Milne & Oberle, 2005; Polit & Beck, 2008; Whittemore et al., 2001)? The purpose of a study influences the procedures used to establish credibility (Milne & Oberle, 2005) thus procedures and techniques that enhance the researcher's ability to collect and connect with the data also enhance credibility. These techniques may be operationalized at multiple points throughout a study, from its inception to its closure.

Closely related to credibility, in fact often considered together, is *authenticity*—the degree to which the emic perspective, experience and meaning are reflected and represented in the findings (Milne & Oberle, 2005; Polit & Beck, 2008; Whittemore et al., 2001). Strategies

that allow the voices of participants to be distinctly heard and accurately represented as having authoritative knowledge of their complex and multifaceted realities (Sandelowski, 1994) again span the inquiry process from choice of methodology to presentation of findings (Milne & Oberle, 2005).

The interrelated criteria of criticality and integrity shift the verification focus from the data onto the researcher in an effort to ensure that the researcher's assumptions and knowledge have not unduly influenced any part of the inquiry (Whittemore et al., 2001). *Criticality* requires that the researcher systematically and critically appraises each decision made throughout the research while *integrity* is manifested when the researcher engages in self-reflection of inherent biases and how they may or may not have distorted the inferences drawn from the data (Milne & Oberle, 2005; Polit & Beck, 2008; Whittemore et al., 2001).

In this study, one of the specific techniques that was used in the pursuit of validity during *data collection* was maximum variation sampling with stratification to allow the multiple realities of women's experiences with HT discontinuation to be portrayed. By using QD methodology, which stays close to the language of the participants (Sandelowski, 1999; Sullivan-Bolyai et al., 2005), women's own voices were heard (Milne & Oberle, 2005) while the use of both qualitative and quantitative QoL measures fostered the emergence of a comprehensive description (Greene, 2008) of QoL with HT discontinuation. Participant description summaries that combined data from demographic material as well as field notes provided a view of the whole person in order to promote contextual understanding (Milne & Oberle, 2005). Prolonged engagement and persistent observation, with both participants and the data, built trust and rapport and promoted open and honest disclosure and in-depth narratives (Creswell & Plano-Clark, 2007; Leckenby & Hesse-Biber, 2007; Milne & Oberle, 2005). Maintaining a reflexive

journal and field notes fostered transparency in the decision-making process and illuminated the perspective of the researcher and the intersubjectivity with the participants.

During the *data analysis* phase, strategies that were used to achieve validity included the use of content analysis which allows for both manifest and latent content to emerge from the data. The hybrid content analytic approach, in particular, fostered authenticity as some of the codes were data-driven—arising from the participants' experiences. Additional strategies that promoted rigor include the online interview format which decreased the risk of transcription error as well as the use of a codebook (Polit & Beck, 2008) and NVivo (Bazeley, 2009) for systematically organizing and coding the data. Stratification of the sample permitted alternative points of view to come forth which strengthened the understanding of the HT discontinuation phenomenon (Patton, 2002; Polit & Beck, 2008). Analysis of the memos and reflexive journal notes that chronicle the researcher's perspective and decision process, was also a part of verification (Polit & Beck, 2008; Whittemore et al., 2001). The use of member checks (Appendix Q) further ensured that the emic perspective was reflected in the findings (Polit & Beck, 2008).

Validation from sources other than the participants and researcher also contributed to the rigor of this study. Peer debriefing sessions to review issues such as sampling, coding and emerging categories were held with a member of the researcher's faculty committee. Another strategy, inter-rater reliability, is particularly pertinent to research using content analysis. In large primarily quantitative content analysis, inter-rater reliability is determined by the degree of agreement between multiple coders and is calculated through a percentage or a *kappa* statistic. The desired level is a kappa of 0.8 to 0.9 (Downe-Wamboldt, 1992). However, in a smaller qualitative content analysis with only one researcher, such as a dissertation study, alternative approaches are often necessary. Intra-rater reliability, where the researcher recodes sections of

the data and then calculates the agreement between the two coding sessions, is one option. Another option, used in this study, is to have a second person, in this case a faculty committee member, code a small sample of the data (Schilling, 2006). This was done several times during the course of data collection and analysis to ensure that the researcher was coding appropriately; there was very good correspondance between student and faculty member coding on these occasions.

Under the heading of *presentation of study findings*, the rich description of women's experiences was another mechanism by which validity was achieved. The use of different techniques for re-presenting the findings, incorporating both narrative and tabular depictions, also helped to enhance the quality of the study. For example, incorporating quotations allows women's individual voices to be heard while tables help patterns or themes become more visible (Creswell & Plano-Clark, 2007; Miles & Huberman, 1994). Recently, some proponents of qualitative research have begun calling for more transparency of the steps undertaken to assure verification through documentation of these procedures in the scholarly literature (Cohen & Crabtree, 2006; Finlay, 2002; Morse et al., 2002; Polit & Beck, 2008; Whittemore et al., 2001).

The six secondary criteria included in the Whittemore (2001) framework provide additional or supplemental principles to guide the researcher in developing a study that meets high quality standards. Whereas the primary criteria are all essential to the development of a valid study, the secondary criteria are more flexible and contextual and not always relevant to every study. The degree to which they may be included as standards of verification will vary depending on the particular study purpose and design (Polit & Beck, 2008; Whittemore et al., 2001). Some of the techniques for meeting the primary criteria may also be used for supporting



the secondary criteria. The following table lists the secondary criteria and the strategies that were used to reflect the supplemental criteria and support the rigor of the study.

Table 13.  
*Secondary Criteria and Related Techniques*

<b>SECONDARY CRITERIA</b>	<b>DEFINITION</b>	<b>TECHNIQUES</b>
Explicitness	Documentation of decisions and interpretations through careful record keeping and detailed results; audit trail	Field notes, memos and reflexive journal Transcribing narratives verbatim Qualitative description Use of CAQDAS
Vividness	Rich, clear, faithful, artful and compelling presentation of the findings	Comprehensive notes Transcribing narratives and notes/memos verbatim Qualitative description
Creativity	Innovative and imaginative study design, data analysis and interpretations; craftsmanship	Use of Internet recruitment and online survey website Mixed methods design
Thoroughness	Comprehensive and adequate sampling, data collection, and analysis	Prolonged engagement and persistent observation Mixed methods Data saturation Stratification of sample Reflexive journal and decision-making notes
Congruence	Interconnections among all facets of the study and to external contexts	Reflexive journal and decision-making memos Quasi-statistical analysis
Sensitivity	Respect and concern for study participants and attention to ethical considerations	Qualitative description Prolonged engagement and persistent observation Member checks Protection of human subjects

*Adapted from:* Polit & Beck, 2008; Whittemore et al., 2001

The use of these strategies to promote rigor allows the reader to understand the experience or meaning and then apply the findings. While qualitative research is not generalizable in the statistical sense, qualitative scholars argue that the findings can be applicable in other contexts or situations. Lincoln & Guba (1985) referred to this as *transferability* although

newer terminology is also emerging here. For example, the term *relevance* is sometimes used instead of transferability when discussing whether qualitative findings can be used elsewhere. Another concept found in the literature is whether the study findings permit the drawing of *extrapolations*: speculations or explorations on the applicability of the findings to similar, but not identical, contexts (Patton, 2002). Morse (1999) argues that the term generalizability can indeed be used with qualitative research however the criteria for evaluation are different from those used in quantitative research. Sampling and study designs that foster the collection of adequate data and the emergence of a rich description of the phenomenon allow for the study findings to be transferred or extrapolated to similar scenarios (Morse, 1999; Patton, 2002). Therefore, in this study, maximum variation sampling and strategies that foster in-depth responses on the qualitative interview guide promoted qualitative generalizability of the study findings.

## **Ethical Considerations**

### **General Ethical Considerations**

Because the goal of clinical research is to generate knowledge in order to improve the health of the human population, it is necessary to use human subjects to obtain this knowledge. However those who choose to participate in research for the good of society may incur risk of harm, guidelines for conducting ethical research have been established to ensure that study subjects are safe and treated with respect. Reports and decision papers such as the Nuremberg Code, the Belmont Report and the Declaration of Helsinki and similar documents invoke specific ethical principles used to develop and review human subjects research (Ezekiel, Wendler & Grady, 2000). Although multiple ethical principles may be applicable throughout the research process, the three principles deemed salient by the Belmont Report were respect for persons, beneficence and justice (Ezekiel et al., 2000; Frankel & Siang, 1999; National Commission for

the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; Penslar & Porter, 1993).

*Respect for persons* is divided into two components: first, participants should be recognized as autonomous or capable of self-determination and second, those with diminished autonomy are entitled to receive special protection (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; Penslar & Porter, 1993). Respect for persons is rooted in communication and actualized through the three elements of informed consent: information, voluntariness and comprehension. The researcher must present details about the study and the inherent risks and benefits to each potential participant, evaluating the subject's ability to comprehend the information and adapting the material as needed for the individual. Consent must be voluntary, free from coercion and influence (Frankel & Siang, 1999; NIH, 1979; Penslar & Porter, 1993). Other issues to be considered under this principle include respect for participant confidentiality and privacy and providing for participant well-being (Ezekiel et al., 2000).

The principle of *beneficence* is seen as an obligation to maximize the benefits of a study and minimize the risks in order to protect participants from possible harm (NIH, 1974; Penslar & Porter, 1993). The benefits, which may be targeted specifically for the participant or more globally for the benefit of society, must be favorably balanced against both the probability and magnitude of harms arising from participation in the study. This risk-benefit assessment is based on a thorough and systematic evaluation of all aspects of the research process, the adequacy of the researcher's estimations of harms or benefits and consideration of possible alternatives (Ezekiel et al., 2000; Gitlin & Lyons, 2004; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; Penslar & Porter, 1993).

Finally *justice* requires fair and equal distribution of the benefits and burdens of research and has its application in the selection of participants (Ezekiel et al., 2000; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1974; Penslar & Porter, 1993). Research subjects must be selected equitably, with no favoritism or bias and with additional considerations for the safety of vulnerable populations. Procedures and treatments must also be administered fairly, and both costs and benefits equally distributed to avoid perpetuating existing societal injustices. Within the quantitative research tradition, randomization and stratification procedures have often been used to achieve equity in participant selection while the qualitative researcher may use techniques such as purposeful sampling to obtain a diverse sample (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; Penslar & Porter, 1993).

### **Ethical Considerations for this Study**

Applying the above ethical principles to this study became challenging because of the primarily online format. While some of the potential barriers to enacting these principles are present in all research projects (Walther, 2002), special strategies were required to address these issues. It must also be remembered that no research, online or not, can satisfy the guidelines completely: there will always be some risks incurred with participation in research. The goal of the researcher is to minimize these risks in order to obtain new knowledge that ultimately benefits society.

With regard to *respect for persons*, one of the primary concerns with online research is how to obtain informed consent. Some online studies make use of a statement at the beginning of the questionnaire informing the participant that consent is assumed by the very act of completing the questions and online interviews. Another option is to provide a box or button for subjects to

check indicating that they are voluntarily consenting to participate (Best & Krueger, 2004; Im & Chee, 2004; Mann & Stewart, 2004). A third choice, used in the proposed study, was to mail participants a consent form (Hamilton & Bowers, 2006). Researcher contact information was provided had any questions or need for clarification arisen (Whitehead, 2007) however full comprehension may be impossible to determine completely (Frankel & Siang, 1999). Access to the study site or scheduling of telephone interviews was not allowed until the consent form was returned signed.

There were several other potential violations of this principle. While it may be assumed that an individual presents her authentic self online, it is possible that unbeknownst to the researcher, the participant may actually be a member of a vulnerable population (Frankel & Siang, 1999; Rhodes, Bowie & Hergenrather, 2003). It was hoped, but not guaranteed, that establishing rapport with each participant promoted full disclosure (Mann & Stewart, 2004) and careful evaluation of the appropriateness of responses helped to identify if there were any issues with comprehension (Dillman, 2007; Mann & Stewart, 2004). Voluntariness may be undermined by forced responses therefore participants were allowed to skip some questions (Im & Chee, 2004). Participants were also informed that they could withdraw from the study at any time. Finally study subjects were made aware that confidentiality and privacy cannot be guaranteed with Internet-based research. Although the study questions were situated at a secure website with restricted access and contact with the researcher was through the firewall-protected University email system, no website or computer system is 100% safe from hacking and this possibility was written into the consent (Frankel & Siang, 1999; Im & Chee, 2004).

When considering *beneficence*, the researcher recognizes the possibility that some women may become emotionally distressed from reflecting on uncomfortable experiences. One

way to address this is to have information available about counseling to provide to the participant as needed. However, emotional distress is more difficult to ascertain and address with Internet-based research. The researcher had to be alert to the overall tone of the response, use of italics, emoticons or bold type, or even absences/silences (Best & Krueger, 2004; Frankel & Siang, 1999; Mann & Stewart, 2004). It would have also been difficult to refer a woman to specific counselors as many participants were actually in a different state than the researcher (Rhodes et al., 2003). A woman experiencing emotional distress would have been advised to seek support from a care provider in her locale. Women were also given contact information for the researcher if they wished to discuss concerns more intimately.

The potential for breaches of privacy and confidentiality must again be addressed, especially as the sense of anonymity conferred by the Internet may result in disclosure of very personal or intimate information (Cotton, 2003; Illingworth, 2006). Participants need to be made aware that their own Internet practices can increase these risks, for example using an old or shared computer system (Im & Chee, 2004) and not understanding that records of browsing or email exchanges may be saved in the Internet service provider's (ISP) logs or in hidden cookies on the hard drive (Cotton, 2003; Eysenbach & Till, 2001; Murray & Sixsmith, 2002). Furthermore, a participant's computer system may be attacked and potentially crippled by a virus (Cotton, 2003). To minimize these risks, participants were asked to password protect any attachments and to avoid sending emails or logging on from shared computers, if possible. They were also encouraged to make sure their computer systems had adequate virus protection and the researcher also took this necessary precaution. A fact sheet (Appendix ) describing possible risks and how to minimize them was developed for participants. Email messages were copied and

pasted into the data management system and then the email with identifying information was deleted (Hamilton & Bowers, 2006).

Because the consent form was mailed to the participant, anonymity was not possible however subjects were assured that their personal information was known only to the researcher and kept in a secure site. Sending the consent also had the potential benefit of minimizing the possibility of deception or data fraud which occurs when an individual ‘poses’ as someone they are not in order to gain access to the study (Im & Chee, 2002; Walther, 2002). Although not a guarantee of identity, it does provide a hard copy of the written signature which confers some protection legally (Hamilton & Bowers, 2006). Because the true identity of online participants can never be assured, attempts to achieve equitable and representative selection of study subjects—*justice*—may never be fully realized (Im & Chee, 2002; Im & Chee, 2004).

Finally, ensuring adequate representation of women from diverse backgrounds was difficult to achieve (Conboy, Domar & O’Connell, 2001; Frankel & Siang, 1999). Conducting research online may limit the ability to attract a diverse sample due to limited computer access among some sociocultural strata (Im & Chee, 2002). However, the ever increasing use of the Internet in the general population may actually offset this limitation (Whitehead, 2007), allowing access to various ethnic/cultural/racial populations as well as women in areas remote from the researcher who may not otherwise be able to participate (Best & Krueger, 2004; Cotton, 2003; Mann & Stewart, 2004). The option for telephone interviews may also make it possible for women with limited computer access or literacy to participate.

### **Protection of Human Subjects**

Sampling and recruitment strategies must always take into account provisions for protection of human subjects (Burns & Grove, 2005). The first steps toward this end for this

study was to obtain IRB approval. Discussion board moderators were contacted for permission to post study invitations. Prior to participating in the interviews, women read and signed an Informed Consent describing the purpose of the study and the benefits and risks. Once the consent was returned, they were granted access to the secure, restricted access survey website developed by the Information Services department at the University of Massachusetts/Worcester. Using this website helped to minimize risks to confidentiality and privacy. The researcher's school email was used for follow-up questions and member checks. Because this email system is secured by more firewalls than personal email accounts, it offered greater protection from privacy intrusions. However, as noted earlier, the fact that the Internet is not 100% safe was written in the consent (Best & Krueger, 2004; Mann & Stewart, 2004).

### **Summary and Conclusions**

The purpose of this study was to explore women's experience with discontinuing HT. The study used an embedded mixed methods approach to elicit information about women's symptom experiences, factors influencing the experience, the role of QOL in the outcome, and women's needs for additional information about HT discontinuance. Women who had attempted to discontinue HT were recruited primarily via Internet menopause-related groups and completed both qualitative and quantitative questionnaires on-line. Through content analysis, the quantitative and qualitative data was integrated, both within and across cases. Study findings yielded a rich description of women's experiences with HT discontinuation. This description will ultimately serve to improve health care for women by providing information to guide the development of education and symptom management interventions.



## CHAPTER IV

### RESULTS

A mixed methods approach was used to explore women's experiences of discontinuing hormone therapy. Because this study was qualitative dominant, the primary methodology was Qualitative Description; an embedded quantitative component was also included for the purpose of complementarity. As a result of the interviews and survey responses provided by the women who participated in this study, a rich description emerged of their experiences, influencing factors, QoL, and informational needs.

The overarching theme that captures the essence of their experiences is: *a solitary journey*. This theme envelopes two subthemes: *symptom experience: burden and interference* and *risk appraisal*. These findings will be presented in this chapter, prefaced by a description of the sample characteristics.

#### **Participants**

A total of 34 women were eligible and participated in this study. Participant ages ranged from 47 to 65 with a mean age of 55. The average length of time on HT was 5.5 years. Nine women (26.5%) had stopped and resumed, five (14.7%) were tapering, and twenty (58.8%) had remained off HT after discontinuing. Several women had stopped and started several times before ultimately stopping and were able to share their experiences from the perspective of resuming as well as ceasing HT.

The sample was predominantly Caucasian, with three African-American women and one Hispanic woman. Most participants were married or partnered. Twenty-one (66%) were working full-time. Eleven (34%) were nurses or nurse practitioners. Thirteen (38%) had no children; most

(n = 16, 47%) of the remainder had either two or three children. Almost half (n = 15; 44%)

reported no health concerns. Further information about the participants is provided in Table 14.

Table 14.

*Sample Characteristics.*

	Total (N = 34)	Internet (n = 21)	Telephone (n = 13)	
<b>Age in Years</b>				
Mean	55.03	54.1	56.46	$H(1) = 1.03, p = .31$
Median	55	55	56	
Standard Deviation	4.92	4.403	5.456	
Range	47-65	47-63	48-65	
<b>Ethnicity</b>				
African-American	3, 8.8%	3, 14.3%		
Hispanic	1, 2.9%	1, 4.8%		
Caucasian	30, 89.2%	17, 81%	13, 100%	
<b>Marital Status</b>				
Married	21, 61.8%	10, 47.6%	11, 84.6%	
Widowed	3, 8.8%	3, 14.3%		
Single	3, 8.8%	3, 14.3%		
Separated	2, 5.9%	1, 4.8%	1, 7.7%	
Divorced	4, 11.8%	3, 14.3%	1, 7.7%	
Living with partner	1, 2.9%	1, 4.8%		
<b>Education in Years</b>				
Mean	16.53	16.1	17.23	$t(30.72) = -1.40,$ $p = .171$ (equal variances not assumed)
Median	16.5	16	18	
Standard Deviation	2.688	3.161	1.536	
Range	10-22	10-22	14-19	
<b>Occupational Status</b>				
Working full-time	21, 61.8%	13, 61.9%	8, 61.5%	
Working part-time	5, 14.7%	4, 19%	1, 7.7%	
Retired	2, 5.9%		2, 15.4%	
Seeking employment	3, 8.8%	3, 14.3%		
Student	1, 2.9%	1, 4.8%		
Other	2, 5.9%		2, 15.4%	
<b>Financial Strain</b>				
Very hard	4, 11.8%	4, 19%		
Somewhat hard	8, 23.5%	4, 19%	4, 30.8%	
Not very hard at all	20, 58.8%	11, 52.4%	9, 69.2%	
Refused	2, 5.9%	2, 9.5%		
<b>HT Status</b>				
Discontinued	20, 58.8%	11, 52.4%	9, 68.2%	
Resumed	9, 26.5%	7, 33.3%	2, 15.4%	
Taper in progress	5, 14.7%	3, 14.3%	2, 15.4%	

As described in Chapter 3, analyses of the telephone and online qualitative responses were initially conducted separately in order to ascertain whether there were any differences between the two types of participants and their experiences. As can be seen in the table above (Table 14), sample characteristics do not reveal any major differences between the two groups with respect to demographic information.

### **Findings**

The overarching theme that emerged from the analysis of women's narratives was: *a solitary journey*. Every woman in this study had discontinued or attempted to discontinue HT within the past two years thus all had chosen to embark on the same journey. Their journeys often followed the same sequence, beginning with their menopause transition and decision to initiate HT, traveling through the experience of taking HT, then the decision to discontinue and the ensuing encounters with symptoms, culminating (for most) in either HT resumption or remaining. It was indeed a 'journey' and several women actually used this word to describe their discontinuation experience.

However, because women's journeys occurred within the context of their individual life circumstances, each woman's path through HT discontinuation was a deeply personal sojourn. As a result, there was also variation and individuation in women's journey narratives. Women also described their perception that, while many chose to take the journey, each of them had to find her own path to traverse in order to reach her destination.

The two conceptual and interactive subthemes (Table 15) encompassed by the overarching theme were *symptom experience: burden and interference* and *risk appraisal*. Women described their discontinuation experiences in terms of the intensity and severity of their symptoms and the difficulties and disruptions that symptoms imposed on their lives. Participant

Table 15.  
Thematic Findings

A Solitary Journey			
<i>Symptom experience: burden and interference</i>			
<i>Risk appraisal</i>			
SPECIFIC AIM AND FRAMEWORK CONCEPT		FINDINGS	
Specific Aim 1	Symptom experience: perception, evaluation and response	The Journey: symptoms, suffering and surviving	The journey begins: menopause and HT At the crossroads: making the decision to stop HT Road blocks: roaring back with a vengeance Navigating the terrain: managing symptoms The journey ends, the journey continues: future plans & life lessons
Specific Aim 2	Influential factors: sociocultural context and personal characteristics	Influential Factors	Roles: professional and personal Cost, financial strain & options Beliefs and expectations: menopause, medications and HT Expectations of discontinuation Readiness to stop Reasons for stopping Appraising risks Symptom tolerance: burden, interference & sensitivity
Specific Aim 3	Symptom evaluation: Quality of Life	Women's Expertise	Menopause, HT and QoL: women's words Menopause, HT and QoL: across dimensions
Specific Aim 4	Symptom response: seeking information	Seeking knowledge, sharing wisdom	Health care providers: information Woman to woman Health care providers: recommendations

also continually compared the risks of their symptoms to the risks of HT when considering the best route along their journey.

The overarching theme encompassed both the similarity and variability in women's stories, the subthemes served as constructs connecting women's journeys. It is within each Specific Aim that the variability in women's experiences can best be seen. Findings, organized by specific aims and incorporating illustrative participant quotations and pertinent quantitative results, will be presented in the remainder of this chapter.

### **Specific Aim 1: explore women's experiences of HT discontinuation**

In order to more fully understand what happens when women discontinue HT, open-ended questions about this experience were posed to all participants. Embodied within this Specific Aim is the story of women's passage through HT discontinuation

**The journey: symptoms, suffering and surviving.** The chronicle of HT discontinuation begins with a discussion of the context and antecedents that led women toward the path of discontinuation and continues with a rich description of their experiences during and after stopping HT. The three components of symptom experience as found in the organizational framework--perception, evaluation and response--as well as the subtheme *burden and interference* can be traced within this description.

***The journey begins: menopause and HT.*** All study participants had completed their menopause transition: 30 (88%) had experienced a natural menopause and four (12%) had undergone a surgical menopause. All but three reported troublesome menopause-related symptoms that arose during this transition. VMS were very common and very distressing: the sudden episodes of intense heat were uncomfortable and unsettling and the ensuing sweating was distasteful. Greater frequency or duration of hot flashes added to the discomfort. Sleep

disturbances were often attributed to nighttime VMS: women described awakening to soaked bedding that required changing, sometimes more than once per night. Lack of sleep led to decreased concentration and memory lapses as well as irritability and moodiness. For a few women, diminished sleep also contributed to exacerbation of pre-existing depression.

VMS (n = 27, 79%), sleep disruptions (n = 10, 29%), and affective concerns (n = 15, 44%) were the most frequently described symptoms and commonly occurred together: 21 (62%) of the 34 participants reported having at least two if not all three of these symptoms. However, they were not the only symptoms that women encountered: participants reported a myriad of other symptoms and changes such as vaginal dryness, decreased libido, memory loss, weight gain, migraines and even facial paresthesias. Symptoms were disruptive in many aspects of women's lives: frequent flushing and sweating caused embarrassment in public situations (work, social gatherings). Forgetfulness and lack of concentration as a result of disturbed sleep contributed to worries about work performance. Mood swings and irritability impacted on relationships with family, friends and colleagues. Even family members were not immune to the effect of women's symptoms as they shared and suffered from the impact of women's mood changes, exhaustion and even VMS: "He also had to leave the bed multiple times during the worst of it because he said it was like being [in bed with] Pele the volcano goddess."

Women began to consider HT when they realized to what degree their symptoms were preventing them from functioning in their normal day-to-day activities:

...one day I was walking in the city and I was so exhausted I was holding on a wall to walk because I was really ready to fall over and I just stopped myself and I thought "okay this is not normal, I really should go to the doctor."

The three most common reasons for starting HT were symptom relief (n = 31, 91%),

recommendation by a health care provider (n = 15, 44%) and health promotion (n = 10, 29%).

Women often reported more than one reason for choosing HT. Of the three women who did not have symptoms prior to initiating HT, two began taking HT for health promotion reasons and the third for both health promotion and post-hysterectomy symptom prevention, all at the recommendation of their health care providers.

Initiation of HT sometimes occurred within a few weeks after the onset of symptoms. Yet some women endured uncomfortable symptoms for months or even years before beginning HT, struggling with the decision because of fears about HT or beliefs that menopause was a natural process that should not require medication. When women finally turned to their health care providers for support, occasionally after trying 'natural' remedies such as black cohosh or over-the-counter 'hormone' preparations, it was most often of their own volition. However, family members or co-workers occasionally needed to intervene, encouraging women to seek help when VMS disturbed their sleep or when mood swings and irritability impacted on work productivity.

To the delight of many, HT brought welcome relief of VMS, sleep disturbances and even mood issues. Women described improvement in concentration, memory and work performance as well as in their personal relationships. Vaginal dryness eased and some women even reported a resurgence of libido. More than one woman spoke about HT helping her to feel 'back to normal.' As one participant summarized: "HRTs were working great--less irritability, better mood, NO HOT FLASHES!, a whole night's sleep, breasts were fuller, sex was better--happy partner, happy family." Although not all women experienced a complete elimination of their symptoms, even partial relief was beneficial, allowing women to manage their symptoms and regain their ability to function with fewer disruptions in their day-to-day lives and personal relationships.

But not all women were happy on HT; some began to experience unpleasant side effects such as bleeding, weight gain, bloating, headaches, breast symptoms and even some irritability for two participants. Bleeding was especially worrisome as it was usually unpredictable and uncontrollable, sometimes prolonged and/or very heavy, and typically necessitated invasive procedures (endometrial biopsy, dilation and curettage) for evaluation or management. Several participants experienced more than one of these adverse effects.

Women also expressed ongoing concern about long-term risks, often arising from their awareness of recent study findings, especially those of the WHI. Most of these fears centered on the risk of breast cancer although several women also worried about heart disease and stroke risks. Two participants also voiced concern about their fear of becoming dependant upon or addicted to HT. Eventually concerns about side effects or potential complications from long-term use began to interfere with women's lives and peace of mind.

*At the crossroads: making the decision to stop.* Every woman in this study had attempted to stop HT. However, there was variability within this universal experience, beginning with the reasons why women chose to embark upon this particular path. For some it was because of concerns about side effects or long-term health risks. Health care providers occasionally suggested that women consider stopping HT although providers differed in how firmly they recommended discontinuation: some left the door open for resumption if necessary while others insisted that women stop. Several women chose to stop HT when they could no longer afford their prescriptions or because transportation or time constraints precluded getting to a pharmacy or seeing providers for prescription refills. For a few women, the decision to stop was also fueled by a curiosity as to whether they were really 'done' with menopause. Pressure from family or friends who were opposed to HT was a motivating factor for several participants and two



participants decided to stop HT because they believed they were becoming addicted to the medication. Fifteen (44%) of the 34 participants reported more than one reason for stopping.

Despite their concerns or doubts about HT, women struggled with the decision to stop just as they had struggled with the decision to begin. Some participants contemplated discontinuation for several months or longer before finally taking the first steps along that route. They spoke of having mixed feelings about stopping, weighing the risk of symptom recurrence against the risk of adverse effects. They were aware discontinuation would end their worries about HT side effects but could also mean an end to any health benefits and a recurrence of menopause symptoms. Several women had actually tried to discontinue HT more than once and were well aware of the potential for symptom recurrence as their prior attempts to discontinue had been derailed by the return of symptoms.

Women chose to discontinue their medications either by abrupt cessation or tapering/weaning, a choice usually made quite arbitrarily. Seventeen women tapered, 11 stopped 'cold turkey' and five were in the process of tapering. Participants who stopped 'cold turkey' often did so because of side effects or because they could no longer afford or obtain their prescription. A few women admitted to letting prescriptions lapse to 'see what would happen.' One woman was not even aware that there was another method besides stopping abruptly.

Among those who chose to discontinue gradually, there was no consistency in tapering regimens: women described cutting pills or patches, skipping doses or changing the strength of their prescription. Some devised their own tapering schedule while others tapered with the guidance of their health care providers. Tapering usually lasted several months although the overall tapering duration ranged from three weeks to three years.

Women who had attempted to stop more than once sometimes chose a different discontinuation method with subsequent trials. If a previous attempt at stopping abruptly had been unsuccessful, the next attempt at discontinuation was often by tapering.

***Road blocks: roaring back with a vengeance.*** All study participants experienced symptoms after they stopped or while weaning from HT (Table 16). While the symptoms that were reported usually represented a recurrence of pre-HT symptoms, sometimes new symptoms appeared. Symptoms typically began within days or weeks of stopping or beginning to taper although here again there was variation as for some women months elapsed before symptoms reappeared or appeared.

Table 16.  
*Symptoms after HT discontinuation.*

	<b>Hot flashes</b>	<b>Night sweats</b>	<b>Total VMS</b>	<b>Sleep issues</b>	<b>Affective issues</b>	<b>Memory issues</b>	<b>Urogenital Symptoms</b>	<b>Libido Changes</b>
<b>Frequency (%) (N = 34)</b>	24 (70.6)	25 (73.5)	28 (82)	17 (50)	20 (58.8)	4 (11.8)	12 (35.3)	6 (17.6)

Most women who had VMS symptoms before HT noticed them again upon stopping although for a few women the episodes of intense heat and sweating were new experiences. Half of the participants reported sleep disturbances, sometimes but not always associated with frequent awakening from night sweats. For eight participants, diminished sleep was a new symptom. Lack of sleep led almost inevitably to complaints of fatigue and lack of energy as well as decreased concentration, diminished cognition, and emotional lability. Over half of the women, five more than pre-HT, reported affective symptoms associated with stopping HT. In addition to mood swings and irritability, they also described decreased enjoyment of life, anxiety and depressed mood.

Women were very forthright about their mood swings and emotional symptoms, expressing both concern and humor in their narratives. Said one participant of her emotional volatility: "I jokingly told people that I finally understood the stories about the 'crazy aunt in the attic'..." But HT discontinuation sometimes led to more serious repercussions: several participants described spiraling into clinical depression as they tapered their medication. One of these women recontacted the researcher one month after completing the study. She reported worsening of her depression symptoms to the point that she had to take a medical leave of absence from her job. She had to resume her HT and she and her health care provider were still struggling to adjust her dose to attain better control of her depression symptoms.

As with pre-HT symptoms, VMS, sleep disturbances and affective changes often occurred together: of the 32 women who reported having at least one of these three symptoms, 15 (47%) had two symptoms and nine (28%) had three. The combination of symptoms was especially uncomfortable:

Thanks to night sweats and accompanying insomnia, I probably did not sleep more than 2 consecutive hours any night that entire summer and fall, which contributed to all the classic sleep-deprivation symptoms: poor memory, irritable, cried too much...And ALWAYS, hot sweaty and miserable...

In addition to the above, over one-third of the sample described urogenital changes, specifically vaginal dryness and dyspareunia. For six (50%) participants this represented a recurrence or worsening of the urogenital symptoms they had noted before HT. One woman who had not experienced any menopause-related symptoms before beginning HT reported vaginal atrophy as her only discontinuation symptom.

Other symptoms and changes reported by women included headaches (n = 2), decreased libido (n = 4), nausea (n = 1) and intense itching (n = 1). Although joint pain was mentioned on several occasions, only one woman attributed it to stopping HT; usually joint symptoms were associated with other health issues such as arthritis. Three women believed their discontinuation symptoms represented a withdrawal phenomenon or 'rebound effect' from stopping HT reinforcing the belief that one could become addicted to HT.

Although many women had expected their symptoms to recur, they often expressed disappointment when symptoms did reappear, especially when they were as bad or worse than pre-HT. Some women described a sense of frustration that they were not 'done' with menopause. and others felt that symptom recurrence served as an unpleasant reminder that they were aging. Disappointment and frustration gradually eased over time and was often replaced by resignation or acceptance that they would just have to 'deal' with their symptoms and 'get through' this transition. A few women voiced anger that they had not been better prepared.

The majority (n = 24, 70.6%) of women rated the intensity of their symptoms as moderate to severe. Symptom intensity was reflected in the common refrain "...my symptoms roared back with a vengeance." Intensity was also apparent in participants' use of adjectives and capital letters, for example: "I also had incredible INSOMNIA and FATIGUE when I tried to wean myself from HT..."

As symptoms recurred and their intensity increased, women reported more interference from their symptoms in their daily lives. Once again, VMS, lack of sleep and mood changes had a negative impact on job performance and professional image. VMS that occurred while women were working were disruptive, not only because they were uncomfortable, but also because they were embarrassing. Women were very sensitive to how their flushed, red faces, wet hair and

damp clothing were perceived by their co-workers or clients, and they described sometimes being the object of teasing because of their VMS. Fatigue, decreased energy and 'brain fog' from lack of sleep limited their capacity to prioritize and concentrate on the job, impeding productivity. Emotional lability (mood swings, irritability) also made it more difficult to focus, compounding the level of distress.

Symptoms also interfered with women's personal relationships. Women were often unpleasantly surprised at the rapid mood shifts that provoked negative interactions with family and friends: "...I cannot believe how nasty I was/can be to the people I love..." Sexual relationships were disrupted: sweating and heat from hot flashes caused women to avoid close physical contact with their partners, vaginal dryness led to painful coitus and decreased libido had a deleterious effect on women's interest in and desire for intimacy. Several of the women had new partners and were very worried about the impact of symptoms on these new relationships. For at least one woman, the new occurrence of vaginal dryness was the catalyst that drove her to resume HT.

The intensity of recurrent symptoms and their ability to interfere in women's lives often varied over time. Women who had tapered/were tapering typically reported their symptoms as milder in the early stages, increasing in severity as HT dose decreased. For example, one participant who had begun tapering HT shortly before her initial interview described only mild very manageable symptoms at that time. However, six months into her taper she experienced a marked increase in symptom intensity necessitating a suspension in her weaning efforts.

Symptom intensity and interference also changed depending on time since stopping, with women more distant from discontinuation usually reporting milder, more tolerable or less frequent symptoms. Some, in fact, no longer had any symptoms at all. However, once again there

was variability in women's experiences: several participants reported persistent (over 1 year) VMS or sleep disturbances that were still uncomfortable and burdensome, occasionally eliciting a lament of "how long do these go on anyway?!" Prolonged duration of symptoms was particularly discouraging.

As previously noted, most women who rated the severity of their discontinuation symptoms said they were either moderate or severe. In a similar vein, many of the participants who compared their discontinuation symptoms to those they had before starting HT described discontinuation symptoms as the same or worse than those pre-HT (Table 17). Few women perceived their symptoms as mild and/or better than those prior to HT, underscoring the discomfort and burden imposed by discontinuation symptoms.

Table 17.

*Symptom Intensity and Comparing Pre/Post-HT Symptoms*

<b>Symptom Intensity</b> (n = 32)		<b>Comparing Symptoms Pre/Post-HT</b> (n = 29)	
Severe	15 (47%)	Worse	8 (29%)
Moderate	9 (28%)	Same	10 (35%)
Mild	8 (25%)	Better	11 (38%)

***Navigating the terrain: managing symptoms.*** As symptoms came roaring back, women employed a variety of strategies in an attempt to decrease symptom discomfort. They tried lifestyle measures such as modifying clothing fabrics and dressing in layers, drinking more fluids, taking daytime naps, and cooling down with ice collars and fans. One participant waxed eloquent about the VMS-eliminating benefits of soy. However there was little mention about other supplements such as black cohosh (although several women had reported these as ineffective in the control of their pre-HT symptoms). Only a very few women talked about

strategies such as acupuncture, exercise or meditation. Several women spoke of the importance of humor and the support of friends.

Adopting a determined or 'just deal with it' attitude was another strategy. Women, especially those who had tried to stop HT in the past or were concerned about future risks, spoke of being resolute in their decision to stop: "I think that my determination obviously is a big part of it. I was determined that this was going to succeed..." Another woman stated that she decided she was just going "to make it happen" and she did. These women stated matter-of-factly that they just accepted or put up with whatever symptoms came their way. One woman spoke of how she talked herself out of catastrophizing and over-reacting to VMS by making a conscious effort to evaluate symptoms objectively and reminding herself that they were 'just' hot flashes..

A few women reported taking other medications, specifically antidepressants, during discontinuation that may have helped ease some of their symptoms. Women with urogenital symptoms often reported continuing or beginning to use vaginal estrogen.

The recurrence of symptoms eventually brought most women to another crossroad: having to choose whether to continue or resume. Although some remained adamant about not resuming, others expressed uncertainty, once again weighing the risks of adverse effects against the risks of symptoms. Ultimately, nine women (26.5%) chose to resume HT. While most (n =8, 89%) resumed for relief of their moderate-severe symptoms, several also stated they wanted 'to feel better' in general. The majority of those who resumed HT did so eagerly, voicing few or no regrets or guilt. However, one woman expressed much disappointment as she felt she had no other options: "I went back on prempo because I was miserable...It was a tough decision because I hate to be on anything and what I hear about the hormone replacement terrifies me."

The range of time from cessation to resumption ranged from 2-3 weeks to over 6 months. The majority of women resumed the same type and dose of HT they had been on prior to stopping although several participants, with the advice of their health care providers, made adjustments in their regimen in the hopes that reducing the dose would reduce their risks. A few women chose not to inform their providers immediately, instead refilling existing prescriptions. This was a common practice among the women whose providers had given them *carte blanche* to resume if they needed to do so. (Women who had stopped and started HT several times also described resuming HT without consulting their providers during prior attempts, sometimes because of time constraints or because they did not want providers to know they had stopped.)

***The journey ends, the journey continues: future plans and life lessons.*** The women who decided to resume HT reported either complete resolution or a reduction in all their symptoms. They spoke of feeling as though their HT-related energy had returned and that they were able to enjoy their usual activities once more. Being able to fully participate in daily activities gave them back a feeling of control and normalcy. A few vowed that they would 'never again' try to discontinue. Others planned to attempt another taper in the future.

As previously noted, some women who remained off HT were no longer having symptoms while others were still having mild, less frequent and more manageable symptoms. Women who had discontinued HT because of side effects or worries about future risks described feeling as though they had regained their health. These women also reported gaining a sense of control or normalcy although here the focus was related to reclaiming control over their bodies. There were numerous comments about feeling less fearful or worried and being more at peace: "An equanimity came. I didn't realize that I was a little bit concerned about the risks...so there was a peacefulness that came with the decision which surprised me." Two women also spoke of



feeling calmer or less irritable. Although many women who had stopped were emphatic about not resuming, a few admitted to some ambivalence: "The reluctant acceptance of this time has mellowed me a bit but a part of me feels defeated..." Acknowledging that HT had controlled their menopause symptoms, some women added that they might consider resuming HT if it was ever deemed risk-free.

The five women who were tapering planned to continue to do so although it was uncertain how many planned to completely discontinue: two women were only several weeks into their current taper when they participated. One woman had suspended her taper when her symptoms made a recurrence six months into the taper and the woman who had struggled with recurrent depression actually had to stop tapering because of her relapse. The fifth woman was cutting back her dose but admitted that part of her current taper was to placate her health care provider and she actually did not plan to stop HT because of concern about recurrent symptoms.

The experience of attempting to stop HT served as a learning experience for many participants. Some discussed realizing their own sense of vulnerability and that asking for help or support from others or through medication was acceptable. Other women reported acquiring a better understanding of their strength and ability to persevere as well as a newfound sense of trust in their intuition and their bodies' wisdom. Menopause was more deeply appreciated as a critical transition in women's lives.

Women were also asked to rate their experience of HT discontinuation on a 1-10 (mild to severe) scale. As to be expected, women who described greater symptom distress or disruption often rated their experience as more severe but this was not always the case. Some very symptomatic women actually rated the overall experience as mild, citing other life experiences such as family illness or financial problems as more difficult or challenging.

The path of HT discontinuation was clearly distressful for many participants due in great part to the recurrence of troublesome and sometimes intolerable symptoms. However, there was great variation in the women's HT discontinuation journeys: symptom experiences differed between women as well as over time for each woman due to the influence of personal and sociocultural factors .

**Specific Aim 2: describe the personal characteristics and sociocultural contexts that influence symptom perception, evaluation and response among women who have attempted to discontinue HT**

Because symptom experiences may be influenced by multiple factors, women were asked to identify or describe any factors that may have played a role in their experiences and to respond to a demographic/lifestyle survey. This Specific Aim continues the story of women's discontinuation journeys by describing these factors which emerged through both separate and integrated qualitative and quantitative analysis. While some of these factors clearly aligned with the conceptual categories (i.e., sociocultural context and personal characteristics) within the organizational framework, other factors were not as easily assigned to pre-existing categories and may indeed bridge the conceptually defined factors.

**Influential factors.** All participants encountered symptoms upon discontinuing HT. The factors described below contributed to women's experience of symptoms and/or whether they chose to resume or remain off HT. The section will include references to the subthemes of symptom burden and interference as well as risk appraisal.

***Roles: professional and personal.*** Many study participants had high stress and/or high profile jobs (e.g. professors, health care providers). They often spoke of needing to be awake, alert and functioning at a high capacity while in the workplace. Therefore, symptoms that

interfered with work performance, such as memory lapses or fatigue from sleep disturbances, were judged as especially bothersome and burdensome. Recurrent symptoms were also poorly tolerated when they caused embarrassment in front of peers, compromised office relationships or necessitated changes in a woman's work environment (portable fans, open windows).

As previously noted, symptoms also had the capacity to negatively transform women's interactions with their family members and friends. Irritability and mood swings provoked arguments and disagreements, lack of energy and interest led to less enjoyment of and participation in social events, and urogenital symptoms threatened sexual intimacy. When these occurred, symptoms were again appraised as burdensome. One participant concisely summarized the impact of symptoms on women's life roles: "I couldn't function at work or home." Symptoms clearly threatened women's functional ability.

***Cost, financial strain & options.*** Approximately one-third ( $n = 12$ , 35%) of the sample reported some level of financial strain (somewhat or very difficult paying for basics). Only a few women had to stop HT because of inability to pay for prescriptions. However, needing to stop HT because of financial concerns added a layer of distress to the overall experience as women had to contend with both financial difficulties and the additional burden of unwanted and uncomfortable symptoms. They realized that some of their control had been taken away. They had to make choices between symptom relief and other important issues: for example, medications for health concerns such as hypertension or rheumatoid arthritis were deemed more important than HT. One woman also described having to choose between HT and going out to dinner, something she enjoyed very much. In making these choices, menopause and discontinuation symptoms were not weighed as heavily as other health concerns or even lifestyle

factors. Ultimately menopause symptoms, while uncomfortable, were not considered an illness and taking medication to relieve symptoms of a non-life threatening condition was not an option.

***Beliefs and expectations: menopause, medications and HT.*** As women described their experiences of contemplating whether or not to begin, discontinue and perhaps resume HT, they often invoked their beliefs and expectations of menopause and HT. These beliefs and expectations had been shaped in women's sociocultural background long before they themselves even entered menopause. Participants described their recollections of family members with menopause symptoms and how these images influenced their expectations. Their expectations and beliefs were also influenced by the media, peers, and the scientific literature (textbooks, medical journals and professional conferences). In addition, several women alluded to a belief that their own good health and healthy lifestyle would allow them to navigate menopause without the need for any intervention. Because of the variability in their backgrounds, women's beliefs about menopause and HT were also quite varied. Overall, twelve (35%) women reported having positive expectations about menopause or negative beliefs about HT. A few (n =7, 20%) women described a general distrust or dislike of all medications.

These beliefs and expectations factored into how readily women chose to begin HT as well as adding impetus to the decisions to stop and remain off HT. For example, women who stopped HT for reasons such as side effects or concerns about risks often added that had always believed menopause was a natural transition or that they had felt negatively about HT. Half of the 20 women who remained off HT described having had positive expectations of menopause and nine (45%) expressed longstanding negative beliefs about HT. Disliking any type of medications in general seemed to serve as reinforcement for discontinuing and not resuming HT.

One noteworthy phenomenon among the participants was a slight shift in attitudes toward HT. For women who had felt positively about HT before menopause, the experience had reinforced those beliefs whether or not they chose to resume HT. However, several participants who had appraised HT negatively prior to menopause reported a moderation of opinion to one of cautious approval once they had experienced firsthand how readily HT had eased their symptoms. HT might be alright, they opined, but only for a limited time and only if women had explored all other options, keeping in mind that symptoms could recur with discontinuation

***Discontinuation expectations.*** The majority of participants were expecting some symptoms to recur when they stopped HT, having been forewarned either by their providers or their own explorations through the lay press and scientific literature. Women who had stopped and started HT in the past were already prepared by their prior experiences of symptom recurrence. Nonetheless, many women harbored hopes to the contrary. A few women even spoke of initiating HT cessation with the belief that their transition through menopause had been completed during their time on HT (several had actually been told this by their providers). They were naively expecting they would not have to contend with recurrent symptoms. Thus, the eventual recurrence of symptoms often brought disappointment, particularly when symptoms were as bad or worse than before HT as previously noted. This added more distress for several women: "I was disappointed, I was really surprised at how bad they were...I just really thought I have been on them for a while maybe I am through it. No such luck."

***Readiness to stop.*** Six (18%) participants, including several women who had made multiple attempts to stop or who had been on HT for many years, talked about the role of timing or 'intuition' in their decisions to stop. They had a sense of being 'ready' to stop, that they had reached a point in their lives where discontinuation might be successful. These women were

usually successful at stopping HT and most ( $n = 5$ , 83%) reported their discontinuation symptoms as being mild, not interfering and better than pre-HT symptoms.

I knew that I would intuitively know when it was time to come off and it would feel right to me. I wouldn't do it out of any kind of negative orientation at all. It would be a positive choice that I made and that is exactly what happened.

However, despite attributing their success to an intuitive sense of timing, they also acknowledged that other forces, such as an awareness that they were approaching the 'safe limits' of HT or the resolution of other life stressors, may have played a role in their sense of readiness and overall experience.

***Reasons for stopping.*** Successful discontinuation of HT was related to both the number of reasons for stopping as well as the specific reason for stopping. Participants who remained off HT ( $n = 20$ ) were more likely to report more than one reason for stopping ( $n = 12$ , 60%). Conversely, the majority of the nine women who resumed HT ( $n = 5$ , 56%) cited only one reason for discontinuing. The two most common reasons for stopping were concern about long-term risks ( $n = 18$ , 53%) and HT-related side effects or complications ( $n = 14$ , 41%). Women who stopped for these reasons were very likely to be successful at stopping: 53% ( $n = 9$ ) of the 17 women who stopped because of risk concerns remained off HT. Similarly, 12 (85%) of the 14 women who stopped because of side effects also remained off HT. In addition, women who stopped due to side effects ( $n = 14$ ) tended to have been on HT for a shorter duration ( $M = 2.90$ ,  $SD = 3.89$ ) than women who did not have side effects ( $n = 20$ ;  $M = 7.33$ ,  $SD = 4.87$ ),  $t(32) = -2.82$ ,  $p = .008$ .

***Appraising risks.*** Women worried about future complications or dealing with side effects often compared these risks against those imposed by disruptive symptoms. Symptoms were

perceived as risky because of their capacity to interfere in or disrupt women's daily lives. When symptoms were weighed as more risky or threatening than the long-term risks of HT, women resumed medication: "I tried to stop, now I am tapering, but to be truthful I do not intend to stop completely, I just feel like that feels too risky for me." Conversely, when the impact of side effects or worry about long-term risks were seen as more cogent than the threat imposed by symptoms, women chose not to resume. This was particularly apparent among several women who had stopped and resumed multiple times before finally discontinuing for good: during initial attempts at discontinuation, the risk of symptoms outweighed the risks associated with HT. However, as the duration of HT use increased, so too did concerns about long-term health issues ultimately fueling the determination to stop HT completely.

One of the noteworthy aspects of this appraisal was women's tendency to focus on risks more than on benefits. While women occasionally acknowledged HT benefits of symptom reduction as well as heart and bone health, these factored less into their appraisal than did HT and/or symptom risks. Participants spoke of choosing to "take my chances" with HT risks because symptoms were "too risky" to try to manage or they preferred to deal with menopause symptoms because of potential long term risks. Thus, appraisal appeared to be less of an analysis of risks and benefits and more of a comparison of risks leading women to choose which symptom was more manageable: "The hot flashes are still frequent enough & maddening but better than dealing with the bleeding."

***Symptom tolerance.*** Perhaps the most salient factors influencing both women's experiences and the outcome of discontinuation attempts were the symptoms themselves, or more specifically specific components of the overall symptom experience. Grouped under the

heading symptom tolerance, these critical factors include: number of symptoms, symptom intensity, symptom interference and sensitivity to symptoms.

Many study participants appeared to exhibit a heightened sensitivity or awareness of their symptoms. This sensitivity was often reflected in the graphic and emphatic manner in which they described their experiences, employing devices such as capital letters, vivid language and punctuation to demonstrate the intensity of their experience. Women described closely monitoring how they felt as they discontinued and were quick to notice the onset of even very mild or subtle symptoms. Symptoms became the center of their attention, constantly in the forefront of their day-to-day awareness and "all-consuming" as one participant described. In addition, women who resumed HT often commented that they could not think of anything that helped, or might have helped, to manage their symptoms other than to resume medication. Conversely, women who remained off HT were more likely to describe a variety of symptom management strategies.

Trying to contend with multiple symptoms also impacted on women's perception of their experiences. Although most participants reported more than one symptom when they stopped HT, women having many symptoms often described them as worse than pre-HT symptoms. They also rated the overall discontinuation experience as more severe. In turn, symptoms that were reported as more severe appeared to influence whether women resumed HT: two-thirds ( $n = 6$ , 67%) of the nine women who resumed rated the intensity of their recurrent symptoms as severe. However, only 30% ( $n = 6$ ) of the 20 women who discontinued described having severe symptoms.

Symptom interference, the degree to which women reported symptoms as disruptive, was closely linked to symptom intensity. Two-thirds of the sample in the present study described



interference from their discontinuation symptoms. The more intense or severe the symptoms, the more women were likely to report that symptoms interfered in their lives: 20 of the 24 women who reported symptom intensity as moderate or severe after discontinuation also described interference from these symptoms. Women were very descriptive in their narratives as to how their symptoms served as barriers, particularly within their jobs and relationships, causing great distress and diminished enjoyment in their lives. Terms such as 'disruption,' 'couldn't function' and 'prevented me from....' revealed the depth to which symptoms interfered with women's ability to participate in their daily activities and cope with the stresses inherent in their work.

The majority (8, 89%) of the nine women who resumed reported interference while discontinuing yet 12 women (60%) who remained off HT also affirmed, often very emphatically, how symptoms had interfered as they were discontinuing. Accordingly, the narratives of these women were re-examined to further explore whether any additional factors may influence women's capacity to tolerate disruptive symptoms.

All but one had started HT for symptom relief although all but one had used for less than five years; all had more than one symptom with discontinuation. Most reported moderate to severe symptom intensity; over half (n=8, 57%) reported affective symptoms in the moderate-severe range on the MRS. A common denominator among them was that they perceived that they had no options other than to discontinue HT (Table 18). Three women were not able to afford their prescriptions and one participant was told she needed to stop HT as it was contributing to an worrisome increase in blood indices for CVD. Five were bothered by HT-induced side effects (including one woman who believed she was beginning addicted to HT); they had chosen to stop when these side effects became more burdensome and difficult to manage. The final three women stopped because of deep-seated concerns about risks: because of a family history of

breast cancer or stroke, these concerns weighed heavily while they were taking HT and served as motivation to discontinue.

Table 18.

*Women reporting interference who stopped HT*

	Age	Age at FMP	HT Duration (in years)	Number of symptoms	Symptom intensity	Reason for stopping
1	57	53	3	6	Moderate	Worried about CVA
2	55	53	1.5	4	Severe	Worried about all risks
3	57	50	0.9	2	Mild	Side effects: weight gain
4	54	50	1.5	5	Moderate	Cost
5	59	39	12	5	Severe	Health issue: cardiac
6	56	50	6	2	Mild	Worried about breast cancer
7	55	51	2	3	Moderate	Side effects: weight gain
8	50	49	1	4	Moderate	Side effects: addiction
9	57	51	4	7	Severe	Cost
10	51	50	2	2	Mild	Side effects: migraines
11	55	52	2	2	Moderate	Side effects: bleeding
12	50	50	2	3	Severe	Cost

As women appraised their symptoms as well as the risks and threats imposed by both HT and discontinuation symptoms, they also weighed the impact of these symptom factors and risks on multiple aspects of their QoL.

### **Specific Aim 3: explore the impact of HT discontinuation on women's quality of life**

In order to look more closely at multiple dimensions of QoL during HT discontinuation, women were asked to respond to both open-ended questions and QoL-related instruments. There was variability in QoL between participants; there was also variability within individual

participants on different domains of QoL. Specific Aim 3 findings captured women's beliefs about QoL and the impact of discontinuing HT.

**Women's Expertise: Quality of Life.** While women often looked to outside resources for information about menopause or HT, women themselves were the experts in their own QoL. Personal definitions of QoL encompassed many of its different facets, with some women focusing on domains of symptom and health-related QoL while others described concepts such as well-being or peace of mind. QoL was highly valued and one of the issues women considered when weighing risks and benefits. The most commonly reported facets of QoL that women held dear were: enjoying being able to do things and participate in activities, good relationships and enjoying time with family and friends, good health and peace of mind.

***Menopause, HT and QoL: Women's Words.*** Women's discussion of how menopause and HT discontinuation impacted on their QoL parallels their discontinuation narrative. For many women the two descriptions are nearly superimposed as symptoms were perceived as being directly responsible for a decrease in QoL.

Menopause symptoms influenced QoL by interfering with women's ability to do the things they needed or wanted to do. Decisions to begin HT were often made when women appraised their symptoms as disrupting their daily activities or enjoyment of life, their relationships and their health (especially emotional health). When these were disrupted, so too was their QoL. Therefore, for the women in this study, QoL was closely connected to their ability to function in their multiple roles and enjoy life: symptoms that interfered with functional ability interfered with QoL.

There was a vast improvement in QoL once HT reduced or eliminated symptoms and stabilized sleep and moods. Thus for many women, symptom reduction was a component of

improved QoL. Several women noted that HT also provided them with a greater feeling of well-being or a heightened energy or awareness: "There is an invisible extra dose of joie de vivre that seems to be estrogen/progesterone related. Something nearly magical in confidence and approach to life..." There was speculation that this sense of 'joie de vivre' was perhaps due to better sleep or mood, or possibly to looking better and feeling younger.

Given the connection between QoL and symptoms, it was inevitable that discontinuing HT also brought changes in QoL that were typically viewed as negative. Recurrence of symptoms once again interfered in women's ability to function and juggle their multiple roles. When symptoms reappeared, women found themselves again dwelling upon and consumed by how miserable they felt as well as how best to manage these negative physical sensations. Symptoms that persisted for a long time, plus uncertainty as to their duration, also had a negative impact on QoL. Losing one's HT-induced joie de vivre evoked sadness, adding to the unpleasantness of the experience:

...everything lost its shine. I could be in a beautiful garden but would have no interest in smelling the roses – I would just feel annoyed over the heat, thorns...I was much less of a human being, and could give much less to the world...

Poor QoL was a primary force behind HT resumption. Although taking HT incurred risks, the impact of discontinuation symptoms on QoL was perceived as outweighing the risks of HT. QoL was indeed a predominant factor in many women's appraisals of HT benefits and risks.

As before, there was variability in women's assessment of QoL. Not all women felt HT improved QoL, citing ongoing life stressors as more salient to their QoL than were symptoms. For women with HT-induced side effects or worries, stopping HT eliminated their fears and physical problems and therefore often enhanced their QoL. They felt as though they had regained

their health and control over their bodies. For those women whose symptoms became less-intense and all-consuming as time passed, QoL also improved.

From women's narratives, it was clear that both discontinuation and resumption had the potential to influence QoL both positively and negatively. Attention was turned to the quantitative analysis in order to more deeply explore the impact of HT discontinuation and/or resumption on different dimensions of QoL.

***Menopause, HT and QoL across dimensions.*** Not surprisingly, women who had resumed HT had the lowest scores on both the MRS and the HFRDIS. When rating symptoms on the MRS, the majority of women reported no or only mild severity for most individual symptoms as well as the overall symptom score (n= 20, 59%). Another 32% (n = 11) reported moderate overall symptom severity. Approximately 75% (n=25) of participants noted sleep symptoms, mostly mild, and 71% (n=24) of participants were still having hot flashes although again, most were rated as mild. Over half (79%, n = 28) of the sample acknowledged currently experiencing some type of affective symptom (Table 19). Although most were in the mild range, 38% (n = 13) were dealing with moderate to severe/extremely severe depression, irritability or anxiety.

Table 19.  
*Frequency of Affective Symptoms*

	<b>Depressed Mood</b>	<b>Irritability</b>	<b>Anxiety</b>	<b>MRS Psych Subscore</b>
None	17 (50%)	14 (41.2%)	16 (47.1%)	7 (20.6%)
Mild	7 (20.6%)	10 (29.4%)	7 (20.6%)	14 (41.2%)
Moderate	5 (14.7%)	6 (17.6%)	6 (17.6%)	7 (20.6%)
Severe	4 (11.8%)	4 (11.8%)	5 (14.7%)	5 (14.7%)
Extremely Severe	1 (2.9%)			1 (2.9%)

A similar pattern emerged on the HFRDIS: eight of the nine women who had resumed HT reported that hot flashes caused minimal to no interference in their daily lives with one

woman still reporting moderate symptoms (VMS, affective and urogenital symptoms) and interference. However, a majority (n = 16, 47%) of the remainder of the participants, including both women tapering as well as those who had discontinued, also reported minimal to no current symptom interference.

Further examination of the HFRDIS scores revealed two additional noteworthy findings. First, it was observed that four other women who had not verbalized interference in their narratives actually had interference scores in the moderate to severe range indicative of VMS that were currently causing some disruption in their lives. Two of these women stopped HT because of side effects, one because of cost issues and the last because of concerns about risk: the same concerns as the women who reported interference verbally. Thus when interference was elicited both qualitatively and quantitatively, past and present, the total number of women whose lives were disrupted by troublesome symptoms yet still remained off HT was 16 (80%). Obviously symptom interference was a common consequence of stopping HT although it appeared to ease over time.

The second finding was the observation that the majority of women with a profile of moderate to severe interference from VMS (n = 9, 26%) were experiencing moderate to severe interference across all domains of life addressed by the HFRDIS. Eight of these women remained off HT; seven of them also reported moderate to severe symptoms on the MRS. Thus there was a small cluster of women who were experiencing challenging symptoms and interference from these symptoms yet remained off HT. Of the eight discontinuing women with high HFRDIS scores, all described that they 'had' to stop HT related to expense, side effects or worry about risk. Four had acknowledged symptom interference in their narratives; the remainder, as noted in the previous paragraph, only reported interference quantitatively. The

narratives of these four women (two online interviews, two telephone) were re-explored to attempt to understand why they may not have reported interference qualitatively. Three of them had stopped HT because of troublesome and disruptive side effects, the fourth because of concerns about risks. While all had described discontinuation symptoms in their narratives, they also described relief at no longer having to deal with symptoms or risk fears and had made up their minds to 'just deal with' their symptoms.

The transcripts of four other women with moderate to severe symptoms but reporting little interference from VMS were also re-examined. One had no VMS, one had already been off HT for a year so her symptoms had diminished and the third had other life concerns that interfered more than did her symptoms. The last woman had also adopted a 'just deal with it' attitude, describing in detail how she would talk herself out of catastrophizing about her VMS.

On the quantitative QoL/well-being questions, over half of the participants rated their well-being as good or very good; 70% (n = 24) of women were satisfied or very satisfied with their health and 76% (n = 26) perceived their overall QoL to be good or very good. The overall QoL responses were consistent with the overall QoL score on HFRDIS and corroborated women's verbal reports about their QoL. Once again, higher scores were seen among the women who resumed HT. There was also a trend among women with moderate-extremely severe MRS Psychological and Somatic subscores to report greater symptom interference on the HFRDIS and scores on the QoL, self-reported health and well-being questions in the moderate range.

A closer look at the quantitative data reveals some discrepancies on the QoL scores for eight participants. Six of these women reported moderate to severe interference from VMS on the HFRDIS and/or moderate symptoms on the MRS yet still rated their overall QoL as good (Table 20). Once again, returning to the narratives of these women revealed that half of them had

Table 20.

*Women with moderate-high MRS & HFRDIS scores but good overall QoL*

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
<b>Age</b>	54	49	48	55	55	55
<b>Age at FMP</b>	50	48	46	50	50	51
<b>HT Duration (in years)</b>	1.5	1.5	0.5	.75	5	4
<b>Number of symptoms</b>	5	5	1	6	4	7
<b>Symptom intensity (qualitative)</b>	Moderate	Severe	Severe	Moderate	Mild (on final attempt)	Severe
<b>Symptom interference (qualitative)</b>	Yes	No	No	No	No (on final attempt)	Yes
<b>Comparison to pre-HT symptoms</b>	worse	same	same	same	better	worse
<b>MRSSoma</b>	severe	severe	moderate	moderate	moderate	severe
<b>MRSPsych</b>	moderate	mild	mild	moderate	moderate	extremely severe
<b>MRSUro</b>	severe	mild	moderate	moderate	severe	extremely severe
<b>MRSTotal</b>	moderate	moderate	mild	moderate	moderate	severe
<b>HFRDIS</b>	moderate	moderate	moderate	severe	moderate	severe
<b>Feeling</b>	Mostly good	Up and down	Mostly good	Up and down	Up and down	Mostly good
<b>Happy</b>	Generally satisfied	Generally dissatisfied	Generally satisfied	Sometimes Satisfied	Sometimes Satisfied	Generally satisfied
<b>Interesting Things</b>	Most of the time	Some of the time	Good bit of the time	Some of the time	Some of the time	Most of the time
<b>Cheerful</b>	Some of the time	Some of the time	Good bit of the time	Good bit of the time	Some of the time	Good bit of the time
<b>Health Status</b>	Neither good nor bad	Neither good nor bad	Satisfied	Satisfied	Satisfied	Satisfied
<b>Overall QoL</b>	Good	Good	Good	Good	Good	Good
<b>Reason for stopping</b>	Cost	Side effects: weight gain	Side effects: weight gain	Side effects: bleeding	Worried about cancer	Cost

stopped HT because of distressful side effects, specifically weight gain and bleeding. One woman was worried about long-term health risks and opted to stop HT to minimize those risks; the other two stopped because of cost issues. One of the women (#6) who stopped due to cost



also struggled with other health-related symptoms when she entered menopause; this other health issue was in better control when she discontinued and thus did not add to her symptom burden. She also recently had obtained a new job and returned to school so other non-menopause related factors were more critical to her well-being and QoL. (Of note: participants #2-5 represent the women who did not report interference in their narratives but did so on the HFRDIS.) For the women with high QoL despite moderate to severe symptom intensity and interference, overall QoL was more positively influenced by reducing HT-related side effects and concerns about risks, finances and other health issues. Several of these women commented that there was more to their lives than symptoms or menopause.

A similar exploration was conducted of the qualitative data from two women who reported poor/very poor overall QoL but little interference. One woman explicitly stated that her low QoL was a product of her poor financial situation and not from discontinuing HT. The other woman was troubled by longstanding mood issues; it was these symptoms that impacted her QoL. Thus, while QoL and symptoms were closely linked for many participants, for a small subset other life factors were more salient in their appraisal of QoL.

Quality of life was an important issue for the women in this study. Appraisals of QoL and the degree to which symptoms interfered with QoL sometimes led to decisions about resuming HT. However HT did not always improve QoL nor did the occurrence of symptoms impact on overall QoL for some participants.

#### **Specific Aim 4: discuss women's preferences for counseling and support during HT discontinuation**

In order to determine what knowledge would be most beneficial along the discontinuation journey, study participants were asked open-ended questions about information they received and/or desired. Specific Aim 4 addresses these responses.

**Seeking knowledge, sharing wisdom.** The degree to which many women suffered from their symptoms and decreased QoL would argue for the need to provide women with up-to-date and relevant information as they attempt to discontinue HT. Study participants appraised the information they were or were not given, making comparisons to the knowledge they believed they needed for managing symptoms and maintaining QoL during HT discontinuation.

***Health care providers: information.*** Most (n =30, 88%) women went to MDs for their menopause-related health care; four (12%) received their menopause care solely from nurse practitioners (NPs). Four other women saw NPs and one saw a nurse midwife (CNM) in addition to their MD providers. Other providers included: Doctor of Osteopathy (1), a homeopath (1), Doctor of Naturopathy (2) and Traditional Chinese Medicine Practitioner (1). Ten (29%) women reported seeing more than one provider.

Providers sometimes offered very detailed information about what women could expect when stopping HT and suggested strategies for symptom management, including the option of resuming HT should recurrent symptoms prove to be intolerable. However, many women did not receive much information when they were contemplating or beginning HT discontinuation. In some instances, this was because the women had stopped taking their medication without informing their providers. In other instances, women stated their providers were aware they were stopping but that the information offered was limited or impersonal. There was a feeling among

some participants that they had been left to find their own way, with no resources to guide them along this journey. One woman related her belief that the lack of guidance from her provider was a contributing factor in her ongoing worry about whether she had made the right decision to resume HT:

I wish my doctor did talk to me a little bit more about it to put me more at ease...he didn't do that with me and I think that scares me even more. I would rather know the worst just so I can make a better decision....

There were inconsistencies in the information that participants were given: some women were told to stop HT because of the risks whereas other women received the exact opposite information. Women often commented about the mixed messages they had encountered about HT and how confusing and unsettling this felt when they were trying to make their decisions. They were distressed and frustrated that health care had not yet arrived at a definitive answer about HT and whether it was harmful or beneficial.

Women also acknowledged that they had received limited education about lifestyle changes such as exercise and nutrition. Some women were comfortable with this situation. They believed that their providers had not discussed these issues with them because they were already knowledgeable about health promotion because of their occupation (RNs or NPs) or existing exercise regimen.

Occasionally providers offered women ongoing support by way of check-in calls during and after discontinuation. While some women felt as though additional contact was not necessary, others wished their providers had done more outreach, even an occasional email. Several women who had not informed their providers about their discontinuation attempts

wished in retrospect that they had communicated with their providers so as to avail themselves of any support that may have been offered.

Not all women wanted their providers to be aware of their discontinuation status: a few women chose not to discuss this out of concern about their provider's reaction, especially if it became known they had gone against the provider's recommendations. Other participants had not informed their health care providers because they did not want to be forced into discussions about unpleasant topics such as weight loss.

Some of the participants actually verbalized anger. Some expressed anger that they had let themselves be talked into stopping by their providers. They were also angry with providers for not being more supportive or for not offering adequate and/or accurate information prior to discontinuation. Anger was also directed toward medical research that more was not being done for women stopping HT or for women's health in general: "...if it was a man's issue – it would have been dealt with in a more effective way..."

***Woman to woman.*** Many women agreed that there was still limited discussion and dialogue about menopause among women. This was sometimes attributed to social norms related to discussing 'women's issues' in public. However, several participants actually stated that they could not talk with family or friends because of differences in opinion about HT and had gone against the advice of their social circle when starting HT. They spoke of having fights with family members about taking HT and feeling as though they had no one with whom to discuss HT questions or concerns.

Yet many women spoke of wanting to be able to connect with women like themselves who had stopped or were attempting to stop HT. They also desired more educational forums and support groups either in person or via online webinars, chat groups or blogs specifically for

women discontinuing HT. Through open discussion with other women through any of these venues, they believed their experiences would be normalized and they could also share ideas and suggestions for making HT discontinuation easier.

Almost universally, participants recommended that women contemplating stopping, or even starting, HT 'do research' to get as much information as possible prior to making a decision. Almost all, even those who held negative beliefs about HT and/or medications, affirmed that women should not be hesitant or afraid to start HT, even if only for a short time, because of the symptom reduction. However, the decision should be made on an individual basis taking into consideration the specific contexts and situations in each woman's life.

***Health care providers: recommendations.*** As such, women asserted that health care providers need to present updated, consistent and accurate information to women with a personalized analysis of each woman's risks and benefits. With a resounding chorus of "listen to women!" participants stipulated that health care providers need to take the time to understand women's concerns and not minimize their symptoms or QoL: "...it is my job to try to fully explain to my physician what my needs are or what my life is...and it is his job to listen to me and to use his knowledge and not to be patronizing."

Several women did report that their providers had been extremely helpful and supportive during this experience. According to the participants, these providers took time to adequately educate the women about their options, explaining risks and benefits clearly, suggesting strategies for managing symptoms and offering encouragement that transcended simple medical care: "I felt (and still feel) very supported by my NP. She was so caring about the moodiness I was experiencing, and offered spiritual support as well as medical support." Having a provider

who was perceived as caring and supportive was comforting for the women fortunate to have access to their services.

These participants clearly desired more information and support to guide them along their journey of discontinuing HT: this information needs to be rooted in evidence yet personalized and relevant in the context of each woman's life.

### **Summary**

The findings from this study which included one overarching theme '*a solitary journey*' and two subthemes reflected each woman's personal and individual experience of discontinuing HT. Most women who stopped HT experienced multiple uncomfortable symptoms but the nature of the symptoms and their inherent *burden and interference* varied for each woman. Women often *appraised risks* of symptoms versus HT when considering their options for managing symptoms. Factors (roles, finances, expectations of menopause, HT and discontinuation, reasons for stopping HT, readiness to stop, and symptom tolerance) that impacted on symptom experience and discontinuation were identified and discussed. QoL was an important consideration and symptom interference on QoL often influenced women's choices, but QoL also varied both between and within women based on their appraisals of risk. Finally, women desired more information about HT discontinuation and menopause in general and preferred that information from their health care providers be personalized to support them on their individual journeys. These findings provide information that will help to enhance health care practice, research and policy in order to better support women stopping HT.

## CHAPTER V

### DISCUSSION AND IMPLICATIONS

The purpose of this mixed methods study was to develop an in-depth description of women's experience of discontinuing HT. This topic was important because few studies in the post-WHI world have described this phenomenon from the viewpoint of the women living through this experience. Findings from this study revealed that women stopping HT undertook a solitary journey that was influenced by their symptoms and symptom-associated burden and interference. Women's tolerance of symptoms and their choice of whether or not to resume HT were impacted by numerous factors; critical among these factors was appraisal of the risks inherent to both HT and symptoms. QoL was a highly valued component of women's experiences and choices and varied between and within participants. Many participants expressed a desire for more information and support on this journey from both health care providers and other women traveling the same path.

The key study findings will be discussed in this chapter in relation to the existing empirical literature about HT discontinuation, menopause symptom burden and interference, risk appraisal, QoL and menopause-related QoL, and health care and promotion for mid-life women. Implications for practice, research and policy will be discussed as will the challenges and limitations of the study.

#### **Discussion**

##### **Sample Characteristics: Comparison to the Literature**

The 34 women who participated in this study displayed similarities and differences to women in other studies on HT discontinuation, especially with regard to the factors related to HT use listed in Table 5 (page 31). Consistent with earlier studies (Grady et al., 2003), most of

participants had started HT for symptom relief. Nine (26%) participants had resumed HT, also a percentage commensurate with that noted previously (Grady et al., 2003). All had experienced symptoms, many recurrent, some new, upon discontinuation. This is a higher number than has been seen in the literature where it has ranged between 30% (Grady et al., 2003) to 55% (Ockene et al., 2005). However, this may be due to selection bias: the study topic may have attracted women who were symptomatic or distressed by their experience and had a story to share.

Some of the factors that in this study were associated with a more difficult experience and/or whether or not a woman chose to resume HT have also been reported in the literature. These factors include troublesome or severe symptoms (Grady et al., 2003), QoL (Welton et al., 2003), occurrence of HT-related side effects (Reynolds et al., 2001), attitudes toward menopause and medications (French et al., 2006), worries about HT risks (Buick et al., 2005), and HT expense (Gerend et al., 2006). Another finding also supported by the literature (Ettinger et al., 1996) was the association between shorter duration of HT use and stopping due to side effects.

Factors such as age, type of menopause and co-morbidities were not able to be evaluated due to the small sample size. In addition, it was not possible to determine any correspondence between symptom experience and discontinuation outcome by type of HT because of the myriad types of HT that women were using as well as the fact that quite a few participants had used multiple types of HT...and some could not recall the type they had most recently used.

Although discontinuation method was postulated as a possible factor, it was not possible to make that determination in this study. There was indeed a trend toward women who resumed being more likely to have tried to taper (7/9, 78%), as was noted in a study by Haskell et al. (2009). However, there were so many disparate tapering methods used (and two of the women



who had tapered and resumed had also tried stopping abruptly in the past) that no conclusions could be inferred as to whether method of discontinuation was a factor.

The small number of non-Caucasian women in this study precluded any assessment of the influence of ethnicity. The lower numbers may reflect previous research which indicates that fewer women of African-American or Hispanic ethnicity seek medical support for menopause or begin HT (Brett & Madams, 1997). However, this could also be indicative of less use of the Internet in non-Caucasian populations (Fallows, 2005).

Several prior qualitative studies on HT discontinuation revealed some of the feelings that stopping HT has evoked among women, including sadness (Welton et al., 2003), worry about the decision (Kolip et al., 2009) and anger (French et al., 2006). Similar emotional reactions were also expressed by some of the women in this study, corroborating that intense and sometimes negative responses can often accompany the experience of discontinuing HT.

### **Symptom Burden and Interference**

For most of the women in this study, discontinuation symptoms were troublesome, however the severity and manageability of these symptoms varied depending on the degree of symptom-related burden and interference. *Burden and interference* emerged as one of the subthemes based on women's descriptions of their distressful symptoms and the disruptions in their day-to-day lives from these symptoms.

Symptom burden is considered to be a component of symptom experience and is defined as either an individual's total number of symptoms or a product of the total number of symptoms and the severity associated with those symptoms (Cleeland, 2007; Gapstur, 2007; Woods, 2010). The latter definition allows for measurement and analysis of both quantitative (number of

symptoms) and qualitative (symptom severity) data and thus is both subjective and objective in nature (Gapstur, 2007).

Symptoms that contribute to burden may occur as a result of illness or the treatment of that illness; it can also arise from comorbid conditions (Cleeland, 2007). Outcomes of symptom burden that continues to worsen or is not alleviated include both physical and emotional sequelae such as impaired functional status or QoL, decreased capacity to perform ADL and worsening economic status (Gapstur, 2007).

Much of the research on symptom burden has been conducted in the fields of oncology and cardiology. In women's health, symptom burden has been explored in studies on endometriosis and PMDD (premenstrual dysphoric disorder). There has been less focus on symptom burden in the menopause literature although that has begun to change in recent years. For example, Bolge et al. (2010) studied the burden of insomnia related to nighttime awakenings among women with menopause symptoms. Insomnia was associated with an increase in health care costs from emergency department visit as well as impaired work productivity and diminished health-related QoL. This is comparable to the findings of the present study wherein many participants complained bitterly of disturbed sleep and the impact in their lives: fatigue related to insomnia resulted in less energy and interest in ADL, hampered women's ability to be focused at work and decreased their overall QoL.

In addition to symptom severity, participants also reported multiple symptoms which amplified their distress and contributed to their symptom burden. In fact, VMS, sleep and mood issues often appeared to co-occur and their impact appeared to be more than simply additive. This is consistent with research on symptom management wherein multiple symptoms are a component of symptom burden (Cleeland, 2007; Woods, 2010). In addition, there is growing

interest in studying, not just multiple symptoms, but also groups or clusters of symptoms that commonly occur together (Dodd et al., 2011).

Symptom clusters have been defined as symptoms that typically share an underlying physiology or etiology and usually appear together in response to an illness, condition or treatment (Barsevick, Whitmer, Nail, Beck & Dudley, 2006). Research on symptom clusters was initiated in the field of oncology where symptoms such as pain, fatigue and nausea were identified as a cluster. Symptom clusters have also become a focus of interest in studies on symptoms of heart disease, irritable bowel syndrome, PTSD and fibromyalgia to name a few. Women's health issues such as PMS have also lent themselves to symptom cluster research: a factor analysis of 57 commonly reported PMS symptoms identified four symptom clusters which accounted for 42% of the variance in premenstrual symptoms (Woods, Mitchell & Lentz, 1999).

Many of the studies on symptom clusters have used factor analysis to explore co-occurring symptoms although cluster analysis, which groups cases or individuals with similar symptoms, has also been used. Looking at cases can help to identify subgroups with similar symptoms or patterns of symptom severity in order to target specific interventions toward these subgroups (Barsevick et al., 2006). In the present study, it was possible to qualitatively identify a cluster of women with high symptom severity and interference from VMS which led to deeper analysis of the interview data revealing that an attitude-based approach to dealing with discontinuation symptoms was helpful for some women. This finding may point toward recommendations for both research and practice interventions that foster the development of greater efficacy among women to self-manage discontinuation symptoms.

Symptom cluster research has started to appear more often in the field of menopause where traditionally, symptoms have been studied as single and/or separate entities. Woods,

Mariella and Mitchell (2006) used cluster analysis to explore depressed mood symptoms in women transitioning through menopause. The researchers identified six patterns or clusters of depressed mood symptoms. Most of the clusters demonstrated stable mood with no/minimal depressed mood symptoms which should offer some comfort to women that menopause does not increase their risk for depression. A small cluster (10%) of women with low and worsening moods, most often predicted by a history of previous depression, was also identified. Although the present study was not able to evaluate mood changes over time, 38% (n = 13) of participants rated their psychological symptoms as moderate to severe/very severe. Given that previous depression is a predictor of depressed mood, it would be prudent to carefully screen women for a prior history of mood issues before they stop HT.

Menopause symptoms have also been explored through latent class analysis (Cray, Woods & Mitchell, 2010) which is a model-based approach to cluster analysis. From a sample of 103 mid-life women, the researchers identified four distinct patterns of symptom severity of five common menopause-related symptoms; 13% of these women (n = 14) rated all their symptoms as high, 65% (n = 67) as low. Ten (10%) were in the high level for joint ache-concentration problems group while the remaining women (n = 12, 12%) scored high in severity for VMS-joint ache-sleep disruptions. The women in the current study also seemed to exhibit variability within their clusters of symptoms: although many noted VMS, sleep and mood concerns, the prevailing symptom or symptoms was different for many women.

In the study by Cray et al. (2010), women with more severe VMS-joint ache-sleep disruptions had higher cortisol levels while those with greater job stress were more likely to be in the groups with high levels of symptom severity. In the present study, only three women (9%) had current overall high severity symptoms ratings although 15 (44%) stated their symptoms

with discontinuation were very severe. Many of these women reported being in high stress jobs and believed their symptoms impacted negatively on their work lives. The increased worry about work performance added to the level of stress perhaps setting up a vicious cycle of symptoms contributing to more work stress leading to a more distressful symptom experience.

Finnegan, Shaver, Zenk, Wilkie & Ferrans (2010) have developed a symptom cluster model that incorporates the concept of systemic stress which is characterized by emotional arousal (e.g. chronic worry, uncertainty) and physiological activation (elevated levels of cortisol and proinflammatory cytokines). Systemic stress can be influenced by factors such as life strain and negative affect and may, in turn, amplify the burden of symptoms such as fatigue, disturbed sleep, mood issues and difficulty concentrating. Although this model has been used primarily in oncology, it may have benefits for the development of both research and interventions targeting menopause and HT-discontinuation symptom clusters. For example, a recent study by Carmody et al. (2011) explored the use of mindfulness-based stress reduction (MBSR) in women with VMS; the results demonstrated a significant reduction in both stress and symptom bother which persisted for at least three months after participation in the program.

While symptom severity and multiple/clustered symptoms contributed to symptom burden with HT discontinuation, symptom interference also emerged as a factor in women's experience. Symptom interference is defined as the degree to which symptoms disrupt or impede an individual's ability to participate or function in their in daily activities (Woods, 2010). Interference is a key consideration in symptom appraisal and may serve as a mediator between symptom perception and seeking help for symptom management (Hunter & Mann, 2010). In the present study, interference was a major factor in women's overall discontinuation experience,

making HT cessation more challenging. Interference also appeared to be a salient factor in whether or not women resumed HT.

In a study conducted by Rand et al. (2011) of 395 breast cancer survivors who were experiencing VMS, greater symptom burden (frequency and severity) led to more perceived symptom interference in participants' ADL. Interference predicted more sleep disturbances ( $\beta = 0.26$ ,  $p < 0.05$ ) which subsequently predicted lower perceived health ( $\beta = -0.29$ ) and more mood concerns ( $\beta = 0.49$ ). A similar theme was noted in the current study: women reporting greater symptom interference on the HFRDIS, most of whom had stopped HT, had slightly higher psychological symptom scores and lower QoL, including self-reported health.

Among a subsample of 184 participants from the Seattle Mid-Life Women's Study (Woods & Mitchell, 2011), women who had lower perceived health and higher stress were more likely to acknowledge symptom interference in their work or relationships. Depressed mood and difficulty concentrating also impacted on both work and personal relationships while anxiety and sleep disturbances, which may be linked to a greater degree of arousal and subsequent amplification of symptoms, were associated with relationship disruptions. Once again, there were similarities to the current study: women described mood swings and irritability when they stopped HT, all negatively impacting on job performance and personal relationships. In addition, women often reported a sense of uncertainty about HT and the accompanying risks. Intolerance of uncertainty has often been associated with anxiety. These symptoms may be indicative of greater arousal and sensitivity to symptoms in the study sample.

Symptom sensitivity, a tendency to focus on and report or seek help for symptoms (Hetherington & Hopkins, 1969), has been associated with both somatization and somatic amplification of symptoms (Barsky, Goodson, Lane & Cleary, 1988) as well as negative

affectivity (Hunter and Mann, 2010). In a study comparing women's self-report of VMS to physiologic hot flash measures (skin conductance), women who over-reported VMS had higher somatization scores (Thurston, Blumenthal, Babyak & Sherwood, 2005). Greater symptom awareness has also been associated with use of HT (Matthews et al., 1996).

The term negative affectivity is used to indicate a tendency toward perceiving and reporting negative mood (Hunter & Mann, 2010). It is associated with affective symptoms or disorders and thus reflected in measures of stress, anxiety and depression (Watson & Pennebaker, 1989). Negativity affectivity in turn may lead to an increase in the awareness of physical sensations (Kolk, Hanewald, Schagen & van Wijk, 2003) and ultimately to greater symptom sensitivity and somatic amplification (Dragos, Tanasescu & Davila, 2009). It would therefore not be unreasonable to expect that increased reporting and more negative appraisals of vasomotor and other menopause-related symptoms would be associated with negative affectivity and this has been demonstrated in the literature. Social stress (Gold et al., 2000), anxiety (Freeman et al., 2005; Gold et al., 2006; Thurston, Bromberger et al., 2005), uncertainty (Obermeyer, Reynolds, Price & Abraham, 2004) and depressed mood (Thurston et al., 2008) have been linked to reporting of more frequent VMS as well as more troublesome symptoms. Psychometric testing during the development of the HFRDIS demonstrated that interference scores were positively associated with negative affect (Carpenter, 2001). Another study comparing self-reported and physiological VMS measures showed that negative affect was associated with self-reporting of symptoms but not objective symptom measures (Carpenter & Rand, 2008).

Negative affectivity may influence symptom reporting through a cognitive as well as an affective pathway. Depression, anxiety, pessimism and low self-esteem, have been associated

with more negative beliefs about menopause and VMS in general (Avis & McKinlay, 1991; Hunter, Coventry, Mendes & Grunfeld, 2009; Hunter & O'Dea, 2001). Negative thoughts and catastrophizing during hot flashes (Reynolds, 1997 & 2000), feeling as though one had little control over VMS (Hunter & Liao, 1995; Rendall, Simonds & Hunter, 2008) and shame or embarrassment with hot flashes (Hunter et al., 2009; Rendall et al., 2008) have been linked to more negative appraisals of these symptoms. Thus, negative affectivity has the capacity to play a role in women's sensitivity to menopause symptoms through several different mechanisms (Hunter & Mann, 2010).

Symptom sensitivity, somatization and somatosensory amplification have been further linked to greater central nervous system (CNS) arousal and activation (Dragos et al., 2009; Hammad, Barsky & Regestein, 2001; Pfaff, Riberio, Matthews & Kow, 2008)). In the brain, activation of the insula and/or the anterior cingulate cortex has been postulated to play a pivotal role in both awareness of interoceptive sensations as well as corresponding affective and subjective responses such as concentration, risk perception, cognitive choices and even self-image (Craig, 2009). In a study exploring cortical activation with VMS (Freedman, Benton, Genik & Graydon, 2006), both the insular cortex and the anterior cingulate cortex were activated during hot flashes. These regions may be critical in the mechanistic processes of VMS-associated thermoregulation as well as women's subjective responses to VMS. This finding implies a common etiology or underlying mechanism for menopause symptom and responses lending support to the concept of menopause symptom clusters.

It is important to understand the links between symptom sensitivity, cognitive appraisal, negative affectivity and CNS arousal as they have implications for how to better support women planning to discontinue HT. It may be prudent to assess a woman's general sensitivity to



symptoms (Barsky et al., 1988) or her underlying beliefs about menopause (Menopause Representations Questionnaire (MRQ), Hunter & O'Dea, 2001) and hot flashes (Hot Flush Beliefs Scale (HFBS), Rendall et al., 2008) as part of counseling her about discontinuing HT. Interventions, such as Cognitive Behavioral Therapy (CBT) to realign women's beliefs about herself, menopause and her capacity to manage her symptoms may be helpful (Hunter & Mann, 2010). Knobf (2008) found that among breast cancer survivors, women adopting a behavioral response of 'making the best of it' were able to more readily cope with and adjust to their situation; this attitude may be akin to the 'just deal with it' strategy used by several women in this study. Strategies to lower the level of neurological arousal such as paced breathing (Freedman, 2005) or mindfulness (Carmody et al., 2011) may also be of benefit to decrease the degree to which symptoms interfere with women's ability to function day-to-day.

The women in this study actually reflected many of the above concepts and linkages. Many reported affective symptoms and conditions, some of which preceded entry into menopause. Life and work stressors impacted on their appraisal of symptoms and, in turn, symptoms interfered with work and personal life, increasing stress and distress and potentially increasing CNS arousal as well. CNS arousal may have further intensified their symptoms. Indeed, many participants commented that stress seemed to bring on more VMS. In addition, the very graphic, impassioned, powerful and negative descriptions of symptoms and the embarrassment they wrought may also represent a tendency among the participants toward catastrophizing and believing they had little control or ability to manage symptoms. The trend for women who resumed HT to assert that 'nothing' would have helped them to manage symptoms or remain off HT implies that some women may benefit from more immediate initiation of alternate therapies and interventions when they attempt to stop HT. Their

discontinuation efforts may also be better supported by more frequent communication with their health care providers along the journey.

Similarly, women who had more positive expectations of menopause were more successful at staying off HT, which may reflect the role of cognitive appraisal in a woman's beliefs about her ability to manage discontinuation symptoms. Cognitions may also help to explain, in part, why women who expressed a sense of intuition, of 'knowing' that it was the right time to stop, tended to notice milder symptoms and were successful at discontinuation despite past unsuccessful attempts. This ability to alter one's beliefs about self-management of symptoms or perceptions of symptom burden lends support to the efficacy of alternate strategies such as CBT (Hunter & Mann, 2010).

In the current study, not all women were troubled by their symptoms: several participants felt that their symptoms were mild or easily tolerated and did not warrant intervention. A study of 165 women conducted by Berg and colleagues (2008) found that the perception of a symptom did not always correlate with the distress associated with that symptom (Berg, Larson & Pasvogel, 2008). This finding implies that other factors may also be operational in women's appraisal of how burdensome their symptoms were. The interconnectedness of symptoms and QoL may be one such factor.

Symptoms and QoL were closely connected for the women in this study. For example, QoL was diminished when women did not have the energy to function at work or participate in social activities because of sleep disruptions. Thus the impact of symptoms on functional status may be a determinant in the relationship between symptoms and QoL. Functional status and QoL have long been associated in the fields of oncology and cardiology but less so in menopause

despite the fact that women have reported their main reason for starting HT was not being able to function (Woods, Falk, Saver, Stevens, Taylor, Moreno & MacLaren, 1997).

Women were also very concerned about the impact of frequent hot flashes on their appearance and the potential negative reactions of colleagues to the physical manifestations of their hot flashes. Women's worries about this may actually be unfounded: in a recent study exploring the reactions of women's co-workers to observed VMS, the co-workers did not readily attribute flushing and sweating to menopause and their responses were mostly neutral or compassionate (Smith, Mann, Mirza & Hunter, 2011). Nonetheless, feeling embarrassed or self-conscious at work had a detrimental effect on the self-esteem of the women in the current study. This was critical to how they perceived their QoL in the workplace and may have further impeded their ability to function in their very stressful and public work roles.

Mood symptoms influenced QoL by interfering with relationships, especially intimate relationships. Several women commented upon not being able to be physically close to their partners or enjoy sexual activities when they were experiencing VMS. Sexuality-related symptoms such as vaginal dryness, dyspareunia and decreased libido also contributed to lower QoL: on the HFRDIS, the greatest frequency of severe scores was on the interference with sexuality item. There is increasing awareness in the menopause literature of the deleterious impact of sexual dysfunction on QoL. Sexual dissatisfaction has been associated with lower well-being (Davison, Bell, LaChina, Holden & Davis, 2009) as well as poorer self-reported health and greater depressed mood (Gallicchio, Schilling, Tomic, Miller, Zacur & Flaws, 2007). However, in a multinational study of 4246 women, 77% were uncomfortable discussing symptoms with their providers (Nappi & Kokot-Kierapa, 2010). Because sexual dysfunction may lower QoL, providers must be cognizant of the fact that a discussion of urogenital and

sexual health is pertinent to providing care for mid-life women. Providers should broach the topic themselves, especially among women who have discontinued HT. In the present study, most of the women noting urogenital/sexual symptoms were those who stopped HT which is not surprising given their lower estrogen levels.

Although QoL was clearly influenced negatively by discontinuation symptoms, other factors may have been involved in women's assessments of QoL. Several women described a sense of *joie de vivre* or 'shine' that they experienced while on HT but which disappeared when they stopped. It is possible that the reduction in symptom burden and interference in ability to function may account for this sense of energy or well-being. However, the 'shine' that women experienced was sometimes expressed as being more than just a product of symptom reduction: several women commented that they resumed HT not only to reduce their symptoms but also to feel better overall and to regain their energy. The use of HT to feel better was noted in prior qualitative studies on HT and menopause (French et al., 2006; Kolip et al., 2008).

It is possible that this HT-induced *joie de vivre* and sense of 'feeling good' may be related to estrogen which is known to have a positive influence on well-being and mood, perhaps through its effect on increasing serotonin levels (Amin, Canli & Epperson, 2005). In addition, estrogen may impact on mood by increasing norepinephrine which may foster a sense of well-being. However, the stimulatory effect of norepinephrine can, in some individuals, lead to an increase in anxiety or fear. This could account for the several women in this study that reported feeling more irritability while on HT.

Differences in reports of well-being while taking HT are one example of the variable impact of HT discontinuation on the QoL of the study participants. Not all women believed that HT made their QoL better. Also, several women specifically reported that their QoL was not

linked to symptoms but was more reflective of other factors in their lives such as finances or employment. Smith-diJulio et al. (2008) also found that women's sense of well-being was positively related to social support and inversely related to negative life events while the menopause transition and associated symptoms had no impact on well being.

Woman who experienced HT-related side effects and those with concerns about long-term health risks from HT constituted another group who reported better QoL after stopping medication. Concern and worry about both side effects and future risks have often been associated in the menopause literature with discontinuation of HT (Reynolds et al., 2002). Early discontinuation of HT in particular has been attributed to the occurrence of side effects; this was also noted in the present study. The impact of these two factors on a woman's QoL may be one of the mechanisms that prompt HT cessation.

The variability in both overall QoL, as well as variations among women as to which QoL domain they deemed most pertinent to their HT discontinuation experience, may partially explain some of the discrepancies in findings from other studies of HT and QoL. HT may enhance QoL through symptom reduction and improved functional capacity, however, it may not necessarily impact on overall QoL which may be more related to other life factors. HT may also decrease QoL by causing worry about side effects or risks. It has been suggested that measuring symptom burden alone may be sufficient in both practice and research (Cleeland, 2007). However, the present study findings demonstrate that there are clearly women for whom symptoms are not the primary component of their QoL. Thus, measuring symptoms may not be sufficient for determining the full impact or outcome of a medication or therapeutic intervention. Research on HT and QoL needs to measure multiple domains of QoL, both qualitatively and quantitatively, or be more specific as to which domain is being measured.

QoL is clearly an important factor in the overall symptom experience. Symptoms associated with HT discontinuation (or with HT-induced side effects) appeared to interfere with QoL. Diminished QoL further contributed to the perception of symptoms as being more burdensome and interfering. When symptom burden and interference were high, women's appraisals of the risks associated with symptoms also increased.

### **Risk Appraisal**

Much has been written with regard to the manner in which women appraise risks and benefits when making decisions about HT. As previously noted, they take into account factors such as health, family history, beliefs about menopause and medications, and perceived advantages and harms of HT (Bravata et al., 2002; Hunter et al., 1997; Marmoreo et al., 1997; Theroux, 2009; Walter & Britten, 2002). The women in this study engaged in a similar analysis as they weighed their options for managing interfering and 'risky' symptoms. However, for many women, their analysis centered on risks with less consideration of benefits. *Appraising risk* was another subtheme in this study.

Focusing on risks rather than benefits is not unusual in the complicated process of risk-benefits analysis. The focus on risk is often emotionally driven, specifically by fear, a critical component in risk perception (Sjoberg, 2000). As fear increases, so too can negative affectivity, symptom sensitivity, CNS arousal and somatosensory amplification as previously discussed. Factors associated with fear and risk perception include *dread* or the conviction that something negative will happen, *personalizing* the risk, perceptions of having *control and choice*, whether a risk is *old or new*, *man-made or natural*, the level of *awareness* of the risk and *trust* in the communicator of the risk (Centocor, 2011). Ultimately, fear has a deleterious impact on the ability to make decisions (Griffiths, 1999).

Several qualitative studies focusing on women's decision-making during the menopause transition (Bravata et al., 2002; Marmoreo et al., 1997; Walter & Britten, 2002) have also demonstrated the same focus on risks among women contemplating the use of HT. Among the women in this study risk appraisal often preceded choosing a path to travel therefore these studies help illuminate how these factors come into play in women's risk appraisal. For example, in some of these studies (Hunter et al., 1997; Theroux, 2010; Wathen, 2006; Welton et al., 2004; Woods et al., 1997) the degree to which symptoms were troublesome influenced women's decisions. Women weighed the risks of menopause or discontinuation symptoms against medication-induced side effects and symptoms (*dread, awareness, personal, old or new*) and made evaluations as to which might be more manageable (*control and choice*) (Theroux, 2010).

In a similar fashion, women in this dissertation study were expecting that their symptoms would recur, particularly those who had already made attempts to stop. They felt they had less control over HT-induced side effects and chose to live with menopause symptoms instead. Women who had to stop HT because of financial considerations felt that having less control over the options available to them added to their symptom distress. As previously noted, perceived lack of control may play a role in women's evaluations of symptom severity.

In other studies, participants perceived symptoms as risky (*dread*) (French et al., 2006; Walter & Britten, 2002) and worried about the negative impact of symptoms on their ability to do their jobs (*dread, control*) (Kolip et al., 2008; Woods et al., 1997). These study participants also evaluated the impact of symptoms on their QoL (*personal, control*) (Schapira et al., 2004; Wathen, 2006; Welton et al., 2004).

Similarly, in the present study, there were some women who very much feared the possible recurrence of their symptoms and how those symptoms might interfere in their lives,

especially work and relationships. A few acknowledged that they had actually resumed HT at the very first indication of symptom recurrence, not because the symptoms were already severe, but because they feared the symptoms would escalate.

Uncertainty about HT risks and lack of personalized definitive answers and information (*dread, choice, personal, control*) (Bond & Bywaters, 1999; Griffiths, 1999; Reece, 2002) contributed to women's fears in some of the studies about HT decision-making. Attitudes about menopause, HT and medications (*man-made or natural*) also influenced the amount of distress women experienced as they evaluated their options (Hunter et al., 1997; Kolip et al., 2002; Schapira et al., 2004; Walter & Britten, 2002). Ever-evolving recommendations for HT use (*old and new*) as well as changes in personal or family health also impacted on women's risk perceptions and decisions, underscoring the contextual nature (Marmoreo et al., 1998) and iterative process (Woods et al., 1997) of making HT decisions.

These same concerns were also apparent in the current study participants who described ongoing uncertainty about current HT evidence and continued changes. They also spoke of how their attitudes and beliefs influenced their experience and choices and how their fears about their own risks were influenced by both their personal and family health.

Family health history, looking to the past to inform future choices, was indeed a strong influencing factor in several prior studies (Bravata et al., 2002; Walters & Britten, 2002) as well as the current one. Obviously family health history is salient in assessing risks: it provides evidence of health concerns that may be more likely for an individual because of shared genetic patterns. In the present study, women's family history influenced the disease process -- breast cancer, heart disease, stroke -- they most feared when they were assessing their HT-related risks.



However, Walter and Britten (2002) suggest that family history may also be critical because it represents the influence of lay beliefs about health and illness. These beliefs are akin to the social and culturally constructed explanatory models proposed by the organizational framework supporting this study (Woods & Mitchell, 2005). The models provide information about how individuals perceive disease states, the likelihood of illness, strategies for coping or managing symptoms and when/where to seek health care and support (Chrisman & Kleinman, 1983; Mechanic, 1962; Mechanic, 1986). Because they are rooted in the context of community and family, an individual's beliefs and perceptions of risk are value and emotionally laden which heightens the fear and dread surrounding the perception of certain risks and may consequently increase the level of emotional and cortical arousal. Thus family history can influence risk perception thorough both cognitive and emotional mechanisms (Walter & Britten, 2002).

The emotional context may help explain why risk perceptions are not easily changed, even in the presence of contrary evidence (Slovic, 1987). It may also explain why individuals can differ in the risk they assign to a given health concern or treatment despite being presented with the same information. Many of the women in this dissertation study spoke of the influence of the WHI on their decision. Yet despite having similar understandings of the study findings, women's perceptions of their personal risks were quite varied and often situated in the context of their family health history.

The emotional nature of risk perception begs the question of how best to help women understand their risks in order to choose between their options with regard to discontinuing HT and managing symptoms. Two important considerations are framing and trust. Framing refers to the manner in which potential harms are presented. Almost half of US citizens are thought to have limited health literacy, which includes an inability to understand numbers and percentages

(Herxheimer, 2005; Rudd, Anderson, Oppenheimer & Nath, 2007; Torres & Marks, 2009).

Innumeracy certainly played a role in women's understanding of the WHI findings, influenced in part by the manner in which the findings were reported in the media and translated by health care providers to their patients (Genius, 2006; Haas et al., 2006). Although subsequent studies have explored models and frameworks for explaining risks to women (Johnson et al., 2006), some of the women in the current study, including several health care providers, expressed conflicting and inaccurate knowledge about their perceived risks. A few women even acknowledged distrust or skepticism as to the accuracy of the information they were given by their providers.

Although perceived risk may be increased by fear, it may be dispelled by *trust*. It is important, therefore, that women receive information about HT and HT discontinuation from providers that they trust. Unfortunately, women in this study did not always believe that the information they received from their providers was accurate, adequate or took into account their personal situations and needs. These concerns are not conducive to the development of a trusting and therapeutic relationship.

Sadly, some of the findings in the current study are not markedly different from those of the pre-WHI and early post-WHI studies. Despite the increase in awareness of the challenges women encounter when stopping HT, there appears to be little change in the way that women are supported as they attempt to discontinue HT. Many of the women received their menopause related care exclusively from MDs. In a recent qualitative study exploring women's decision making about HT (Theroux, 2010), women described feeling empowered by engaging in a shared decision making process with a nurse practitioner (NP). Care for midlife women attempting to discontinue HT may be enhanced by including nurses and NPs knowledgeable about menopause and skilled in decision coaching (Carpenter, Byrne & Studts, 2011; Theroux,

2010). Several women in this study did actually comment that the counseling and support they received from they received from an NP was a positive and calming influence on their experience.

Also disturbing in the current study were the discrepancies in discontinuation recommendations given by health care providers as well as women's reluctance to seek support and advice within their social circle for fear of negative comments. This points to an increasing polarization in current opinion about HT in both the lay and health/research literature. Many other women's health issues, such as childbirth and breastfeeding, have also been dichotomized. This leads to inconsistencies in women's health care and diminishes the quality of their care. Providers, researchers and policy makers need to develop strategies to bridge these divides in order to ensure that women receive health care that is safe and equitable.

### Implications

The findings of the study led to the development of recommendations that could be implemented in order to promote better health care for women discontinuing HT.

Table 20.  
*Practice, Research and Policy Implications*

Practice	Research	Policy
Assessing readiness to stop Assessing beliefs Closer monitoring and support Improved communication with providers Improved access to alternate symptom management strategies Shared medical appointments Decision making and lifestyle coaching competency Individualized risk assessment and counseling	Theories and models Symptom clusters Symptom interference Non-VMS Interference scales Longitudinal studies Discontinuation methods	Health promotion for mid-life women Health literacy initiatives Partnering with the community Industry standards

## **Implications for Practice**

Several practice implications have already been discussed in the previous discussion. For example, it may be helpful to assess women's beliefs about menopause and VMS using established measurements prior to initiating HT discontinuation. Determining a woman's readiness to stop may decrease the rate of resumption related to women not being fully prepared or committed to discontinuing. General decision models such as the stages of behavior change (Prochaska et al., 1994) or HT-decision specific models (Woods et al., 1998) may be useful to guide understanding of a woman's beliefs about stopping at a given time. Developing better decision coaching skills would enhance providers' ability to counsel and support women at this crossroad.

Lifestyle coaching would also be an important skill (Theroux, 2010): despite the fact that women stopping HT have greater risks of developing osteoporosis and CVD, only about half the women said their providers offered this information. Assumptions were made that women already knew what to do but this may not always be accurate. Studies have also shown that providers are not always knowledgeable about how to educate about exercise (Anis et al., 2003; Rogers et al., 2002).

Both decision-making and lifestyle coaching must be based upon a thorough assessment of each woman's risks. Women were very emphatic in their desire for counseling and care that was personalized and relevant to their individual needs and life status. Providers must also strive to provide information that is up-to-date, accurate and balanced so that women develop more trust in providers' ability to support them.

Many women clearly wanted more support from their providers when stopping HT. This would be especially critical for women with a history of affective disorders who may have a higher risk of developing clinical depression. Support need not always be face-to-face but could

come in the form of telephone or online communication therefore providers need to be able to offer a variety of communication methods to their patients. Health care providers may also wish to consider alternative forms of providing care to these women. For example, shared medical appointments may provide a mechanism for women to receive more support and education from their providers (Thacker, Maxwell, Saporito & Bronson, 2005) as well as build connections with other women, another desire that women expressed. Women in the past have described a feeling of isolation as they traversed HT discontinuation (Bond & Bywaters, 1999),

Women stopping HT may benefit by learning about relaxation strategies or receiving other therapies such as CBT which may help them to 'just deal with' their symptoms, that is, foster a sense of self-efficacy in symptom management. However, not all providers are equipped to offer the range of therapeutic options that may be helpful. Providers may need to build networks of community resources that offer alternate therapies so that women discontinuing HT will have better access to a variety of modalities and symptom management strategies.

### **Implications for Research**

Health practice could be enhanced by the development of menopause-specific theories and models for decision-making and symptom management. The organizational framework (Woods & Mitchell, 2005) used in this study may provide a good start in this endeavor but it has several limitations that became apparent during the data analysis. For example, in the framework symptom perception and evaluation are depicted as linear processes. In reality, women described perceiving and evaluating symptoms as though they were occurring simultaneously thus the two processes may actually overlap. The experience of symptoms was also iterative: women moved back and forth through the stages. Finally the list of potential influential factors was limited and did not allow for factors that may bridge both physiologic and sociocultural definitions.

It may also be possible to adapt existing models from other disciplines to be more menopause and HT-specific. For example, the Commonsense Model (Leventhal, Weinman, Leventhal & Phillips, 2008) may be particularly useful in understanding women's appraisals of risks as it specifically incorporates representations of fears and dangers as salient to choices for coping strategies. This model has already been successfully used in other menopause-based research (Hunter & O'Dea, 2001) and may be applicable for further HT discontinuation research. An uncertainty framework (Mishel, 1990) could also serve to support research on this topic.

Research also needs to be directed toward explorations of symptom burden, symptom clusters and symptom interference to better understand their impact and where interventions need to be targeted to minimize symptom distress. As variations in reporting of interference among the women in this study testify, it would be important to assess these factors using both quantitative and qualitative methods. The HFRDIS was limited because it did not capture interference from non-VMS; therefore instruments for measuring interference from multiple symptoms would be helpful for understanding the disruptions wrought by other menopause and HT-induced symptoms.

Longitudinal studies incorporating both physiological and self-report measures of VMS would help to elicit a more detailed understanding of the entire HT-discontinuation experience and the changes that occur over time. Further studies on various methods of discontinuation would also be pertinent. Finally, grounded theory could provide a better understanding of the complex process that women undertake in deciding to stop or resume HT.

### **Implications for Health Policy**

The findings from this study underscore the need for changes in health policy. First, there needs to be a greater emphasis in both health care and society on health promotion initiatives for

mid-life women. These initiatives must be available and accessible to all women regardless of ethnicity, location, insurance or financial status in order to eliminate existing disparities and barriers to quality health care. This may require more partnering with resources within communities, as previously discussed, in order to build health care teams that promote and provide health and illness prevention strategies specific to the needs of the women within those communities. However, it also speaks to the need for the development of regulations and standards of practice for other health-related industries such as exercise-fitness training and mind-body practices.

In order to improve health outcomes, there is a need to improve health literacy so that women can understand basic health information and make more informed health care decisions (Genius, 2006). This includes not only improving women's capacity to understand health information but also helping providers and researchers realize that the way they communicate information and risk may result in confusion, misunderstanding and distrust of both the messenger and the message (Herxheimer, 2005).

### **Limitations**

There were a number of limitations to this study. The cross-sectional design prevented exploring changes in women's experiences over time. Because some participants stopped HT over one year ago, their responses may have been subject to recall bias. Social desirability bias in responses must also be considered with any research using a volunteer sample.

The smaller number of women who resumed HT also limited the ability to make quantitative comparisons across strata. Another limitation was related to the fact that one-third of the sample was health care providers; this particularly limited the findings of Specific Aim 4 as

many women were already knowledgeable about health promotion strategies they needed to initiate once stopping HT.

The participants in this study were a relatively homogenous group despite the fact that they came from multiple states. Many researchers believe that the potential for recruiting participants from varying ethnic/cultural/racial populations is enhanced with Internet research (Best & Krueger, 2004; Im et al., 2008; Mann & Stewart, 2004). Im and colleagues (2008) were able to obtain an ethnically diverse sample of 192 mid-life women through study announcements posted at Internet discussion groups for mid-life women. However, it has also been noted that non-Caucasian women use HT with less frequency than European-Caucasian women therefore recruiting from the Internet and using a web-based survey, as well as limiting participation to English-speakers (Im & Chee, 2002), may have made it more difficult to recruit a diverse sample. It was hoped that placing advertisements on websites visited by non-Caucasian women would foster a diverse sample however no participants were recruited from these sites. Diversity of participants was an important goal for this study as sociocultural contexts are key concepts in the organizational framework. Thus the relative homogeneity of participants may limit qualitative generalizability (Morse, 1999) or the ability to make extrapolations from the findings to similar situations in women's health care (Patton, 2002).

Another limitation that arose from the on line format was the tendency for women to make abbreviated responses to the open-ended questions. This necessitated more email correspondence to elicit further information as well as more telephone interviews than were originally anticipated. Future studies using an on line format could be improved by using a series of email correspondence for the open-ended questions, or perhaps developing a website site where the study questions could be posted. On line focus groups (asynchronous) could also be



used and may perhaps enhance connection and communications between the researcher and participants as well as among participants. This could foster intersubjectivity which would improve the validity of the study.

### **Conclusions**

The findings from this study show that women discontinuing HT still encounter many challenges in the form of troublesome symptoms and diminished QoL with little to guide them as to the best strategies to manage their symptoms. Consequently some resume HT while others endure much disruption in their personal and professional lives and QoL. Confused and uncertain because of conflicting research findings and recommendations, women feel that they travel this path alone as evidenced by the overarching theme *a solitary journey*. Factors that may make this experience more distressful are primarily related to the symptoms themselves and include symptom *burden and interference*, symptom clusters and sensitivity to symptoms. Women's beliefs about menopause, reasons for stopping HT and readiness to stop may also influence the outcome of their efforts. All of these factors are salient in women's *risk appraisal* and the choices they make as to how to navigate the path of HT discontinuation. In addition, there continue to be inconsistencies in the amount and quality of information and support that women receive from health care providers during this journey adding to women's distress.

These findings lay the foundation for implementing changes in practice and policy to improve care and support for women choosing or needing to discontinue. There is a great need for individualized counseling about symptom management and health promotion and better communication between women and their providers. Strategies that enhance efficacy for coping with symptoms may be of benefit during this challenging transition. More research is needed to develop better guidelines for counseling and caring for women as they are discontinuing HT.

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## APPENDICES

## Appendix A

### Glossary

**Menopause**—a women's final menstrual period (FMP) defined after 12 months of amenorrhea

**Menopause transition**—the time between the onset of menstrual and endocrine changes and the FMP

**Perimenopause**—early menopause transition through 12 months post FMP, sometimes used synonymously with the term climacteric

**Premenopause**—literally \_before menopause, 'ambiguous; term should not be used

**Postmenopause**—after the FMP (Early postmenopause is defined as five years since the FMP marked by ovarian hormone function dropping to a permanent level as well as accelerated bone loss. Late postmenopause goes from 5 years post-FMP to demise.)

**Induced menopause**—due to removal of ovaries or ablation of ovarian function

**Premature menopause**—FMP at or under age 40

**Early menopause**—FMP at or under age 45

**Estrogen Therapy (ET)**—unopposed estrogen, estrogen-only; primarily for women who have had a hysterectomy

**Estrogen plus progestogen therapy (EPT)**—a combination of estrogen and a progestogen (either progesterone or progestin, a synthetic form of progesterone)

**Hormone therapy (HT)**—may encompass both ET and EPT but more frequently used for EPT

**Biidentical hormones**—chemically identical to those produced by the body

**Custom compounded hormones**—biidentical hormones that are compounded in variable doses and mediums based on individual women's preference and tolerance

**Cyclic EPT**—either or both estrogen and a progestogen given for specific days each month

**Continuous EPT**—estrogen and/or progestogen given every day each month

## Appendix B

### STRAW Stages/Nomenclature of Normal Reproductive Aging in Women

<b>Menopause</b>	12 months of amenorrhea following the final menstrual period (FMP). reflecting a near complete, natural decrease of ovarian hormone secretion.
<b>Menopausal Transition</b>	Encompasses both Stages -2 (early) and -1 (late) defined by menstrual cycle and endocrine changes. The menopausal transition begins with variation in menstrual cycle length occurring in a woman who has a monotropic FSH rise and ends with the FMP.
<b>Postmenopause</b>	Encompasses Stages +1 (early) and Stage +2 (late). Early postmenopause is defined as five years since the FMP and reflects a further dampening of ovarian hormone function to a permanent level as well as the period of accelerated bone loss. Stage +1 was further subdivided in segment "a" -- the first 12 months after the FMP and "b" the next four years. Stage +2 begins at 5 years post FMP but the duration is variable since it ends with the woman's death. Further divisions may be warranted as women live longer and more information is accumulated.
<b>Perimenopause</b>	Literally means "about or around the menopause." It begins with Stage -2 and ends 12 months after the FMP. Climacteric is sometimes used synonymously with perimenopause, however neither should be used in scientific papers but only with patients and in the lay press.

Final menstrual period (FMP)								
Stages:	-5	-4	-3	-2	-1	0	+1	+2
Terminology:	Reproductive			Menopausal transition		Postmenopause		
	Early	Peak	Late	Early	Late*	Early*		Late
Duration of stage:				Perimenopause				
	Variable			Variable		(a) 1 yr	(b) 4 yrs	until demise
Menstrual cycles:	Variable to regular	Regular		Variable cycle length (>7 days different from normal)	≥2 skipped cycles and an interval of amenorrhea (≥60 days)	Amen x 12 months	None	
Endocrine:	Normal FSH		↑ FSH	↑ FSH		↑ FSH		

\* Stages most likely to be characterized by vasomotor symptoms, ↑: elevated.  
Adapted from Soules, MR et al. Fertil Steril 2001; 76:874. (©2009 UpToDate®)

## Appendix C

### Hormone Therapy Timeline

TIME PERIOD	HORMONE THERAPY EVENTS
1920-1929	1928 – Progesterone identified 1928 – Searle introduces estrogen patch 1929 – Estrogen identified 1929 – Attempts to treat menopause using amniotic fluid from cattle
1930-1939	1930 – Pregnant mares' urine found to contain estradiol 1933 – Emmenin, made from pregnant mares' urine, becomes first HT 1938 – Estradiol synthesized 1939 – DES replaces Emmenin a more potent estrogen; it was used for the next 30 years to treat threatened miscarriage 1939 – progesterone synthesized
1940-1949	1941 – Mexican yams first used for progesterone 1942 – Premarin introduced
1950-1959	1952 – First synthetic progesterone 1959 – Barbara Seaman, feminist & women's health advocate, recognizes link between use of estrogen and endometrial cancer Link found between low estrogen and osteoporosis
1960-1969	1966 – Robert Wilson writes <i>'Feminine Forever'</i>
1970-1979	1971 – FDA withdraws approval for DES 1973 – Clinical trials using estrogen in men were halted due to increasing heart attacks in men 1975 – Ads by Wyeth for Premarin
1980-1989	1988 – Robert Wilson's wife dies of breast cancer
1990-1999	1996 – WHI begins
2000-2011	2002 – EPT arm of WHI stopped in July due to a decrease in global health index based on increased in CVD, stroke, breast cancer and thromboembolism risks 2004 – ET arm of WHI stopped 2007--Report of decrease in breast cancer among women stopping HT after the WHI 2007-2011--Subgroup analyses of WHI show evidence for a 'window of opportunity' for cardiovascular benefits with early initiation of HT as well as no increase in breast cancer rates in women on ET only

## Appendix D

### Websites for posting study advertisement

SITE	TYPE OF SITE	NUMBER OF MEMBERS	PERMISSION
www.minneapauz.com	Discussion groups/forums at menopause information website	4100	Granted
Peri/Menopause	Special interest group on Facebook (social networking site)	400	Granted
BoomerWomenSpeak	Discussion groups/forums at midlife women's information/networking website	Unknown	Granted
Linked-In Power Women	Special interest group for women on Linked-In (networking site)	883	Granted
Linked-In Women of Wisdom	Special interest group for midlife women on Linked-In (networking site)	185	Granted
Ethnic Majority	Information website for African-Americans, Asian-Americans, and Latinos	Unknown	Granted
Asian-Nation	Information website for Asian Americans	Unknown	Granted
LatinoLA	Information website for African-Americans, Asian-Americans, and Latinos	Unknown	Granted
Perimenopause Blog	Blog related to menopause health issues	Unknown	Granted
Journey to Wellness	Information website related to African-American health	Unknown	No response
Asians in America	Website/online magazine for Asian Americans	Unknown	No response
Menopaus	Listserv	Unknown	Granted
Red Hot Mamas	Discussion groups/forums at menopause information website	8600	No response
Craig's List	Social networking site	Overall site: 50 million hits/month	NA
UMass/Worcester Message Board	University intranet message board	Unknown	Granted
Clinician 1	Online professional networking group for advance practice clinicians	Unknown	Granted
Nurse Practitioners in Women's Health	Online professional networking group for women's health NPs	Unknown	Granted
NHNPlistserv	Listserv for NPs in New Hampshire	Unknown	Granted



## APPENDIX E

### Advertisement on Internet Website

#### Menopause Research Study!!

I am a Nurse Practitioner and also a doctoral student at the University of Massachusetts Graduate School of Nursing in Worcester, MA. For my dissertation, I am conducting a research study about women's experiences with discontinuing menopause hormone therapy.

Currently there is little information to support women who are stopping menopause hormone therapy. This study will explore women's experiences with discontinuing menopause hormone therapy. The results will provide information for developing programs to educate and support women during hormone therapy discontinuation.

Women who have attempted to discontinue menopause hormone therapy within the past two years are eligible. Participation in the study will involve one 30-60 minute interview (either online through a protected server at the university or by telephone). During the interview, participants will be asked to describe their experiences of discontinuing hormone therapy and then answer a short questionnaire. Compensation will be provided.

This study has been approved by the Committee for the Protection of Human Subjects in Research at the University of Massachusetts/Worcester and is being supported by a grant from the American Academy of Nurse Practitioners.

If you are interested in participating in this study please call (508-877-3316) or email me at [mary.fischer@umassmed.edu](mailto:mary.fischer@umassmed.edu). You may also respond via *(insert appropriate website name such as Facebook or LinkedIn)*.

Thank you for your consideration and I look forward to hearing from you soon.

Mary Fischer

Women's Health Nurse Practitioner

Certified Menopause Practitioner

University of Massachusetts/Worcester

Graduate School of Nursing



## Appendix F

### UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

#### FACT SHEET

The title of this research study is:

#### **Women's Experiences of Hormone Therapy Discontinuation**

- A. You are participating in a research study.
- B. The purpose of this research study is to explore women's experiences of discontinuing menopause hormone therapy. This study has been approved by the Committee for the Protection of Human Subjects in Research at the University of Massachusetts/Worcester is being supported by a grant from the American Academy of Nurse Practitioners
- C. You will be enrolled in this research study for up to 12 months. The primary portion of the study will consist of an interview and responding to a questionnaire which will take about 30-60 minutes and may be conducted either online or by telephone. There is a possibility that we may need to contact you again to clarify your responses to the questions or for the purpose of verifying the findings.
- D. As part of this research study, you will be required to complete a short questionnaire as well as an interview describing your experiences while stopping menopause hormone therapy.
- E. The risks associated with participating in this research could be emotional distress from recalling your experience of discontinuing hormone therapy.

There is a very small risk to your privacy and confidentiality as no website or computer system is 100% safe from hacking. To minimize this risk, the study questions will be located at a secure Intranet website with restricted access. Contact with the researcher will be through the firewall-protected University of Massachusetts email system.

There are also some steps that each participant can take to decrease this risk. Whenever possible, do not use a shared computer to contact the researcher or access the study as records of these exchanges may be saved in the Internet service provider's (ISP) logs or in hidden cookies on the computer's hard drive. Be sure your system has adequate antivirus protection. When responding to questions from the researcher, if possible insert your responses into a Word document and send this document as a password-protected attachment (check your operating manual for instructions on how to password protect a document).

- F. **You can choose to withdraw (quit) from this research study at any time without any penalty to you. If you choose to withdraw from this research study, the care you receive at UMass Memorial Medical Center will not be affected.**
- G. If you have any questions about this research study, you can call Mary Fischer MSN WHNP-BC NCMP at 508-877-3316. If you prefer to speak with someone not associated with this research study, please call the Committee for the Protection of Human Subjects in Research at the University of Massachusetts Medical School. The telephone number is (508) 856-4261.

## Appendix G

### Sample Flyer (with/without tabs)

Theroux-Fischer/GSN/HT Discontinuation v. 3.28.10

UMMS HSC Docket # H- 13696  
(MAH IRB Approval 6.10)

## **Have You Ever Taken Menopause Hormone Therapy?**



## **Have You Attempted to Stop Taking Hormone Therapy?**

**If So, You Could Be Part of a Research Study sponsored  
by the University of Massachusetts/Worcester  
Graduate School of Nursing**

The purpose of the study is to understand what it is like to stop  
taking menopause hormone therapy.

Results will help researchers develop education and support programs  
for women who are discontinuing hormone therapy.

**If you are interested in taking part in the study, you should:**

- be over 45 years old and in good general health
- have taken menopause hormone therapy for 3 or more months
- have attempted to stop hormone therapy in the past two years
- agree to participate in an interview lasting 30-60 minutes (online or telephone)
- be able to read and write English and have access to the Internet or a telephone

**Compensation will be provided.**

**Contact: Mary Fischer MSN WHNP-BC NCMP  
(PhD candidate)  
508-877-3316**

**Mary.fischer@umassmed.edu**



## Appendix H Sample Brochure

### WOMEN'S EXPERIENCES OF DISCONTINUING HORMONE THERAPY FOR MENOPAUSE

Thank you for your interest in this important study which will explore women's experiences while stopping hormone therapy for menopause.



If you have stopped or attempted to stop hormone therapy for menopause, you may be eligible to participate!

(MAH IRB Approval 6.10)



### WOMEN'S EXPERIENCES OF DISCONTINUING HORMONE THERAPY FOR MENOPAUSE

For more information, please contact:

Mary Fischer MSN  
WHNP-BC NCMP  
(Doctoral student)

508-877-3316

Mary.fischer@umassmed.edu



### Have You Ever Taken Hormone Therapy for Menopause?

### Have You Ever Attempted to Stop Taking Hormone Therapy?



### WOMEN'S EXPERIENCES OF DISCONTINUING HORMONE THERAPY FOR MENOPAUSE

#### A Research Study

University of Massachusetts/Worcester  
Graduate School of Nursing

Therous-Fischer/GSNHT Discontinuation v. 3.28.10 UMMS HSC Docket #H-13696

### WOMEN'S EXPERIENCES OF DISCONTINUING HORMONE THERAPY FOR MENOPAUSE

The purpose of the study is to explore women's experiences when stopping or trying to stop hormone therapy for menopause.



This information will help researchers and health care providers to prepare and support women who are discontinuing hormone therapy for menopause.

(MAH IRB Approval 6.10)

#### ELIGIBILITY

If you are interested in taking part in the study, you should:

- be over 45 years old and in good general health
- have taken menopause hormone therapy for 3 or more months
- have attempted to stop hormone therapy in the past two years
- agree to participate in an interview lasting 30-60 minutes (online or telephone)
  - be able to read and write English and have access to the Internet or a telephone



#### WHAT IS INVOLVED?

Women in this study will be asked to:

- Answer several interview questions
- Complete a short questionnaire
- Respond to follow-up questions from the researcher at a later time
- Provide feedback on the study findings

Compensation will be provided.

This study has been approved by the Committee for the Protection of Human Subjects in Research at the University of Massachusetts/Worcester and is supported by a grant from the American Academy of Nurse Practitioners.

Therous-Fischer/GSNHT Discontinuation v. 3.28.10 UMMS HSC Docket #H-13696

## Appendix I

### Fact Sheet for Clinical Staff

#### **Women's Experiences of Hormone Therapy Discontinuation**

Mary Fischer MSN WHNP-BC NCMP (Doctoral Student)

University of Massachusetts Graduate School of Nursing/Worcester

**Overview:** a mixed methods study to explore women's experiences discontinuing hormone therapy (HT) for menopause

**Goal:**

- to develop a better understanding of the factors that influence recurrent symptoms, quality of life (QoL) and discontinuation outcome
- This information will help to develop counseling and support interventions for women discontinuing HT

**Principal Investigator:** Rosemary Theroux WHNP-BC PhD, Associate Professor (advisor)

**Co-Investigator:** Mary Fischer MSN WHNP-BC NCMP, Doctoral Student

*(This study is the doctoral dissertation research of the co-investigator.)*

**Sample:** 40 women who:

- are 45 years of age or older;
- are in good health;
- are in either the late menopause transition or postmenopause;
- have used HT for a minimum of 3-4 months;
- have attempted to discontinue HT (by any method of discontinuation) within the past 2 years, regardless of outcome;
- are able to read, speak and write English; and,
- have Internet or telephone access.

**Procedures:**

- Informed Consent and screening questionnaire reviewed and returned to co-investigator
- Online Participants sent email with password, participant ID and link to Survey Tool or telephone call to participant to schedule telephone interview
- Participant logs into study and completes interview questions and questionnaire or co-investigator contacts participant at scheduled time and administers interview questions and questionnaire
- Participant may be recontacted by co-investigator for clarification of responses
- Participant may be recontacted by co-investigator for member checks

**Compensation will be provided.**

**Human Subjects Protection.** This study has been approved by the Human Subjects Committee at the University of Massachusetts Medical Center/Worcester. The welfare, privacy and confidentiality of all participants will be considered at all times. No identifying information about participants will appear in the transcripts or dissertation. Participation is voluntary. No harm to participants is anticipated.



## Appendix J

### Participant recruitment sources

Recruitment	Number
Health care provider referral	4
Colleague referral	2
Community posting	2
Facebook	1
Menopaus Listserv	1
UMassMed Intranet	2
Minniepauz	1 + 1 referral
New Hampshire NP Listserv	3
Nurse Practitioners for Women's Health	4 + 1 referral
Craig's List	12

### Location of participants

Location	Number
Massachusetts	9
New Hampshire	3
Maine	3
New Jersey	1
Delaware	1
Maryland	1
Georgia	1
Florida	1
Pennsylvania	1
Ohio	1
Illinois	1
Missouri	1
Louisiana	1
Texas	1
Nevada	1
Idaho	1
California	4
Hawaii	1
Canada	1

## Appendix K

### Screening and Demographic Questionnaires

#### Screening Questions (accompanying consent)

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Study ID # \_\_\_\_\_

Name	
Date of Birth	
When was your Final Menstrual Period?	
Have you ever taken hormone therapy for menopause?	Yes <input type="checkbox"/> No <input type="checkbox"/>
How long did you take hormone therapy?	_____years
What type of hormone therapy did you take?	Pill <input type="checkbox"/> Patch <input type="checkbox"/> other _____
Have you attempted to stop hormone therapy?	Yes <input type="checkbox"/> No <input type="checkbox"/>
How?	Cold turkey <input type="checkbox"/> Tapered <input type="checkbox"/>
What is your current hormone therapy (HT) status?	No HT <input type="checkbox"/> Resumed HT <input type="checkbox"/> Taper in process <input type="checkbox"/>
Can you read and write English?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Do you have any health issues that would prevent you from completing the questionnaires and interview?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have you ever been told you have cancer, heart disease or any other serious medical condition?	Yes <input type="checkbox"/> No <input type="checkbox"/>

### Demographic, Health & Menopause-related Questionnaire

DEMOGRAPHIC & HEALTH INFORMATION	RESPONSES
Age at last birthday	_____ years
Race/Ethnic-Cultural background	1 = African-American 2 = Hispanic 3 = Asian American 4 = Native American 5 = Caucasian 6 = Other (specify: _____)
Location of residence	1 = city 2 = suburbs 3 = rural
Education level	_____ years completed
Occupation	Specify: _____
Occupational status	1 = working full-time 2 = working part-time 3 = on disability 4 = retired 5 = seeking employment 6 = student 7 = other (specify: _____)
Financial strain (difficulty paying for basics)	1 = Very hard 2 = somewhat hard 3 = not very hard at all 4 = don't know 5 = refused 6 = other (specify: _____)
Marital status	1 = Married 2 = widowed 3 = single 4 = separated 5 = divorced 6 = living with partner 7 = other (specify: _____)
Gravity/Parity	Number of pregnancies: _____ Number of births: _____
Children	Number: _____
Age at final menstrual period	_____ years
Type of menopause	1 = natural 2 = surgical 3 = induced
When started hormone therapy	Year: _____
Reason for starting hormone therapy	1 = symptom relief 2 = prevent bone loss 3 = prevent heart disease 4 = recommended by health care provider 5 = suggested by family or friend 6 = other (specify: _____)



Type of hormone therapy (more than 1 answer possible)	1 = oral/pill 2 = patch 3 = spray 4 = gel 5 = estrogen alone 6 = both estrogen & progesterone 7 = combined (taking both everyday) 8 = cyclic (taking progesterone intermittently) Dose (if known): _____
Length of time on HT	_____ years
Health care provider for menopause concerns	1 = MD (medical doctor) 2 = DO (osteopathic physician) 3 = NP (nurse practitioner) 4 = CNM (certified nurse midwife) 5 = PA (physician's assistant) 6 = Homeopath 7 = ND (naturopathic physician) 8 = Traditional Chinese Medical Practitioner 9 = Chiropractor 10 = Other (specify: _____)
Number of office visits in the past year for menopause-related concerns	_____ number of visits
Sources of information about menopause	1 = health care provider 2 = family member 3 = friend 4 = TV 5 = newspapers, magazines, books 6 = Internet 7 = Other (specify: _____)
Please list any current health problems	_____ _____ _____
Please list any other medications	_____ _____ _____
Please list any over-the-counter or non-prescription medications	_____ _____ _____
Please list any complementary therapies (such as herbal medications, massage, acupuncture)	_____ _____ _____
Please describe your location during this interview	Place: (work/home/other) _____ Weather: _____ Time of day: _____
How did you hear about this study?	1 = website (specify: _____) 2 = health care provider (who: _____) 3 = referred (by whom: _____) 4 = community flyer (where: _____) 5 = other (specify: _____)

## Appendix L

### Menopause Rating Scale (MRS)

Which of the following symptoms apply to you at this time?

(X ONE Box For EACH Symptom) For Symptoms That Do Not Apply, Please Mark "None".

Symptoms:

	none	mild	moderate	severe	extremely severe
Score =	0	1	2	3	4
1. Hot flashes, sweating (episodes of sweating) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Heart discomfort (unusual awareness of heart beat, heart skipping, heart racing, tightness) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Sleep problems (difficulty in falling asleep, difficulty in sleeping through the night, waking up early) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Irritability (feeling nervous, inner tension, feeling aggressive) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Anxiety (inner restlessness, feeling panicky) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Physical and mental exhaustion (general decrease in performance, impaired memory, decrease in concentration, forgetfulness) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Sexual problems (change in sexual desire, in sexual activity and satisfaction) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Bladder problems (difficulty in urinating, increased need to urinate, bladder incontinence) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Dryness of vagina (sensation of dryness or burning in the vagina, difficulty with sexual intercourse) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Joint and muscular discomfort (pain in the joints, rheumatoid complaints) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Appendix M

### Hot Flash Related Daily Interference Scale

Please circle one number to the right of each phrase to describe how much **DURING THE PAST TWO WEEKS**, hot flashes have **INTERFERED** with each aspect of your life.

	Do not interfere										Completely interfere	
	0	1	2	3	4	5	6	7	8	9	10	
1. <b>Work</b> (work outside the home and housework)	0	1	2	3	4	5	6	7	8	9	10	
2. <b>Social activities</b> (time spent with family, friends, etc)	0	1	2	3	4	5	6	7	8	9	10	
3. <b>Leisure activities</b> (time spent relaxing, doing hobbies, etc.)	0	1	2	3	4	5	6	7	8	9	10	
4. <b>Sleep</b>	0	1	2	3	4	5	6	7	8	9	10	
5. <b>Mood</b>	0	1	2	3	4	5	6	7	8	9	10	
6. <b>Concentration</b>	0	1	2	3	4	5	6	7	8	9	10	
7. <b>Relations with others</b>	0	1	2	3	4	5	6	7	8	9	10	
8. <b>Sexuality</b>	0	1	2	3	4	5	6	7	8	9	10	
9. <b>Enjoyment of life</b>	0	1	2	3	4	5	6	7	8	9	10	
10. <b>Overall quality of life</b>	0	1	2	3	4	5	6	7	8	9	10	

**Appendix N**  
**Well-being Scale**

QUESTION	RESPONSE
How have you been feeling in general during the past month?	5 = in excellent spirits 4 = in very good spirits 3 = in good spirits mostly 2 = I have been up and down in spirits a lot 1 = in low spirits mostly 0 = in very low spirits
How happy, satisfied or pleased have you been with your personal life during the past month?	5 = extremely happy, could not have been more satisfied or pleased 4 = very happy most of the time 3 = generally satisfied, pleased 2 = sometimes fairly satisfied, sometimes fairly unhappy 1 = generally dissatisfied, unhappy 0 = very dissatisfied, unhappy most of the time
My daily life was full of things that were interesting to me during the past month.	5 = all of the time 4 = most of the time 3 = a good bit of the time 2 = some of the time 1 = a little of the time 0 = none of the time
I felt cheerful and lighthearted during the past month.	5 = all of the time 4 = most of the time 3 = a good bit of the time 2 = some of the time 1 = a little of the time 0 = none of the time

## Appendix O

### General Health Status and QoL Questions

QUESTION	RESPONSE
How would you rate your overall quality of life?	5 = very good 4 = good 3 = neither poor nor good 2 = poor 1 = very poor
How satisfied are you with your health?	5 = very satisfied 4 = satisfied 3 = neither satisfied nor dissatisfied 2 = dissatisfied 1 = very dissatisfied

## Appendix P

### Qualitative Interview Guide & Additional Prompts

<b>SPECIFIC AIMS</b>	<b>QUESTION</b>	<b>PROMPTS/PROBES (postulated a priori)</b>
Explore women's experiences of HT discontinuation	Please tell me about your experience when stopping hormone therapy	<p>Why did you start HT?</p> <p>Why did you decide to stop?</p> <p>Tell me about any symptoms you had when you were discontinuing HT. What symptoms do you have now? Were the symptoms better, worse, same as before you started HT?</p> <p>What did your symptoms mean to you? What did stopping HT mean to you?</p> <p>Was this experience what you expected? Was there anything that surprised you about this experience?</p> <p>How has your life changed since stopping HT?</p>
Describe the personal characteristics and sociocultural contexts that influence symptom perception, evaluation and response among women who have attempted to discontinue HT	Please tell me what you think might have influenced this experience and your decision to stay off /resume HT	<p>Describe what or who helped you when you were stopping hormone therapy. Describe what or who made the experience difficult.</p> <p>Looking back, what would have made this experience better or more tolerable for you?</p>
Explore the impact of HT discontinuation on women's quality of life (QoL)	<p>Please describe your QoL while you were stopping HT.</p> <p>Please tell me about your QoL now.</p>	<p>What does QoL mean to you? What is the most important part of QoL to you?</p> <p>How did stopping HT impact on your QoL? How did your QoL impact on your decision to remain off/resume HT?</p>
Discuss women's preferences for counseling and support during HT discontinuation	Please tell me what information your health care provider gave you when you were stopping hormone therapy	<p>How did you feel about the information you received?</p> <p>Was it enough?</p> <p>What else would have been helpful for you to know? What do you think women stopping HT should know before they stop?</p> <p>Where do you get information about menopause?</p>

### **Follow-up Questions/Prompts Evolving with Interview Analysis**

I would like to learn more about your discontinuation experience but first I'd like to back up a bit and ask you about your experiences before beginning hormones and while you were taking them.

First, please describe what menopause means to you. For example: some women think of it negatively (getting older for example) while other women think of it positively (no more worries about getting pregnant). What do you think influenced your beliefs about menopause?

I've found that some women going through menopause are very interested in taking hormone therapy, some are very much against it and some are undecided or prefer to keep an open mind and re-evaluate their decisions as time goes on. Please tell me what your thoughts were about hormone therapy before you started taking it and what you think influenced your beliefs about hormone therapy? Had you ever considered taking hormone therapy before your provider recommended it to you? Was it recommended for symptom relief or health promotion?

Did any friends or family or co-workers encourage you to take hormone therapy or try to discourage you from taking it? Why or why not?

You mentioned that you started hormone therapy for symptom relief. Please tell me more about those (and any other) symptoms: for example, how long you had them, how troublesome they were, what you had been doing to manage them before hormone therapy?

Did you notice any other symptoms or changes that you thought were related to menopause? If so, can you also tell me more about those?

Some women notice triggers for their hot flashes (caffeine, stress, heat and so on). Have you noticed any triggers? If yes, what are they?

Please describe how you felt after you started taking the medication? Did you notice any changes or improvement in your symptoms or overall health? Did your family or friends notice any changes? Were your symptoms completely relieved?

Did you have any negative effects from the hormones and if so what were they? How did you manage them? How did they impact on your feelings about hormone therapy?

How long did it take you to make the decision to stop? Was it a difficult or easy decision to make, and why? Did anyone help you to make your decision?

What influenced your decision to stop the way you did? If you had to discontinue again, would you do it the same way? Why or why not?

What was the reaction of your family/friends/co-workers when you stopped hormone therapy?

Please tell me more about the symptoms you had when you were discontinuing HT: for example, how soon did they resume, how long did they last, were the symptoms better, worse, or

the same as before you started taking hormone therapy? What did you do to help you manage these symptoms? How did you feel when the symptoms came back? Were you surprised that some symptoms came back or were you expecting this?

Did you notice any new symptoms or changes that you attribute to stopping hormone therapy? If so, were you surprised to experience new symptoms or changes? What did you do to help you manage these symptoms?

On a scale of 1 to 10, with 10 being the worst you have ever felt, how would you rate your experience of stopping hormone therapy and why? Was this experience what you expected? Was there anything that surprised you about this experience? Did this experience change your feelings or beliefs about menopause and how? Why?

How has your life changed since stopping HT? Did you 'learn anything new about yourself' as a result of this experience?

\*\*\*\*\*

Some women have described certain factors that have made the experience of stopping hormone therapy easier or more difficult, for example, the weather, stress, beliefs about hormone therapy, other health issues, support from family or friends, exercise or meditation, or other medications, to name just a few. Looking back, please describe any factors that you think made the experience more difficult or made the symptoms more uncomfortable. How did they make it worse?

Can you think of anything that might have made stopping hormone therapy easier for you or helped you to manage the symptoms and if so, how?

Many women who stop hormone therapy resume taking it. What has helped you to remain off? You mentioned that you are still symptomatic -- what are you doing to manage or cope with your symptoms now?

Is there anything that would make you consider resuming? If you had to stop hormone therapy again, what would you do differently?

What would make you consider stopping hormone therapy again?

Some women have discussed that they knew intuitively or had a sense that it was right time to stop. Did you have a similar sense and if so can you describe what factors or issues made you feel that this was the right time?

\*\*\*\*\*

Please tell me what quality of life means to you or how you define quality of life? In general, what makes your quality of life better or worse? Some people say that quality of life is made up of many different parts such as health, symptoms, ability to participate in daily living activities, social support and so on. What do you consider to be the most important aspects(s) of your quality of life and why?



Please rate your quality of life before you started hormone therapy? How did it change when you were taking hormone therapy? Which aspect of your quality of life was most affected by starting hormone therapy and how? Which aspect was most affected by stopping hormone therapy?

Does your quality of life impact on your decision to remain off/continue taking hormone therapy?

How long had you been tapering/how long after you stopped before you noticed that your quality of life was changing?

Some participants have described a type of hormone 'energy' or increased enjoyment in life that just was not there before or after taking hormones -- have you noticed anything like that? Please tell me more about this.

You indicated that you are currently having some symptoms that moderately interfere with your work, mood, sleep and sexuality. Many women who have symptoms such as yours report that their quality of life is very low. Yet you reported that your overall quality of life is good. How would you explain this difference? What makes your quality of life good even though you are having some interfering symptoms?

What would it take to make your quality of life very good?

\*\*\*\*\*

Did you feel your health care provider supported your decision to stop hormone therapy? How did you feel about the information you received from your health care provider about stopping hormone therapy? Was it enough? Please tell me what information would have been helpful for you to know when you were stopping?

When you started hormone therapy, did your provider make any recommendations to you about how long to stay on hormone therapy?

When did your health care provider learn that you stopped hormone therapy? How did your health care provider react when you told him you had stopped? Did he support resuming hormone therapy or has he tried to encourage you to stop again? Did you feel your health care provider supported your decision to stop hormone therapy, even though s/he may not have agreed with it?

Did s/he provide you with any additional support or counseling (phone calls, prescriptions for other medications and so on) during or after this process? Did you provider discuss any other recommendations such as making changes in your exercise or diet?

What else would have been helpful for you to know? What do you think women stopping HT should know before they stop?

You also said you saw a health care provider \_\_\_\_ times in the past year for menopause issues. Can you tell me more about those issues: which symptoms or concerns did you have and how you and your provider decided to manage them.

What advice would you give to other women stopping hormone therapy?

What advice would you give to women who are thinking about starting hormone therapy?

## Appendix Q

### **DISCONTINUING MENOPAUSE HORMONE THERAPY STUDY** **MEMBER CHECK**

The Member Check is a very important part of Qualitative research: it helps the researcher to know that s/he has been true to the voice of the participants when analyzing the data. Below is a summary of the preliminary findings from the open-ended question and interview components of this study. Please review this summary and provide your feedback to let me know if I have accurately represented your experiences with discontinuing hormone therapy. Please also provide any additional comments or thoughts that come to mind as you read these findings and if your hormone therapy status has changed (stopped or resumed) please provide any updates.

#### **Before Hormone Therapy**

- Women's expectations and beliefs of menopause were mixed: either looking forward positively or worrying about negative changes.
- Many women were surprised when they started having uncomfortable symptoms during menopause. The most common symptoms mentioned were hot flashes/night sweats, lack of sleep, and moodiness. Most women had more than one symptom.

#### **Voices:**

*"Menopause always carried a negative connotation for me--'old', finality, loss of youth, loss of sex appeal & sex drive, body changes, loss of fertility/sexuality."*

*"I thought it was going to be a breeze, it's kind of like you are not going to have any more periods, you are not going to have any more worries..."*

*"I didn't really think the hot flashes would be as bad as they are...so even though it was winter I had the window open and I was sleeping on ice packs and I would be awake most of the night flipping the pillow over...Besides the hot flashes, lack of sexual desire, just general sleeplessness."*

**Comments:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

#### **Deciding to take Hormone Therapy**

- Before menopause began, women also had mixed feelings about hormone therapy: some believed it could be helpful if necessary while others expressed concerns about risks they had heard in the media.
- Although a few women took hormone therapy only for health promotion purposes, the majority of women eventually decided to take hormones because of symptoms that were interfering with women's daily activities and impacting on their quality of life.
- Women carefully considered hormone therapy benefits and risks before starting these medications.

#### **Voices:**

*"I decided to take hormone replacement therapy way before I reached menopause ...."*

*"Prior to menopause, I was opposed to HRT due to my strong opposition to any meds... "*

*"...then I started not sleeping ... one day I was walking in the city and I was so exhausted I was holding on a wall to walk because I was really ready to fall over and I just stopped myself and I thought, okay this is not normal..."*

*"...they were coming almost like on schedule all of the time...it was embarrassing at work but the worst part was I just wanted to get some sleep...I was emotional, I felt beaten..."*

**Comments:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### **Hormone Therapy: Relief or Worry?**

- Most women found that hormone therapy relieved their symptoms and gave them back a sense of normalcy or control.
- Several women described an increase in energy or interest in life that was not present off hormones.
- Some women developed side effects or concerns while taking hormones (bleeding, bloating, or weight gain) and a few women did not get complete relief of their symptoms.
- Women who had concerns about hormones before menopause expressed worries about continuing to take hormone therapy even though they felt better on it.

#### **Voices:**

*"I loved the elimination of the hot flashes and my memory seemed to be a bit better."*

*"...my husband notices that I am not waking up as much, not waking him up... I am much more level now...."*

*"On hormone therapy, I'm the way I've always been – enjoying life, finding pleasure in both big and little things in my days. Off therapy, everything lost its shine. I could be in a beautiful garden but would have no interest in smelling the roses – I would just feel annoyed over the heat, thorns, etc."*

*"I was getting a lot of headaches while taking HT..."*

*"I had irregular bleeding & staining for days/weeks at a time."*

**Comments:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### **Deciding to stop Hormone Therapy**

- There were many reasons why women stopped hormone therapy: advice from providers, curiosity, convenience, cost, incomplete relief or concerns about side effects or risks.
- Some women described having an intuition or feeling as to whether or not it was the right time to stop.

#### **Voices:**

*"I began weaning off hormone therapy ... because my GYN had recommended discontinuation..."*

*"The prescription ran out and...this really isn't making that big of a difference and I don't want to spend the money and also ... I don't know how much of a danger it is."*

*"I knew that I would intuitively know when it was time to come off and it would feel right to me..."*

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### **A Personal Journey: The Experience of Discontinuing Hormone Therapy**

- Although a few women had no symptoms after stopping, most women had a recurrence of symptoms and in some instances even noted new symptoms that were not present before hormone therapy.
- Most women who noticed symptoms thought they were the same or a little milder than before taking hormone therapy but several women reported that their symptoms were worse when they stopped.
- For many women, the recurrent symptoms greatly interfered with their daily activities and quality of life.
- After careful consideration of the benefits and risks, about a third of the women resumed hormone therapy. Some of them were still worried about risks and hoped to stop completely some day; several had stopped and started multiple times.
- Many but not all women who remained off hormones found that their symptoms eased or disappeared with time. Although some women stated they would go back on hormones if it were not for the side effects or risks, others reported feeling better being off hormones and happy that they stopped.

### **Voices:**

*"When I stopped HRT, the hot flashes and problems sleeping started up again within 3-4 days. They were both horrible – wet hair from the hot flashes and the need to change bedding 2-3 times a night."*

*"I went back on...mostly because I wasn't able to sleep. It was a tough decision because I hate to be on anything..."*

*"...actually stopped and started several times before I 'finally quit' Each time I tapered down to quit, my symptoms would roar back in a vengeance... I would be dysfunctional at work sometimes..."*

*"I resumed because I was always miserable. What kind of life is it when one is always miserable and trying to hide the hot flashes from others?"*

*"I feel a lot better without the patch. I feel a lot more healthy."*

*"One less worry in my life, worrying about the long term effects of the medication that I'm taking."*

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### **Women's Words of Wisdom**

- Some women discussed stopping hormone therapy with their health care providers but many stopped without mentioning it to their providers.
- Information given by providers was inconsistent and often limited and most women did not receive any ongoing support or counseling during discontinuation even if they were having a difficult time.

- Women offered suggestions for what health care providers should offer to other women stopping hormones: specific information about what to expect, more support from health care providers, support groups, peer support.
- Women also made suggestions for women starting or stopping hormone therapy: evaluate symptoms, get more information, weigh risks and benefits carefully, and get support along the way.

**Voices:**

*"I would make sure that they know what they are doing, do your research, talk to your doctor. I wish my doctor did talk to me a little bit more about it to put me more at ease rather than saying oh just don't worry about it."*

*"I would love to have groups where women talk to each other...."*

*"Make sure it is something you want to do because you need to know the side effects as well as the good benefits."*

*"I just wish that my doctor would have taken more time to listen to my concerns..."*

**Comments:** \_\_\_\_\_  
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**Updates or additional information:**

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 \_\_\_\_\_  
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If you would like to receive a summary of the final results, please indicate whether you prefer to receive it by email or as a hard copy and provide your contact information below:

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Email copy ☐ Paper copy ☐

Thank you once again for your participation!

Mary Fischer MSN WHNP-BC NCMP, Doctoral Student

mary.fischer@umassmed.edu

1-508-877-3316

Rosemary Theroux WHNP-BC PhD, Associate Professor (advisor)

University of Massachusetts Graduate School of Nursing

55 Lake Avenue North

Worcester, MA 01655