# GETTING THE WORD OUT: SHARING THE BENEFITS OF VAGINALLY APPLIED TESTOSTERONE CREAM IN THE PERIMENOPAUSAL YEARS

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A Thesis

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by

Carolyn Cook

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Testosterone has been used for over 40 years to treat symptoms of decreased libido in menopausal women. This thesis describes a qualitative study in which six women of perimenopausal age were interviewed about their experiences with testosterone replacement therapy using a vaginally applied testosterone cream. In-depth interviews were conducted and four themes emerged: seeking to combat the consequences of aging, gaining benefits of testosterone, balancing the side effects, and appreciating the male perspective. While the benefits and side effects of testosterone use in women are well-documented in the literature, little has been written about women's overall perceptions of their experiences with testosterone. This information may be useful to nursing educators, students, and nurses practicing in the field of Women's Health, all of whom

should be aware of the potential benefits of testosterone therapy in women, as hormone replacement therapy becomes more widespread.

# CHAPTER I

# INTRODUCTION TO THE STUDY/PROJECT

Testosterone, although traditionally thought of as a male hormone, is also produced by women, in the ovaries and the adrenal glands. As testosterone levels decline with age and menopause, women may experience symptoms of what is now being referred to by some researchers as an "androgen insufficiency syndrome," as well as the common symptoms of menopause (Basaria & Dobs, 2006; Cameron & Braunstein, 2004; S. R. Davis & Burger, 2003; Guay & Davis, 2002; Davison & Davis, 2003). Traditionally, testosterone is viewed as a "male hormone." This view may deprive women of effective treatment for these symptoms, as recent research has demonstrated the benefits of testosterone replacement therapy for women (J. A. Simon, 2001).

Testosterone replacement therapy (TRT) is becoming increasingly popular for perimenopausal and postmenopausal women, both alone and in conjunction with estrogen replacement therapy (ERT) (A. S. Davis, Gilbert, Misiowiec, & Riegel, 2003). Prescriptions for testosterone are being written at a rapidly escalating rate. A 500% increase in the sale of pharmaceutical testosterone was documented between 1993 and 2001 (Margo & Winn, 2006). Doctors wrote nearly 2 million prescriptions for testosterone in 2002 (Noonan, 2003). About 20% of testosterone prescriptions are written for women (Yoffi, 2005).

Women may experience many significant and largely undesirable changes, both physically and emotionally, during menopause and the perimenopausal period**.** In addition to the commonly reported physical discomforts, such as hot flashes and night sweats, women may experience mood swings, a decreased energy level, irritability, and diminished sexual desire and/or response. While estrogen replacement therapy has generally been effective in treating the most common somatic complaints of menopause, it may not be as effective in treating changes in mood, energy level, and libido (A. S. Davis et al., 2003; Palacios, 2008). Women experiencing a deficient level of testosterone, due to natural or surgically induced menopause, may experience decreased libido, hot flashes and other menopause-related symptoms (Burger & Papalia, 2006; S. R. Davis & Burger, 2003; Guay & Davis, 2002). Recent research has clearly demonstrated the benefits of exogenous testosterone therapy in the treatment of menopausal symptoms (Abdullah & Simon, 2007; Bolour & Bronstein, 2005; Burger & Papalia, 2006; Buster et al., 2005; Drillach & Davis, 2007; Goldstat, Briganti, Tran, Wolfe, & Davis, 2003; Shifren et al., 2006), and yet there appears to be a lack of consensus among physicians regarding the effectiveness or appropriateness of this therapy (Basaria & Dobs, 2006; Davison & Davis, 2003; Drillich & Davis, 2007; Margo & Winn, 2006; Padero, Basin & Freidman, 2002; Somboonporn, 2005).

In an informal survey of University-affiliated and private practice Obstetrician/Gynecologists, conducted by the author, responses to the question, “Do you prescribe testosterone for your female patients?” ranged from, “No, I don’t think it’s safe,” to, “I would, for libido, but there’s no formulation that’s good for women,” to, “Yes, all the time… patients love it.” Dosages and formulations mentioned by these

physicians (*N*=7) included oral Estratest, testosterone gel in an unspecified dose, and testosterone cream in preparations ranging from .25 to 2 percent. Many physicians also reported being unfamiliar with the dosing of testosterone preparations for women, stating, "I would need to look it up."

In a survey of prescribing practices in one community, conducted by Freeman (2004), physicians reported a variety of indications and formulations for the use of testosterone in pre- and postmenopausal women. The most common indications were libido, hot flashes, and low energy. The most common formulations prescribed by respondents were 1) oral preparations of esterified estrogens and methyl-testosterone (Estratest or Estratest HS), 2) testosterone compound cream, and 3) testosterone troches. In a letter to the editor of the Journal of Women's Health, Freeman (2004) noted that there are few data to advise the clinical practice of physicians prescribing testosterone supplementation for women. Padero, Bhasin, and Freidman (2002, p. 1131) stated that "in spite of the growing media attention, the issue of androgen supplementation in women has remained controversial in the scientific community."

In an article entitled "Androgen Supplementation in Older Women: Too Much Hype, Not Enough Data," Padero et al. (2002, p. 1131) stated "there is enormous public interest in and media fascination with the issue of androgen supplementation in women." At the same time, with regard to testosterone supplementation, Guay and Davis (2002, p. 108) stated that there is a "paucity of statistically significant research to justify [testosterone] treatment despite its increasing usage." It has also been noted that little is known about women's perceptions of the benefits and risks of testosterone therapy (A. S. Davis et al., 2003).

This study will examine the perceptions of perimenopausal women using vaginally applied testosterone compound cream, which has rarely been studied alone in the current literature. The compounded formulation of testosterone may constitute a higher dose than that which is derived from the currently available oral preparations and the doses may vary widely among individual users. The author is interested in determining what symptoms were present in the survey group prior to receiving the testosterone cream, what dosing instructions were given to the respondents, and what the expectations of these women were prior to initiating the therapy. The author also hopes to discover what the women's perceptions were of the benefits and side effects experienced during the course of their treatment.

## Background of the Problem

There is no androgen preparation that has been specifically approved by the FDA for the treatment of androgen insufficiency in females. The concept of an androgen deficiency in women is itself questionable, because there is only minimal correlation between low serum testosterone levels and female sexual functioning (Basaria & Dobs, 2006; Basson, 2007; A. S. Davis et al., 2003), and, as noted by Padero et al. (2002, p. 1131), "androgen deficiency has no clear-cut definition."

Female sexual functioning is a complex issue, involving many non-hormonal variables, as well as physical, psychological and relationship issues. Female sexual dysfunction is at best a condition with a multifactorial etiology. At the same time, many authors have associated a testosterone deficiency with absent or greatly diminished sexual desire, lack of satisfaction or difficulty with orgasm, lack of energy, persistent

unexplainable fatigue, and the lack of a sense of well-being (Bartlick & Kaplan, 1999; Basaria & Dobs, 2006; Bolour & Braunstein, 2005; Cameron & Braunstein, 2004; S. R. Davis & Burger, 2003; Guay & Davis, 2002; Davison & Davis, 2003).

Normal changes of aging have the greatest impact on androgen levels in women. Testosterone levels decline by about 50% between the ages of 20 and 40 in women, with the greatest decline occurring in the early reproductive years (Cameron & Braunstein, 2003). Menopause itself does not necessarily precipitate sexual dysfunction (Basson, 2007; Bolour & Bronstein, 2005), and androgen insufficiency is not a consequence of natural menopause (S. R. Davis & Burger, 2003). Evidence to the contrary notwithstanding, testosterone supplementation in the perimenopausal period has been demonstrated to improve both mood and sexual functioning in women (Chudokov, Ben Zion, & Belmaker, 2007; Freeman, 2004; Goldstat et al., 2003). Literature from the North American Menopause Society (NAMS) stated,

> Published evidence data from randomized controlled trials, although limited, indicates that exogenous testosterone, both oral and nonoral formulations, has a positive effect on postmenopausal women's sexual functioning, primarily desire, arousal and orgasmic response, in women after spontaneous or surgically induced menopause. (2005, p. 497)

## Statement of the Problem

Androgen therapy has been used for over 40 years to treat low libido and sexual dysfunction in women, but this generally involved the off-label use of various testosterone preparations (Bolour & Braunstein, 2005) in a variety of formulations and dosages. Topical testosterone compounds have not been studied singularly in the current literature. There is little to document the effectiveness or the side effects of these

preparations from the perspective of women using these products. It is not known whether women perceive that the benefits outweigh the side effects. This study will explore the lived experience of women who have undergone treatment with vaginally applied testosterone compound cream.

## Relevance/Importance of the Project

Little is known about women's perceptions of the benefits and risks of testosterone therapy, and how their experience with TRT compares to their expectations (A. S. Davis et al., 2003). There is currently a "paucity of research to justify treatment," and most forms of treatment currently in use are based on anecdotal evidence from patients (Guay & Davis, 2002, p. 108). Despite recent interest in this topic, there are still no clear indications for the use of exogenous testosterone in women (Drillach & Davis, 2007). There is an exceptional lack of data with regard to women's responses to the use of compounded testosterone cream, although it is among the more commonly prescribed formulations in some communities.

Lisa Martinez, RN, JD, writing in *AWHONN Lifelines* (journal of the Association of Women's Health, Obstetric, and Neonatal Nurses) stated, "Some professionals have concerns that if testosterone is approved for women it could be abused or misused. To minimize this concern, women and health care providers need to be educated on the appropriate uses of [this] hormone" (2006, p. 211). She further noted that "we have few options for treating female sexual health disorders" and, with regard to options in hormone treatment for women, "we have lack of knowledge…" and a need for more studies, as well as more research dollars, contributed to this research (2006, p. 211).

## Conceptual Framework

The conceptual model for this project is Dorothea Orem's Self-Care Deficit Theory of Nursing. While Orem's model focuses, to some extent, on self-care deficits in patients/clients, emphasis is also placed on the patient's ability to perform self-care, with the nurse acting as an educator or consultant. Self-care theory is also relevant to education and research that focuses on issues related to self-care. Orem (2001) discusses three basic variations in nursing systems: 1) wholly compensatory nursing systems, 2) partly compensatory nursing systems, and 3) supportive-educative nursing systems. In the supportive-educative model, the patient/client is capable of performing self-care actions, but lacks the necessary knowledge or skill. The nurse's role is one of support, guidance, and teaching. The individual's requirement for help is confined to decision-making and the acquisition of knowledge. When this has occurred, the individual, according to the model, can take responsibility for his/her own health. By asking women to reflect on their knowledge and experience related to the use of vaginally applied testosterone cream, this research will encourage them to take greater responsibility for their own health and better equip them to make health care decisions.

Orem (2001) stated,

> In modern society, adults are expected to be self-reliant and responsible for themselves and for the well-being of their dependents. Most societies accept that persons who are helpless, sick, aged, handicapped, or otherwise deprived should be helped… Thus both self help and help to others are valued by society as desirable activities. Nursing as a specific type of human service is based on both values. (p. 81)

The goal of self care is to empower clients, and Orem's model focuses on the individual's ability to perform activities to promote his or her own health and well-being. By

reflecting on their embodied understandings, experience with, and knowledge related to the use of testosterone cream, women will be empowered to make health-promoting decisions and improve their well-being. The client's competence in self-care impacts the quality of his/her life. In the educative-development system, the client has the primary responsibility for his or her personal health, and the nurse assists in this process through informing and motivating clients in the practice of activities to maintain and enhance their health. In the case of TRT, the client and the RN should both be well informed about usual and safe doses and the potential for undesirable side effects to be experienced by the client.

Asking the study participants to reflect on their perceptions regarding the effectiveness of testosterone cream underscores their involvement in the decision making process about whether to initiate testosterone treatment and subsequent decisions about whether to continue to use it. Involvement in the qualitative research process, by participating in the interview, encourages women to reflect on any associated side-effects and the specified benefits of treatment. Women are thus encouraged to consider the research literature on the subject, to weigh their personal experiences against reports in the literature, and to select an approach to treatment that best supports their own health and well-being.

## Purpose of the Study

The purpose of the study is to document the lived experience of individual women using topical testosterone cream, with or without other hormone replacement therapy, through a qualitative interview process.

## Research Question

What is the lived experience of women specific to the efficacy and side effects of testosterone replacement therapy using vaginally applied testosterone compound cream?

## Definition of Terms

### Androgen

Any of several steroids, produced as hormones by the testes or made synthetically, that promote development of male sexual organs and male secondary sexual characteristics ("Androgen," 2008). Testosterone is an androgen.

### Androgen Insufficiency Syndrome or Female Androgen Insufficiency Syndrome (FAIS)

A syndrome recognized by some authors as being characterized by reduced libido, diminished well-being and lowered mood due to decreased serum testosterone levels (Burger & Papalia, 2006; Papalia & Davis, 2003).

### Compounding

A pharmaceutically compounded prescription is one that has been individually prepared to address the needs of a particular patient. Almost any type of medication can be created through compounding. During the 1950s, compounding became less common as commercially available medications became readily available (Pharmacy Solutions, 2009).

Compounding Pharmacy

A pharmacy where drugs are made from raw materials and chemical compounds, as opposed to one which sells mass-produced, pre-packaged drugs from a pharmaceutical manufacturer (Pharmacy Solutions, 2009).

Hormone (Testosterone) Replacement/ Therapy/Supplementation

Used synonymously in this case; refers to the use of exogenous testosterone administration in women, regardless of the route, for the purpose of hormone replacement. Hormone replacement therapy (HRT) is the use of synthetic or natural female hormones to make up for the decline or lack of natural hormones produced in a woman's body (“Hormone Replacement Therapy,” 2008).

## Qualifications of the Researcher

The researcher is a Registered Nurse and graduate student with 17 years experience in the field of women’s health and obstetric and gynecological nursing. The researcher holds a Bachelor of Science degree in Nursing and a Bachelor of Arts in Psychology. The researcher has completed the coursework for the CSU, Chico MSN program, including courses in Nursing Research and Advanced Pathophysiology.

In summary, exogenous testosterone therapy for women has been utilized in many countries for a number of years. While no form of androgen therapy for the treatment of sexual dysfunction in women has been approved by the FDA for use in the United States, the off-label use of compounded testosterone cream is becoming more common. Substantial use of compounded testosterone products by women has been reported (Shifren et al., 2006). No large controlled trial of testosterone therapy in

naturally menopausal women has ever been reported (Shifren et al., 2006). Little is known about the dosing, efficacy and side effects of the compounded form of testosterone cream currently being prescribed in the U.S., nor is there much available information about women's perceptions of this therapy or their perceived responses to treatment with compounded testosterone. Chapter II will focus on the current literature regarding testosterone treatment in women.

# CHAPTER II

## INTRODUCTION

This chapter will discuss the current literature regarding the use of exogenous testosterone in women and the currently available information regarding the benefits and side effects of this therapy. Various formulations of testosterone have been discussed in the literature, but there is little available research that specifically addresses the use of vaginally applied testosterone compounded cream. The proposed study will examine the subset of women who have used the vaginally applied formulation of testosterone and document their perceptions of the therapy.

## Literature Review

### Biology of Androgens in Women

The term “androgens” refers to a group of 19-carbon steroid hormones that includes testosterone. Although they are often associated with “maleness” and male sex-linked characteristics, androgens are the most abundant circulating sex hormone in women, as well as in men. Levels of testosterone fluctuate during the menstrual cycle, with a midcycle peak and higher levels noted during the luteal phase than in the follicular phase (S. R. Davis & Burger, 2003).

In females, the biosynthesis of androgens takes place in the ovaries and the adrenals. In addition, peripheral structures such as adipose tissue, muscle and fat convert

androgens and androgen precursors from the ovaries and adrenal glands into androgens which then enter the circulation. Androgens are also the obligatory precursors of estrogen synthesis (S. R. Davis & Burger, 2003).

Androgen synthesis and serum androgen levels decrease with age. In women, the mean serum testosterone level at age 40 is approximately half what it was at age 21, with a decrease of an additional 25% occurring between ages 42 and 50. It is unclear whether there is a further decline after menopause (Cameron & Braunstein, 2003).

Oral preparations of testosterone are metabolized in the liver. For this reason, hepatotoxicity may be a consequence of oral testosterone replacement (Bolour & Bronstein, 2005; Nathorst-Böös, Flöter, Jarkander-Rolff, Carlström, & Schoultz, 2006). Oral testosterone preparations are also associated with the suppression of circulating high-density lipoprotein (HDL) cholesterol, potentially leading to an increase in low-density lipoprotein (LDL) cholesterol (Somboonporn, Davis, Sief, & Bell, 2007). The long term use of oral testosterone preparations in women is hence undesirable.

In females, androgens undergo aromatization, a chemical change involving the addition of a benzene ring to the androgen compound, which then becomes an estrogen compound. Androgens which have been aromatized to estrogens may increase serum estradiol levels (and hence breast cancer risk) as well (Abdallah & Simon, 2007; Basaria & Dobs, 2006).

Measurement of Testosterone in Women

Laboratory measures of testosterone include total testosterone, free testosterone, and steroid hormone binding globulin (SBHG). Free testosterone appears to have the greatest bioavailability, and a free testosterone index can be calculated as the

sum of the free testosterone and a portion of the bound testosterone. However, many laboratory assays are not sensitive enough for the concentrations normally found in women (S. R. Davis & Burger, 2003; Margo & Winn, 2006).

Serum levels of androgens have very little correlation with women's sexual functioning (Basson, 2007). No association between specific androgen levels and low sexual function has been documented in the literature (Basaria & Dobs, 2006; Katz, 2006), and no specific testosterone level has been clearly linked to a clinical syndrome of testosterone insufficiency (NMAS, 2005). Some clinicians have argued that there is a lack of normative data with regard to testosterone ranges in women, and hence no need to measure testosterone levels in order to make a presumptive diagnosis of androgen insufficiency (Bolour & Braunstein, 2005). While many authors have identified and defined an Androgen Insufficiency Syndrome in women (Basaria & Dobs, 2006; Burger & Papalia, 2006; Cameron & Braunstein, 2003; S. R. Davis & Burger, 2003; Guay & Davis, 2002; Davison & Davis, 2003), a 2005 study by Davis and colleagues, published in the Journal of the American Medical Association, concluded that there is no absolute cutoff level for androgens that defines female androgen insufficiency syndrome, and that the measurement of androgen levels does not aid in making the diagnosis of insufficiency (S. R. Davis, Davison, Donath, & Bell, 2005).

Androgens and Female Sexuality

Many of the studies regarding the use of testosterone replacement therapy have focused on women who have undergone surgical removal of the uterus and ovaries. It has been noted by various authors that these women frequently experience a decrease in sexual response, difficulty reaching orgasm, and a diminished or absent libido

(Abdallah & Simon, 2007; Bartlick & Kaplan, 1999; Basaria & Dobs, 2006; Basson, 2007; Buster et al., 2005). Bartlik and Kaplan, writing in the Harvard Mental Health Letter (1999), noted that many women who undergo hysterectomy lose some sexual functioning, and went so far as to state that, "many women would forgo elective hysterectomy entirely if they were aware of this complication" (p. 4). They further stated that women with testosterone deficiency will report a "loss of responsiveness in all phases" (p. 4) of sexual arousal; they often "…lose the capacity for …orgasm as well; women who could formerly be brought to orgasm in 5 to 10 minutes may now require a half hour or more of intense clitoral stimulation…" (p. 4) to achieve orgasm. Most studies addressing this population have documented the benefits of exogenous testosterone supplementation for the surgically menopausal woman (Basaria & Dobs, 2006; Buster et al., 2005; Chudakov et al., 2006; S. R. Davis et al., 2005; Goldstat et al., 2003; Kingsburg, 2007; Palacios, 2007; J. Simon et al., 2005).

Androgen Insufficiency Syndrome

Currently there are four types of female sexual dysfunction recognized by the American Psychological Association in the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (American Psychological Association, 2001.) These include sexual desire disorders (hypoactive and aversion), sexual arousal disorder, orgasmic disorder, and sexual pain disorders, such as dyspareunia and vaginismus. Hypoactive Sexual Desire Disorder (HSDD) is believed to be the result of a deficiency in androgens (Cameron & Braunstein, 2003).

A sudden unexplained increase in the prevalence of female sexual dysfunction (43% of American women in an oft-cited national study [Basaria & Dobs, 2006; Buster et

al., 2006; Laumann, Paik, & Rosen, 1999, as cited in Katz, 2006]) has not escaped researchers. Basaria and Dobs (2006) noted that the incidence of female sexual dysfunction may increase to as high as 88% during the menopausal transition. Other authors have noted that an increase in the diagnosis of this type of "disorder" has coincided with the marketing of products used to treat it (Ducharme, 2005; Palacios, 2007). The editorial members of *Prescrire International* stated, "A new disorder, 'hypoactive sexual desire disorder' (HSDD), has recently been promoted, just around the same time as the market release of testosterone patches" (Kopp, 2007, p. 190). The European counterpart of the FDA, the European Agency for the Evaluation of Medical Products [EMEA], recently approved the testosterone patch for use in the treatment of HSDD in European women (Palacios, 2007). Additionally, in an editorial entitled "In Search of Female Viagra," it was noted that, "in the case of sexually related medications, many critics believe that drug companies are defining *middle age* as a condition that needs to be treated with medication" (Ducharme, 2005, p.48).

True physiologic androgen insufficiency can be the result of disorders such as hypopituitarism, adrenal insufficiency, ovarian failure, and Turner's syndrome; or medical intervention such as radiation, chemotherapy, or surgical removal of the ovaries, resulting in "surgical menopause." Exogenous oral glucocorticoid therapy and oral estrogen therapy can also induce an androgen insufficiency (S. R. Davis & Burger, 2006).

Although there is no clear cut definition, many authors have identified an androgen deficiency or an "androgen insufficiency syndrome," as defined by such subjective symptoms as diminished libido, a decreased sense of well-being, and unexplained fatigue, as well as the objective measures of decreased muscle mass and

increased bone loss (Bartlick & Kaplan, 1999; Burger & Papalia, 2006; S. R. Davis & Burger, 2006; Papalia & Davis, 2003; Padero et al., 2002). Basaria and Dobs (2006) cited the Princeton Consensus Conference meeting of an international panel of experts from various fields of medicine and women's health in June 2001, which established diagnostic criteria for the diagnosis of Female Androgen Deficiency Syndrome (FADS). The committee found the presence of the above mentioned symptoms to be a prerequisite for the diagnosis of FADS, but stated that the symptoms alone were insufficient to make the diagnosis. They suggested the additional criteria of adequate estrogenization, and free testosterone levels below the lowest quartile of the normal range for the patient's age.

Age is the most common reason for declining androgen levels (Basaria & Dobs, 2006; Bolour & Braunstein, 2005). Age-related androgen deficiency can occur in women as young as their 30's, due to the normal physiological decline in testosterone levels associated with aging (Burger & Papalia, 2006). The effects of supplemental testosterone in premenopausal women are largely undocumented.

Effects of Androgen Replacement

Testosterone has been used for decades to treat sexual dysfunction in menopausal women (Martinez, 2006; Palacios, 2007). Women with decreased libido and/or the subjective symptoms of "androgen insufficiency" as described above, have been noted to respond well to testosterone replacement (Abdallah & Simon, 2007; Buster, et al., 2005; Cameron & Braunstein, 2003; A. S. Davis et al, 2003; S. R. Davis et al., 2005; S. R. Davis & Burger, 2003; Freeman, 2004; Katz, 2006; Kingsberg, 2007; NAMS, 2005; Nathorst-Böös et al., 2006; Palacios, 2007; Papalia & Davis, 2003; Shifren, 2004; Shifren et al., 2006; J. Simon et al., 2007). Testosterone replacement therapy shows

promise in treating many of the common complaints of menopausal and perimenopausal women.

A statistically significant improvement in sexual function, as well as mood and sense of well-being, was also reported in one of the few studies using younger, pre-menopausal subjects (Goldstat et al., 2003). This study used a sample of 34 pre-menopausal women with low libido and a mean age of 39.7 years. The women used a daily dose of 10 mg of 1% testosterone cream, applied to the thigh, for two 12-week periods, separated by a 4-week period. The Psychological General Well-Being Index, a validated, 22-item, multiple-choice questionnaire, was utilized to assess general well-being. The Sabbatsberg Sexual Self-Rating Scale, which was used to assess sexual function, is a multiple choice questionnaire that contains items related to seven aspects of sexuality (sexual interest, sexual activity, satisfaction of sexual life, experience of sexual pleasure, sexual fantasy, orgasm capacity, and sexual relevancy) and has been validated in premenopausal women.

The participants, thirty-four women with low libido, reported improvements in well-being, mood, and sexual function. In a randomized controlled crossover efficacy study, the authors noted statistically significant improvements in composite scores on both the Sabbatsberg Sexual Self-Rating Scale, and the Psychological General Well-Being Index in the testosterone group, as compared with placebo. No adverse effects were reported. The authors noted that the transdermal cream was well-tolerated, and that the improvement in the participants' scores was "substantial and clinically meaningful." The findings indicate that women in the latter premenopausal years may benefit from testosterone treatment for improved psychological and sexual health.

This study documents the potential benefits of testosterone treatment in women who are not menopausal. It is also one of the only available studies that focused on the use of testosterone cream. Most of the studies in the U.S. and Europe have focused on women using either oral combined estrogen/testosterone preparations or testosterone delivered transdermally by a patch.

Side Effects

Reports in the literature regarding the side effects of testosterone replacement therapy range from "well tolerated and devoid of serious side effects" (Cameron & Braunstein, 2003, p. 282) to "the risks associated with testosterone do not justify its use" (Kopp, 2007, p. 190). Commonly noted potential side effects include hirsutism, acne, clitoral enlargement, lowering of the voice, hair loss, weight gain, and lipid profile changes and hepatotoxicity with oral preparations (Abdallah & Simon, 2007; Bolour & Braunstein, 2005; Drillach & Davis, 2007; Nathorst-Böös et al., 2006; Shifren, 2004).

Androgen Preparations

Androgen preparations made by compounding pharmacies include pellets, creams, gels, drops and lozenges (Cameron & Braunstein, 2003). Other formulations include oral methyltestosterone or testosterone undecanoate, the transdermal testosterone patch, intra-muscular (IM) injections of testosterone enanthate or cypionate, and testosterone implants (Basaria & Dobs, 2006; Cameron & Braunstein, 2003; Drillach & Davis, 2007).

In the U.S., no existing androgen preparations have received FDA approval for the treatment of female sexual dysfunction. In 2004, after clinical trials in the U.S., the FDA voted not to approve a patch marketed by Procter and Gamble named "Intrinsa."

The only testosterone preparation made specifically for women that is produced by a pharmaceutical manufacturer is Estratest. It contains esterified estrogen in doses of either 1.25 mg with 2.5 mg methyltestosterone, or 0.625 mg estrogen with 1.25 mg testosterone, and is approved only for treatment of the vasomotor complaints of menopause (Bolour & Braunstein, 2005). Research has demonstrated that this combination improves sexual satisfaction in women to a greater extent than does the supplementation of estrogen alone (Basaria & Dobs, 2006).

Oral preparations of testosterone reduce both the production and the androgen binding capacity of SHBG, making them more biologically potent. However, oral preparations of testosterone also undergo first pass metabolism in the liver, making hepatotoxicity a potential side effect of therapy (Bolour & Braunstein, 2005). For this reason, a transdermal approach to testosterone delivery is often preferred.

The testosterone patch has been tested extensively in Europe, where, as noted above, it was recently approved for use in women. Topical preparations include testosterone cream or gel made by a compounding pharmacy. There are no published data on the safety or efficacy of these preparations (Bolour & Braunstein, 2005). The only research study that specifically addresses the use of vaginally applied testosterone cream was done in the Netherlands, using a single dose of 2mg of testosterone propionate and a sample of ten healthy premenopausal women. A significant rise in serum testosterone levels was noted, with the peak occurring 5.5 hours after application. The study concluded, however, that there was no effect on female sexual functioning (Apperloo et al., 2006). Upon further scrutinization, the limitations of this study were evident. It is a randomized, double-blind study. The sample consisted of 10 women, presumably 5 each

in the control and experimental group. The participants were given a *single* vaginal dose of testosterone or placebo, not a daily dose. It has been noted by more than one author that testosterone replacement in daily doses may take several weeks to be effective (Nathorst-Böös et al., 2006; Shifren et al., 2006).

In Apperloo et al.'s 2006 study, erotic video fragments and erotic fantasies were used as stimuli. The genital sexual response was measured using vaginal plethysmography. A plethysmograph is an instrument for measuring changes in volume within an organ, usually resulting from fluctuations in the amount of blood or air it contains (*Plethysmograph*, 2001). The "subjective" sexual response was measured not with a rating scale of female sexual response, (of which there are many), but with a "visual analog scale." In retrospect, the results of this study may have been interpreted incorrectly. It was documented that serum testosterone levels did increase significantly, and levels were described by the authors as "markedly elevated." The lack of "subjective sexual response" in women who were essentially exposed only to visual stimuli, and who did not participate in any type of sexual activity with a partner, hardly proves anything, except that female sexuality is complex; an observation that has already been well documented (Basaria & Dobs, 2006; Basson, 2007; Bolour & Braunstein, 2005; A. S. Davis et al., 2003; Guay & Davis, 2002; Drillach & Davis, 2007).

Burger and Papalia (2006) noted that one of the barriers to treatment of HSDD in women is the lack of satisfactory preparations of testosterone for use by women. According to Nathorst-Böös and colleagues (2006, p. 12), "the ideal androgen preparation should be easy to administer, produce stable serum levels, and not cause any negative effects on the liver." The compounded testosterone cream, applied vaginally, as

discussed in the above study, shows promise in this area. Although the sample size was exceedingly small, data show that the testosterone was well absorbed.

## Summary

The use of exogenous testosterone in women, although it has existed for decades, is controversial at best. Some Obstetrician/Gynecologist (OB/Gyn) physicians are not well versed in treatment options, and there appears to be a lack of consensus among the providers who do prescribe it with regard to dosing and choice of preparation. Lisa Martinez, a registered nurse and attorney for the Women's Sexual Health Foundation wrote in the *AWHONN Lifelines* (2005, p. 210) that "what many do not know is that testosterone has been given to postmenopausal women for decades… [and the] off-label use creates at times somewhat of a guessing game for the appropriate dose."

Although some large scale national studies have documented some degree of sexual dissatisfaction among nearly half of American women, its diagnosis and treatment is not a topic of inquiry among many women's health practitioners (Guay & Davis, 2002). Numerous studies have demonstrated the benefits of testosterone in improving women's sexual function (Abdallah & Simon, 2007; Basaria & Dobs, 2006; Burger & Papalia, 2006; Buster et al., 2005; Cameron & Braunstein, 2003; Davison & Davis, 2003; Goldstat et al., 2003), but very little is known about women's perceptions of the effects of vaginally applied testosterone cream. The one existing study in the literature that addressed this specific question had a very limited sample, as noted above, and some possible deficiencies.

Despite much discussion, there is still no clinical definition of androgen insufficiency, and its treatment remains controversial, as discussed above. Treatment guidelines are based mainly on anecdotal evidence. Studies have focused mainly on postmenopausal women, but benefits of testosterone therapy have been demonstrated in premenopausal women as well (Guay & Davis, 2002). Further study is also warranted regarding the dosing, efficacy, and side effects of testosterone compounds, especially vaginally applied testosterone cream.

Chapter III will describe the methods this researcher utilized to answer the question, “How do women perceive the efficacy and side effects of testosterone replacement therapy using vaginally applied testosterone compound cream?” The next chapter includes an in-depth discussion of the process of phenomenological research and discusses the research questions utilized. The issue of rigor in qualitative research is also addressed.

# CHAPTER III

## RESEARCH METHODOLOGY

The methodology utilized for this project was phenomenological research. Phenomenology is the study of structures of consciousness as experienced from the first-person point of view ("Phenomenology," 2008). The purpose of phenomenological research is to describe the participant's experience as it is "lived." Phenomenology, according to Moustakas, "is the first method of knowledge because it begins with 'things themselves'; it is also the final court of appeal" (Moustakas, 1994, p. 41). Moustakas (1994) further stated that phenomenology sets aside presuppositions, attempts to eliminate everything that represents a bias, and is a "readiness to see in an unfettered way, not threatened by the customs, beliefs and prejudices of normal science, by the habits of the natural world or by knowledge based on unreflected everyday experience" (p. 41).

Evidence from phenomenological research is derived from the participants' first-person reports (Moustakas, 1994). Participants were asked to verbally describe their perceptions of their experience with exogenous testosterone replacement therapy (TRT), using vaginally applied testosterone cream. Moustakas (1994) noted that in phenomenology, perception is regarded as the primary source of knowledge, one that cannot be disputed. Moustakas described the interview process as one that "involves an informal, interactive process and utilizes open-ended comments and questions" (p. 114).

He further noted that it is the responsibility of the interviewer to create a climate in which the participant will feel comfortable and respond in an honest and comprehensive manner. The interview should be lengthy and focus on the research question (Moustakas 1994).

The researcher utilized this process to examine the participants' experiences. Open-ended, probing questions were asked to elicit the subjects' responses. Study participants were asked about their reasons for initiating testosterone replacement therapy, their expectations, their perceptions of the effectiveness of TRT, and their experiences with and perceptions of the side-effects. Responses were tape-recorded, with the permission of the participants, and transcribed verbatim.

## Content

The interview was given orally, and took between 30 to 60 minutes to complete. All participants were assigned a number protect their anonymity. In this manner, quotes from participants were utilized without publicly identifying the source participant. Only quotes that cannot be linked to a specific participant were published. All transcripts were reviewed for responses that could identify a specific participant. Responses that included identifying information such as a participant's home town, name of practitioner, or other information that could be linked to a specific participant were modified.

A demographic questionnaire (see Appendix A) was administered. It included non-identifying demographic information, such as age, occupation, and questions about menstrual status and pertinent medications. The oral interview questions were designed to

elicit a description from the study participant of the lived experience with the treatment. Moustakas (1994) noted that, while the researcher may begin the interview with a set of questions aimed at evoking a comprehensive account of the experience of the subject (who he refers to as the "co-researcher") with the phenomenon, these questions may be altered, varied, or discarded entirely when the participant shares the full story of his experience (p. 114).

Probing questions were asked in order to gain greater depth of the data. The initial questions included the following:

1. What has been your experience with vaginal testosterone?
2. Tell me how well the testosterone worked for you.
3. What side effects did you experience?

## Population

The population was a convenience sample of women using a topical testosterone compound cream, applied vaginally. The expected sample size was five or six women. The sample group was accessed by having local pharmacists include fliers along with the prescriptions of patients who met the inclusion criteria. The subjects were asked to contact the researcher by phone to participate in an individual interview. A list of compounding pharmacists was obtained from an on-line local phone directory.

Six subjects were interviewed about their experiences with treatment using vaginally-applied testosterone cream. The interviews took place in either the home of the researcher, or the home of the participant, at the discretion of the subject. All of the subjects were middle-class Caucasian women. All were employed, and four of the six

subjects were nurses. All were in their late 40's to early 50's (age range 45-53 years), and all could be classified as "perimenopausal" by both their age group and their reported subjective complaints. Unlike the subjects of many published studies, all of the subjects in the study were experiencing a "natural" menopause; none had undergone a hysterectomy or oophorectomy. Four of the six subjects were married, one was living with a partner, and one was divorced and did not mention a current relationship. All were using (or had recently used) the vaginal testosterone cream daily in varying doses, with or without other hormones. Of the six, only two were using vaginally applied testosterone cream alone. Another was using the testosterone cream in combination with estrogen, and the remaining three were using testosterone cream as part of a "bioidentical" hormone replacement regimen that also incorporated estrogen and progesterone. The length of treatment time varied from one month to several years. A wide range of testosterone doses was noted. Table 1 depicts the dosing of testosterone among the study participants.

Two primary reasons for seeking treatment were identified: concerns related to libido issues and concerns related to the subjective complaints of menopause and the perimenopausal period. Using open-ended questions followed by probing questions to elicit additional in-depth responses, the researcher documented each participant's experience in audio taped interviews. In this manner, several themes were identified.

The participants (who will be referred to by number in future discussion) had several different reasons for initiating testosterone therapy, and fell into two specific groups: those who sought out and/or were prescribed testosterone cream primarily for specific testosterone-related benefits, and those whose exposure to testosterone was more incidental. In the latter group, testosterone was prescribed as part of a regimen of HRT

TABLE 1

*Testosterone Among the Study Participants*

| Subject | Testosterone Dose | Other Hormones |
|---|---|---|
| #1 | 2mg daily, divided | Estrogen |
| #2 | 2-10mg per day | No |
| #3 | 3-4mg per day | No |
| #4 | 1mg per day | Estrogen, progesterone |
| #5 | 3mg per day | Estrogen, progesterone |
| #6 | 2mg per day, divided | Estrogen, progesterone |

initiated for general complaints of menopause, and not because they had specifically requested testosterone therapy. As might be expected, each group had a somewhat different focus, although many of the issues mentioned were common to both groups of women. Two major concerns were identified. One common complaint was related to issues of decreased libido and/or sexual response and its effect on the participants' personal and relationship satisfaction; the other encompassed issues related to the physical and psychological discomforts of menopause and its effect on the participants' quality of life. The length of treatment time varied from one month to several years. A brief description of the subjects follows.

Subject number one, a massage therapist, was unique among the study participants, in that the focus of her treatment was neither menopausal nor libido-related complaints. She had been diagnosed with Multiple Sclerosis (MS) and was subsequently

prescribed testosterone mainly to alleviate symptoms of fatigue. Although she mentioned her decreased libido, it was not her primary reason for seeking treatment. Subjects two and three, both nurses, had heard discussion about the benefits of testosterone among their peers and at conferences, and had initiated treatment themselves (by requesting testosterone prescriptions from their providers.) Both were in relationships with new partners and were experiencing age-related difficulties with sexual response. They were interested in testosterone primarily for purposes of libido enhancement. Subjects four and five, also both nurses, had initially begun hormone replacement therapy with bioidentical hormones, to alleviate severe symptoms of menopause, most notably hot flashes. Both were married, and while each mentioned some libido issues, each was more concerned currently with the symptoms of menopause. Prior to treatment, each felt that her symptoms were severe enough to interfere with her quality of life and daily functioning. For these two subjects, testosterone was added to the hormone regimen upon the recommendation of the health care provider, to treat the lesser complaints of decreased libido or sexual response. Subject number six, a supervisor in a clerical setting, had initially begun therapy for decreased libido with testosterone pellets, had tried other testosterone preparations, and eventually settled on testosterone cream. Her initial concerns in seeking treatment were also libido issues in a second marriage; however, she is currently also using testosterone in combination with bioidentical HRT for a variety of menopause-related complaints.

In summary, the study participants had two primary reasons for seeking testosterone treatment. They were motivated to treat either complaints of decreased

libido, or complaints related to the discomforts of menopause. The themes noted during interviews with the participants will be discussed in Chapter IV.

## Protection of Subjects

Consent was obtained from the subjects and documented (see Appendix B). Subjects were assured of their anonymity, and no identifying data were collected. An interview number was utilized when discussing the participants' responses. The general purpose of the study and the subjects' rights were delineated to the participants. Human subjects' approval was obtained from the IRB at California State University, Chico. Transcripts of the subjects' responses are in possession of the researcher and were coded by number. No names were used on the audio tapes. Data are kept in a locked file cabinet in the home of the researcher. Only the researcher has access to the participants' identifying information.

## Data Collection and Analysis

Data collection was accomplished by conducting oral interviews. Field notes were also taken during the interviews. Data analysis was completed by transcribing the interviews verbatim and reviewing the transcriptions and field notes. Moustakas (1994) noted that the process of organizing and analyzing data begins when the researcher places the transcribed interviews before him or her. The researcher then studies the material using the methods and procedures of phenomenal analysis. Giorgi's method was used to analyze the content and synthesize outcomes from the data with regard to the participants' experiences. Each transcript was initially read as a whole, and then reviewed with a research mentor experienced in qualitative data analysis to determine the themes

and sub-themes in the data. In Giorgi's method, the individual elements of the phenomenon are identified, but their importance is established more by the intuitive judgment of the researcher than by the frequency of their occurrence in the transcripts. The researcher strives to delineate the units of the phenomenon being studied, and to express the psychological insight contained in the meaning of the units. The researcher then synthesizes all of the units into a consistent statement of the participant's experience (Burns & Grove, 2005).

The researcher exercised care to "bracket" the findings so as not to allow any personal experiences or opinions to influence the findings of the study. "Bracketing" is a strategy used to control researcher bias and is defined by Houser (2008, p. 311) as "the process of explicitly reflecting on and documenting the researcher's biases," These biases are then "bracketed" so that they can be set aside. Additionally, findings were reported from the orientation of the participants (Burns & Grove, 2005). Themes were identified and explored.

The importance of rigor in qualitative research cannot be overemphasized. Researchers must be scrupulous and proactively take responsibility for the attainment of rigor. "Without rigor, research is worthless, becomes fiction, and loses its utility" (Morse, Barrett, Mayan, Olson, & Spiers, 2002, p. 1).

Considerable debate exists, however, over how (and when) rigor is established in qualitative research. According to Burns and Grove (2003), rigor is associated with openness on the part of the researcher, scrupulous adherence to a philosophical perspective, thoroughness in collecting data, and consideration of all the data in the subjective theory development phase. In an article entitled, "Verification Strategies for

Establishing Reliability and Validity in Qualitative Research," Morse et al. (2002) stressed that the responsibility for rigor should fall on the investigator throughout the research process, and not on external judges of the completed product.

Even the terms used in the discussion of rigor are subject to examination. Until the 1980s, the concepts of "reliability and validity" were the pivotal points upon which the discussion of rigor hinged. In a seminal work on the subject, Guba (1981) substituted the concept of "trustworthiness" for the more commonly used terms of "reliability" and "validity." Trustworthiness, under this paradigm, is often established by external reviewers at the end of a study.

Morse et al. (2002) argued that researchers should reclaim the responsibility for rigor. They advocated for a return to the original terminology and assert that the development of alternative criteria actually undermines the issue of rigor. They stated that strategies for assuring rigor must be built into the qualitative process per se, and that the researcher must proactively take responsibility for ensuring rigor through strategies inherent within the qualitative design.

Even the quality of transcription contributes to the attainment of rigor in the qualitative process. Poland (1995, p. 299) pointed out that "verbal and written communications are very different mediums," and noted that "…much of the emotional content of the interview as well as nonverbal communication are not captured at all well in audiotape records… ." Poland (1995, p. 292) went on to state that "the full flavor of the interview as a lived experience is therefore unlikely to be represented in the transcript without fuller description of the emotional context and other aspects, as per the

recollections of the interviewer…" and recommended detailed field notes and other recollections of the interviewer as a supplement to the completed interview transcripts.

The researcher remained mindful of all of these principles and attempted to demonstrate rigor throughout the research process. Rigor in qualitative research, according to Guba's 1981 work, is based on trustworthiness and includes the specific characteristics of credibility, confirmability, dependability/auditability and transferability. These concepts are defined below.

Credibility is established when the researcher has achieved "intimate familiarity" with the topic and strong logical links exist between the gathered data and the researcher's argument and analysis (Munhall, 2007, pp. 563-564). Credibility is threatened when the researcher incorrectly interprets the data by drawing premature conclusions or basing themes on isolated responses (Houser, 2008).

Confirmability is established when the researcher reduces bias in both methods and procedures. Bracketing is one method of limiting the effects of researcher bias. It requires the researcher to examine and reflect upon his or her own position on the topic and acknowledge biases and values. The researcher must also identify his or her assumptions based on theory or experience, and identify the process for setting aside personal biases. Reflexive introspection is a key component of bracketing and requires honesty and maturity on the part of the researcher (Houser, 2008).

Auditability/dependability is established when audit trails are made available for review by peer reviewers and other interested investigators – an external audit (Munhall, 2007). An external audit involves a researcher who is not involved in the original research process and who examines both the process and the product of a

research study. The purpose is to evaluate whether or not the research findings are supported by the data. An audit trail is “a thorough conscientious reflection on and documentation of the decisions that were made, the procedures that were designed, and the questions that were addressed during analysis” (Houser, 2008, p. 485). The audit trail also helps to support confirmability of the research analysis.

Transferability occurs when the results of qualitative research can be applied to studies with similar subjects and settings. For this to occur, the researcher must provide a rich and complete description (also known as a “thick description” (Lincoln & Guba, 1985) of the research setting, transactions and processes observed throughout the research process (Houser, 2008). By describing a phenomenon in sufficient detail, one can begin to evaluate the extent to which the conclusions drawn are transferable to other settings and research populations.

To promote validity and trustworthiness in the study, the researcher utilized the strategies of prolonged field experiences (interviews), verbatim accounts, participant feedback, bracketing, and documentation of an audit trail, as described by Houser (2008). Interviews were as lengthy as was comfortable for the participant. Accurate field notes were maintained, and results reported as direct quotes (where this was possible without compromising the anonymity of the subject.) The accuracy of observations was checked directly with the subjects, by discussing observations and conclusions with them. The researcher’s personal biases and inclinations were critically examined. An audit trail was documented, including field notes and reports, interpretations and thorough descriptions. The researcher has documented human subjects’ protection and the steps taken to ensure that the data obtained are representative of the data as a whole. Care was taken to assure

that all elements of the study are presented concisely. Data were accurately recorded, and the transcription process was scrutinized to assure the highest possible quality of interview transcripts.

## Summary

The process of phenomenology involves obtaining descriptions of “lived” experience through first person accounts and searching for meanings and the “essences of experience” (Moustakas, 1994 p. 21). The phenomenological approach was well suited to this project, since the participants were describing in detail their experiences with a particular phenomenon; in this case, the use of exogenous testosterone supplementation by perimenopausal women. The researcher has attempted to capture the details of each participant’s perception of the entire experience with TRT, from the initiation of therapy to the subject’s expectations and concerns, and the subject’s perceived experiences throughout the treatment. The subsequent organization and documentation of the themes and outcomes obtained from the data complete the thesis project.

# CHAPTER IV

# RESULTS

The participants' descriptions of their lived experiences with testosterone treatment during the perimenopausal period included many of the expected effects of testosterone, both desirable and undesirable, that were previously reported in the literature, as well as some new findings not previously discussed in the existing body of testosterone research. The main themes identified were: 1) Seeking to Combat the Consequences of Aging, 2) Gaining Benefits with Testosterone Therapy, 3) Balancing the Side Effects of Testosterone, and 4) Appreciating the Male Perspective.

The experiences of the participants leading to the decision to undergo testosterone therapy included many struggles related to the effects of aging and declining hormone levels. Most found the testosterone treatment to be helpful. The positive benefits noted included an increased libido and a return to previous levels of sexual interest, as well as an increased energy level. Among the negative side effects discussed were an increase in facial and body hair growth, and, in some cases, an increase in feelings of aggression or anger. Women using testosterone also reported new feelings of identifying with men as a result of suddenly finding themselves in the position of being preoccupied with thoughts of sex. Some reported a new feeling of empathy for men as a result of this experience. While it was noted that most women also experienced relief of hot flashes

and other somatic complaints of menopause, the results were much more profound in the HRT group and therefore cannot be attributed to the use of testosterone alone.

## Themes Identified with Testosterone Use

1. Seeking to Combat the Consequences of Aging. Several of the participants described a difference in their level of interest in sex as younger women when compared to the present. Most expressed some distress over this, either in terms of their personal satisfaction with sex or their partner's perceived satisfaction with the relationship. Some women hoped to restore previous levels of interest or sexual satisfaction. Among the statements made were, "I felt like, as a younger person, my orgasms were more intense, and I was hoping that this would bring me back to more of my youthful self." "I'm in a relationship where I have somebody I feel comfortable with but my response is just really decreased because of my age." "I should be having a good time [but] I'm almost too old to be having sex."

Others expressed guilt or distress over their partner's perceived lack of satisfaction with the relationship due to the participant's decreased libido. "When I was a lot younger, I had a really high sex drive, but my husband didn't know me in those days and I think he was wishing he did." "[Prior to treatment] I had sex more for his benefit." "My husband and I have always had a pretty good sex life but it was definitely waning." "… the first six years of my ten-year marriage, I was frigid, and didn't want my husband to touch me…"

All six subjects, in discussing their pre-treatment concerns, expressed an age-related decrease in either sexual desire or sexual response. "My libido was really depressed." "I

felt like my sex-drive was down." "My sexual response is really decreased." "My sex drive was non-existent." "I started taking it with the hopes of increasing my libido and my sex drive."

2. Gaining Benefits of Testosterone. All subjects reported experiencing beneficial effects of testosterone therapy. In discussing these benefits, two main sub-themes were mentioned. These were an increase in libido or sexual response, and an increase in the level of energy, as noted by the participants.

A. Increased Libido. All subjects reported an increase in sexual thoughts and an increased interest in sex while using testosterone preparations and most viewed this as a positive effect. Subjects reported the increase as being anywhere from mild, "it may have helped," to extreme, "I've been sex-crazed ever since." Participant number 6, in discussing her initial treatment with implanted testosterone pellets, stated, "it was like I was a sex fiend," but she felt that her response was dose-related and was better controlled with the cream. In discussing her current use of the cream, she stated, "for once I have a normal sex drive." Other participants reported new feelings of obsession with sex. "I really did become sex-crazed… I thought about it all the time… I started looking at people and wondering what they'd look like with their clothes off." "I'm thinking about sex almost all the time." "It's been a nice bonus… it's been great." "It totally increased my sex drive and my sexual response." Still others mentioned a new sense of urgency about sex, stating, "I was so horny that I couldn't sleep… I couldn't wait to get my hands on my boyfriend." "I couldn't stop thinking about sex… I was attacking my husband as soon as he came home."

B. Increased Energy Level. Five of the six subjects noted an increase in energy and all viewed this as a positive effect. Subject number one stated that her purpose in participating in the study was to help "get the word out" about the potential benefits of testosterone to other women suffering from MS or other chronic illness. The participants stated, "I noticed it more in terms of my general level of energy and the reduction in fatigue." "I also had more energy." "I had more energy, I felt better at the gym." "I do have better energy." "I have energy to play with my grandkids; I have energy to make love to my husband."

3. Balancing the Side Effects of Testosterone. Undesirable side effects of testosterone treatment that were reported included an increase in facial and body hair growth, increased feelings of anger or aggression, and, in two subjects, clitoral enlargement and/or sensitivity. The majority of the participants did not feel that the undesirable side effects were bothersome enough to discontinue treatment. Side effects in some cases appeared to be dose-related, and lower doses of testosterone were generally well-tolerated. The side effects were severe enough in one case of the vaginally applied testosterone cream that the subject elected to discontinue treatment; the subject who started with implanted pellets also discontinued them for this reason.

All but one subject reported an increase in facial and/or body hair growth, with the effects again ranging from mild to more severe:

- "…[J]ust slightly more hair growth… to me that wasn't really a big deal because, of course, since I'm taking it for multiple sclerosis and for all of those positive benefits, it seemed like a very inconsequential side effect."

Another participant, discussing mild hair growth, stated "…I'm noticing a little more facial hair, like on my chin… maybe more body hair… but I don't mind that much, I guess I think it's worth it."

At the opposite end of the spectrum of reactions to hair growth, other subjects stated:

- "[T]hen, all of a sudden, I got really hairy… I looked down at my arms one day and they looked really hairy and I definitely noticed more hair on my legs, and when I started taking a good look at my face, there was even hair on my neck… so I got kind of panicked and I quit using it completely."
- "[T]he growing of hair is still kind of an issue. I do have to shave a moustache, and I have to pluck a couple of hairs around my chin, and I still grow hair around the nipples too, but it's not as bad as what it was [with testosterone pellets]."

Three subjects mentioned feeling more aggressive while using testosterone. "[I'm] feeling somewhat more… I want to use the word 'aggressive,' and feeling more like, 'okay, don't get in my face' kind of thing." "I do feel like, when I get mad, and I can get mad at times, the ferocity of my madness is a little more, like I get a little more barking mad." "I think it's possible that I might have upped my manly aggressions." "I was more aggressive, I found out that I was more aggressive, and I tended to get angry faster."

4. Appreciating the Male Perspective. Among the most intriguing findings were statements made by four of the six participants about having a greater empathy with men, or a better understanding of the male experience with regard to being inundated and

preoccupied with thoughts of sex. Several subjects wondered how men are able to accomplish anything while thinking constantly about sex.

- "I never used to relate to men, but now since I've started taking testosterone, it's like, wow, men really show a lot of self-restraint, because I feel like I'm thinking about sex almost all the time and I gained a whole new appreciation for my male counterparts."

In discussing the feelings associated with frequent sexual thoughts, others stated: "I finally understand what it's like to be a guy, like, I think about sex all the time." "I really can't fathom how they go about their day, when all they think about is sex." "I think this must be what it's like for men; I had no idea how distracting it is when all you can think about is sex."

One participant related her sense of urgency about sex to the male experience. "[One] thing I noticed that was just so like a guy, was that when I wanted to have sex, I had to have it right then." Another participant, in discussing testosterone-related feelings of aggression, also mentioned relating to men for that reason. "When I'm sitting there in a moment of rage, just ready to take off someone's head, I'm thinking, so, I wonder if this is what it's like to be a guy."

An incidental finding was the significant number of women in the sample (one-half) who were using the bioidentical hormone combination of estrogen, progesterone, and testosterone and the fervor with which these women discuss the change that this form of HRT has made in their lives. Two of the three mentioned never wanting to go back to the experience of life without HRT, and downplayed concern for the potential health risks. "I was talking to a friend who had gone on bioidentical hormones, and she said it was just

amazing, what a change in her life it had made." "My hot flashes stopped immediately; I've had a good experience." "…but this is working, why would I change it?" "I have a million friends that are all on it." "…it was like my life was given back to me." "I don't want to ever go off of it was far as I'm concerned now." "I am willing to take the risk because it has given me my life back." "If I get cancer… I'll probably [say] 'just take it out and let me keep on doing my bioidenticals.'"

In general, the women responded well to testosterone treatment, but reported a variety of results, both positive and negative. Only one subject had discontinued the use of the vaginally applied cream due to side effects, and was still considering other dosing options. Another incidental finding mentioned by one subject was relief of migraine headaches with testosterone, and the participant with MS mentioned the "immune-modulating effects" of testosterone in passing, although these effects are undocumented in the literature and were each mentioned by only one woman in the sample.

In summary, all of the subjects believed that they had benefited in some manner from testosterone treatment. They were willing to discuss their most intimate personal struggles and experiences in order to help "get the word out" about the potential benefits to women of testosterone treatment. The benefits included an increase in energy levels and an increased libido and/or improved sexual response. The majority of the subjects reported having a new understanding of the male experience of being preoccupied with thoughts of sex and seeking to balance this with daily life. They reported having a greater empathy toward men as a result. This study suggests that the standard questionnaires used to assess the effects of testosterone in women in the previously reported studies may have missed an important component of the women's

lived experience with testosterone therapy. Testosterone offered the women in this study a unique glimpse into the male psyche and the ability to appreciate sex from the male perspective.

# CHAPTER V

## DISCUSSION AND REFLECTION

The findings of the study with regard to the positive benefits and negative side effects of testosterone treatment are consistent with those reported previously in the literature. Testosterone shows promise in treating many of the common complaints of menopausal or perimenopausal women, and has been demonstrated to improve libido, mood, and energy levels in this population. However, the existing research has failed to fully document the perceptions of women regarding testosterone therapy. Several themes emerged as the participants discussed their experiences with using the testosterone cream. The four themes were: 1) Seeking to Combat the Consequences of Aging, 2) Gaining Benefits of Testosterone, 3) Balancing the Side Effects of Testosterone, and 4) Appreciating the Male Perspective.

The phenomenological nature of the study allowed for greater insight into the women's emotional and physical reactions to testosterone therapy by eliciting a wider range of responses. In many of the available studies, researchers have used a standardized rating scale or questionnaire to determine the extent of women's response to testosterone treatment in a particular area, such as improvement in mood or sexual response. While this approach generates responses appropriate to the items included in the survey, it does not allow insight into relevant issues not included in the questionnaire, thus limiting the

potential of the standardized survey to provide a full understanding of the participants' lived experiences.

The data generated by this phenomenological study provide a greater understanding of women's responses to the effects of testosterone, including those of an increased libido and an increase in sexual thoughts. In a previously unreported finding, women using testosterone in this study reported developing new insight into the daily experiences of men, with regard to frequent thoughts of sex and, in some cases, the urgency of men's sexual needs. They mentioned having a greater appreciation for the pervasiveness of men's sexual thoughts, and a greater empathy toward men in terms of the difficulties involved in going about one's daily activities while being preoccupied with thoughts of sex.

It has been previously mentioned that testosterone is frequently viewed in our society as a "male hormone." While it was noted by the researcher that some women did seem to expect to have some "male" effects as a result of testosterone therapy, they were more concerned about the usual side effects such as an increase in the amount of body or facial hair growth. All of the women who reported feeling a greater level of identification with men seemed surprised by this effect, so the researcher would not conclude that this was an incidence of "self-fulfilling prophecy." The newfound ability to experience and empathize with the male perspective was a surprising finding to both the subjects and the researcher, and not an expectation of the participants prior to the initiation of therapy.

## Limitations of the Study

The greatest limitation of the study was the lack of a readily available pool of subjects to be interviewed. Because of the design of the study, the researcher had to solicit interviews via fliers and then wait to be contacted by potential participants. Responses were solicited from a group of women receiving prescriptions for vaginally applied testosterone cream through a compounding pharmacy. The researcher worked with two different pharmacists (both of whom were very enthusiastic about the study) to accomplish this goal. After distributing the fliers to the pharmacists, who then included them with the filled prescriptions, the researcher had to wait for each potential participant to make contact. Every one hundred fliers produced only about two responses, delaying completion of the project until an adequate number of responses could be obtained. While it is likely that there were many differences between the 98 percent of women who did not choose to participate in the study and the two per one hundred who did, no demographic information on the women who declined is available. Therefore it is not possible to evaluate in detail the differences between the two groups.

Additionally, the subjects who did participate were using widely varying doses of testosterone cream with or without other hormones, which made it difficult in some cases to determine which effects to attribute to testosterone alone (for example, the relief of hot flashes, which could also be the result of estrogen replacement). A study comprised of a more homogeneous group of subjects, using a more consistent dose of testosterone might yield more clarity in the resulting descriptions of the benefits and side effects. An approach that may help to address both of these issues is described below.

## Implications for Nursing Research

There is much that remains to be determined about the potential benefits of testosterone therapy for women. The phenomenological approach is well-suited to this research. By using this approach, a wider range of the women's experiences can be discovered and documented.

It might be beneficial to the phenomenological researcher conducting a similar study in this area to solicit the involvement of a physician or practitioner whose patient population includes women using the vaginal testosterone cream without other hormones, in a more specific dosage range. With the practitioner's involvement, subjects could be introduced to the study at an office visit, and give consent to be contacted later by the researcher. A list of potential participants could then be made available, simplifying the process of obtaining a suitable sample for the researcher, who would then follow up by contacting the potential participants to schedule and obtain the in-depth interviews.

## Implications for Nursing Practice

Nurse Practitioners in the area of women's health might benefit from an increased knowledge base about the potential benefits of testosterone therapy for women in the perimenopausal phase. Much of the existing research deals with women who have had menopause induced by surgical removal of the uterus and ovaries. This study suggests that even some women who have not undergone these procedures still suffer greatly from declining hormone levels and may benefit from testosterone replacement. Health care providers may also want to consider the potential benefits of testosterone that fall outside of the standard indications for treatment. Patients with MS and other chronic

illnesses may benefit from the relief of fatigue and improved energy levels, as noted by subject #1, who reported considerable relief with twice-daily dosing of testosterone. There appears to be substantial uncharted territory in terms of potential new findings in the field of testosterone therapy for women. Further research in this area could prove beneficial to persons suffering the effects of chronic illness and fatigue.

## Implications for Nursing Education

Educators in the field of women's health may want to consider teaching nursing students at all levels about the potential usefulness of testosterone therapy to the middle-aged female population. As public interest in the areas of combating the effects of aging with hormone replacement therapy continues to expand, students are likely to be beset with questions from clients about a variety of hormones and their effects. Nursing students working with an older female population are likely to encounter clients who are already using a variety of hormone preparations.

Nurses working in the field of women's health will need to be knowledgeable in this area in order to counsel female patients about treatment options. The fervor with which some women have embraced the concept of "bioidentical" hormone therapy will likely lead to an increased number of women sharing the positive effects with their friends and encouraging them to try it. This in turn will lead to an increased demand for practitioners who are well-informed in this field.

# Summary, Conclusions and Recommendations

The data from this study suggest new considerations in testosterone research that have been largely overlooked in past studies. The findings of this study imply that those studies utilizing the data generated by having participants complete a questionnaire or standardized rating scale are lacking in terms of their ability to adequately portray the subjects' perceptions and describe thoroughly the experience of the participants. Many of the published studies have not successfully documented the full range of each subject's lived experience with testosterone therapy due to constraints associated with the data gathering techniques of standard research approach.

Future researchers might consider using a more comprehensive methodology to evaluate the perceptions and responses of the subjects. In-depth interviews provide the range of responses necessary to draw conclusions about the participants' overall experiences with testosterone treatment. These responses offer more insight into the lived experience than would otherwise be derived from a standardized questionnaire.

Lastly, testosterone may offer a previously unrecognized benefit for women – the rare opportunity for a glimpse into the workings of the male psyche. An enhanced understanding of the experience of the opposite sex, especially with regard to sex and relationship issues, is a benefit that would appeal to many women. Those who initiate testosterone therapy with the desire to improve or enhance relations with their significant other might find this aspect of treatment especially appealing, as it could lead to improved understanding and communication between the partners. Further research is needed into the lived experience of women undergoing testosterone therapy to develop an

enhanced awareness of their perceptions surrounding the treatment and to provide more insight into this field of study.

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# REFERENCES


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# APPENDIX A

PARTICIPANT QUESTIONNAIRE

Demographic Information:

1. Age:

2. Marital or relationship status:

    a. Single or never married

    b. Married or live with partner

    c. Divorced

3. Type of employment, if employed:
    _____

4. Menstrual status:

    a. Still menstruating

    b. Natural menopause

    c. Surgical menopause

4. Have you had any gynecological surgeries?
    a. hysterectomy (uterus removed)
    b. oophorectomy (ovaries removed)
    c. other surgery
5. Are you taking any other medications (especially hormones)?
    a. Estrogen
    b. Progesterone
6. What dose of testosterone are you using/did you use?

# APPENDIX B

CONSENT TO PARTICIPATE IN A

RESEARCH STUDY

California State University, Chico

**Title of Study:** Effects of Exogenous Testosterone in Women: the Lived Experience of Women Using Vaginally Applied Testosterone Compound Cream

**Investigator's Name, Departments, Telephone Numbers:**
Carolyn Cook, CSU-Chico Graduate Student, MSN Program, 916-715-8845

You are being invited to participate in a research study. Before you agree, the investigator must tell you about:

1. The purposes, procedures, and duration of the research study. The purpose of the study is to determine women's perspectives regarding and experiences with the use of vaginally applied testosterone cream. You will be asked to participate in a 30 to 60 minute interview that will be tape-recorded. No names or identifying information will be associated with your response.

2. Any procedures which are experimental. In this study you are being asked to discuss your experience with using vaginally applied testosterone cream. You are not being asked to begin using vaginally applied testosterone cream, as you have already made that decision.

3. Any reasonable foreseeable risks, discomforts, and benefits of the research. There is no (additional) risk involved in the study, as you are only being asked to discuss your experience with the treatment that you have already undergone. It is possible that, in discussing why the cream was prescribed for you, the side effects, or your medical history that you may become uncomfortable. If you are uncomfortable with a question, you are free to decline to answer it or to stop the interview at any time.

4. Any potentially beneficial alternative procedures or treatments. You are free not to participate in the study.

5. How confidentiality will be maintained. No names or identifying information will be collected. All interviews will be anonymous. Transcripts of the interviews will be shredded five years after the study has been completed, as is consistent with American Psychological Association Guidelines. During that time, the transcribed interviews will be stored in a locked cabinet that only the researcher can access.

Only quotes that cannot be specifically linked to a particular woman will be published. All transcripts will be reviewed for responses that could identify a specific participant. Responses that involve a specific town, a particular practitioner, or any other identifying information that could be linked to a specific woman will be modified so that no woman's particular response can be identified.

Where applicable, the investigator must also tell you about:

1. Any available compensation or medical treatment if injury occurs. There is no compensation for participating in this study. The only access to medical treatment will be through you primary care physician and using your own health care insurance.

2. The possibility of unforeseeable risks. It is possible that discussing the reason(s) that testosterone was prescribed for you, your medical history, or any side effects experienced may make you uncomfortable. If this occurs, you are free to decline to answer the question of stop the interview at any time,

3. Circumstances when the investigator may halt your participation. Should talking about any of the questions related to your use of testosterone cream result in your becoming upset to the point that you do not wish to continue the interview, then the investigator will stop the interview.

4. Any added costs to you. There are no added costs to you associated with participating in this study.

5. What happens if you decide to stop participating. If you wish to stop the interview at any time, the investigator will stop the interview. You are free not to participate in the study without any risks to you. No one will be notified if you decide not to participate in the study.

You may contact the CSU, Chico Institutional Review Board for the protection of human subjects at: 530-898-4766 if you have any questions about your rights as a research participant.

Your participation in this research is voluntary and you will not be penalized or lose benefits if you refuse to participate or decide to stop once the study has started.

**Signing this document means that the research study, including the above information, has been described to you verbally and that you voluntarily agree to participate.**

_____ _____

Signature of Participant Date

_____ _____

Signature of Researcher Date