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# Hypoactive Sexual Desire Disorder in Postmenopausal Women: Quality of Life and Health Burden

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#### ABSTRACT

**Objectives:** To describe the health-related quality of life (HRQOL) implications of hypoactive sexual desire disorder (HSDD) in a national sample of postmenopausal women ages 30–70.

Methods: The Nationwide Survey of Female Sexual Health, a random-digit telephone survey of US households, collected information on female sexual function, demographic characteristics, HRQOL, and the presence of specific medical disorders from 1189 naturally or surgically postmeno-pausal women in stable relationships of ≥3 months duration. HSDD was defined as <40 on the Profile of Female Sexual Function® scale and <60 on the Personal Distress Scale®. Short Form-12 Health Survey (SF-12) summary and domain scores, and EuroQol (EQ-5D) index score and dimensions were compared with population-based norms for healthy individuals and selected chronic conditions.

Results: HSDD was associated with significant HRQOL decrements, with the largest SF-12 score differences in mental health (HSDD: 45.4 [standard error 1.9] vs. no HSDD: 51.0 [0.6], P < 0.01), vitality

(HSDD: 47.7 [1.3] vs. no HSDD: 52.0 [0.7], P < 0.01), social function (HSDD: 47.3 [1.4] vs. no HSDD: 50.9 [0.7], P < 0.05), and bodily pain (HSDD: 41.4 [2.2] vs. no HSDD: 46.7 [0.9], P < 0.05). EQ-5D index was 0.08 points lower (HSDD: 0.76 [0.03] vs. no HSDD: 0.84 [0.02], P < 0.05) for those with HSDD compared with those without. HSDD was associated with a 0.1-point decrement in naturally menopausal women (HSDD: 0.78 [0.03] vs. no HSDD 0.88 [0.01], P < 0.01). Women with HSDD showed more HRQOL impairment than healthy population norms but were similar to adults with other chronic conditions such as diabetes and back pain.

Conclusions: Women with HSDD showed substantial impairment in HRQOL. Given a prevalence of 6.6% to 12.5% among US women, HSDD represents an important burden on quality of life.

*Keywords:* health-related quality of life, hypoactive sexual desire disorder, menopause, Profile of Female Sexual Function (PFSF<sup>©</sup>), sexual dysfunction.

#### Introduction

Hypoactive sexual desire disorder (HSDD) is defined as the persistent lack of sexual desire causing "marked stress or interpersonal difficulties" as described in the Fourth Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) [1]. This definition, based on the model of sexual response posed by Masters and Johnson [2] and Kaplan [3] focuses on sexual thoughts and fantasies and assumes that desire occurs before initiating sexual intercourse and between experiences of sexual intercourse [4]. Recent guidelines have further refined the definition of HSDD [4-6], taking into account "the inability to access any desire during the experience (emphasis in original)," and considering lessening in desire beyond what would normally be expected across the life cycle and with relationship duration [4,6]. Only a few researchers have undertaken studies to determine the prevalence of HSDD among women in the United States [7,8] and Western Europe [9], reporting prevalence ranging from 7% to 26%. Variations in reported prevalence are associated with differences in the populations studied (national vs. community vs. clinic), data collection approach, definition of sexual dysfunction and desire disorder, and period of observation [10].

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Furthermore, a few studies have suggested that the prevalence of HSDD is higher among surgically menopausal women [8,9,11]. A recent study by Leiblum and colleagues [8] reported results from US women in the Women's International Study on Health and Sexuality (WISHeS) showing that the prevalence of HSDD ranges from 9% to 26% depending upon the woman's current age and her menopausal status. Specifically, they found that younger surgically menopausal women were at highest risk for HSDD. This finding was further supported by the European arm of the study by Dennerstein and colleagues which also reported the highest prevalence of HSDD, 16%, among the younger population of surgically menopausal women [9]. A recent, nationally representative prevalence study (the Nationwide Survey of Female Health) by West and colleagues [11] confirms these results, reporting HSDD prevalence ranging from 6.6% to 12.5%, with surgically menopausal women at highest risk. Although HSDD is classified by the DSM-IV as a disorder, some questions still exist whether this condition represents a significant and clinically relevant problem for women or whether it represents a disorder that has become "medicalised" because of its pharmaceutical market potential [4,6,7,12-17]. This skepticism suggests the need for evidence on the effects of HSDD on health status and health-related quality of life (HRQOL). That is, does HSDD affect a significant number of women (and does it target some women disproportionately) and what effect does it have on relationships, quality of life, and social interaction?

Recently, Leiblum and colleagues [8] reported preliminary health status data from the WISHeS study using the Medical

Outcomes Study Short Form (SF)-36. They found that women with HSDD experienced large and statistically significant decrements in health status, with much larger decrements on domains that measure aspects of mental health status (i.e., MH, social functioning [SF], vitality [VT], and emotional role fulfillment). Nevertheless, they did not report data by menopausal status. Women who have undergone surgical menopause, as opposed to those who progress through menopause naturally, experience abrupt and dramatic declines in hormones that may be associated with more dramatic declines in libido and may result in sexual dysfunction [18]. The resulting dysfunction has been shown to be related to problems of mood, self-esteem, and emotional distress [5], which may translate into lower quality of life.

To our knowledge, no other study reports HRQOL data for this group of surgically and naturally postmenopausal women. Using the groundwork laid by Leiblum and colleagues [8], we present here a systematic and detailed description of the health burden and HRQOL among women with HSDD. We use a nationally representative sample of US women ages 30 through 70, and well-validated instruments to assess the burden and to systematically evaluate the relationship between HSDD and health status and HRQOL. We also compare our results with national norms, allowing us to place HSDD into context with other common disorders and to add to the growing catalogue of national preference scores available for use in cost-effectiveness analyses [19,20].

#### **Methods**

#### Data Source

The Nationwide Survey of Female Sexual Health collected information on female sexual function and factors that were hypothesized to affect function. Data were collected between September 9, 2004 and March 30, 2005, from a total of 2207 women (weighted response rate 56.7% [21]). Detailed discussion of the study methods is provided elsewhere [11].

Briefly, women ages 30 to 70 were selected from a national sample of households using a dual-frame probability sampling approach. One-tenth of the sample was selected from a random digit-dialing frame, while the remainder came from a frame of telephone directory-listed residential telephone lines for which recent demographic data were available. Women were eligible to participate if they were between the ages of 30 years and 70 years, inclusive, were involved in a stable sexual relationship of at least 3 months duration, and either had both ovaries or no ovaries at all (i.e., they were bilaterally oophorectomized). Computer-assisted telephone interview technology was used by female interviewers to collect information on demographic characteristics, smoking and alcohol use, the presence and treatment of specific medical disorders, female sexual dysfunction, family stress, satisfaction with relationships, and burden of illness including quality of life and medical resource use. Informed consent was obtained from the women, and ethics approval was obtained from the Office of Human Research Ethics at the University of North Carolina at Chapel Hill. The survey data were collected by the Survey Research Unit at the University of North Carolina at Chapel Hill.

#### Description of Instruments

Four well-validated instruments were used as part of the survey questionnaire: the Profile of Female Sexual Function<sup>©</sup> (PFSF<sup>©</sup>), Personal Distress Scale<sup>©</sup> (PDS<sup>©</sup>), the Short Form-12 Health Survey (SF-12) version 2, and the EuroQol descriptive system (EQ-5D).

Developed by Procter & Gamble Pharmaceuticals (Mason, OH), the PFSF is a 37-item questionnaire that measures various aspects of sexual function. Seven individual domains of sexual function include: sexual desire, sexual pleasure, sexual arousal, orgasm, sexual responsiveness, sexual concerns, and sexual selfimage. Women responded to questions on a scale from 1 (always) to 6 (never). Additionally, one item assesses overall sexual satisfaction. Originally developed and validated with postmenopausal women [22,23], the PFSF also has been used in several clinical trials [24-27] and population surveys [8,9]. The sevenitem PDS<sup>©</sup> [28] was used to measure distress caused by low sexual desire. High scores from the PDS instrument represent greater distress, whereas for the PFSF instrument, higher scores represent better sexual function status. The PFSF<sup>©</sup> and PDS scores were calculated according to the methodology described by Dennerstein and colleagues [9].

We measured health status and HRQOL using two previously validated instruments, the SF-12 v.2, and the EQ-5D, respectively. The SF-12 is a 12-item generic health status questionnaire that was derived from the longer and widely used SF-36 and is used in situations where a more concise survey is desirable [29]. Head-to-head comparisons of the instruments suggest that the SF-12 is most appropriate for population-based surveys such as ours [30,31]. As with the SF-36, the SF-12 is composed of eight domains (physical functioning [PF], role physical [RP], role emotional [RE], bodily pain [BP], general health [GH], MH, VT, and SF) and two summary scores (physical component summary [PCS-12] and mental component summary [MCS-12]) [29]. All scores are reported on a scale from 0 to 100, with higher scores representing better health. We employed the algorithms of Ware and colleagues [29] to combine data from the individual items into the eight individual domain scales. Norm-based scores subsequently were constructed and the two summary measures were constructed using Ware and colleagues' [29] algorithm and the 1998 US general population means and standard deviations (SD). The mean and SD for the normed MCS-12, PCS-12, and individual domain scores are 50 and 10, respectively. Norm-based scores are critical to meaningful comparisons between the scales and the summary measures, and allow comparison between different health conditions; scale scores less than 50 indicate that health status is below average.

The EQ-5D is a 5-item descriptive system measuring health status along five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). The EQ-5D has been used widely for clinical trials, economic studies, and population health surveys worldwide, resulting in more than 800 publications through June 2004 [32]. Using the EQ-5D, women rated their own difficulty for each dimension as no problems, some problems, or severe problems. All possible combinations of dimensions and levels result in 243 unique health states. Previous studies have developed multi-attribute utility functions (i.e., scoring algorithms) to assign preference weightings or utilities to each of these health states [33,34]. Preference weighting represents individual desire for or value for particular health states. Over the past several decades, preference weightings, like those from the EQ-5D, have been used to adjust survival for quality of life in cost-effectiveness analyses [35]. These scoring algorithms are used to calculate the EQ-5D index score from the responses to the five-item questionnaire. The US preference weighting system developed by Shaw and colleagues [34] was used to estimate the index score for the women involved in this study. Scores ranged from negative values (i.e., states worse than death) to 1 (perfect health). We report the index as well as the proportion of women experiencing limitations in each of the dimensions.

SF-12 scores are available for the general population, by age and sex, for "healthy" individuals (i.e., individuals without any chronic diseases), and for various chronic conditions [29,36]. Ware and colleagues [29] provide norms by age, sex, and for various chronic conditions in the general US population based on a national postal survey conducted between October and December 1998. Sampling weights were adjusted using 1998 US Census data to match age, sex, and the age-within-sex distribution. Hanmer and colleagues [36] use data from the 2000 Medical Expenditure Panel Survey (MEPS) to establish national agestratified and gender-stratified norms for several preference and non-preference-based HRQOL measures including the SF-12 and EQ-5D. EQ-5D index scores were compared with US values [19,36,37]. Sullivan and Ghushchyan [37] report EQ-5D values by clinical diagnoses derived from the 2000–2002 MEPS as part of a catalogue of nationally representative, community-based preferences.

We compared SF-12 and EQ-5D scores for women with and without HSDD with those of healthy individuals and individuals with other chronic conditions, including diabetes and back pain. These conditions were chosen because they have a major impact on physical and emotional function.

#### Depression and Antidepressant Use

Depression was measured using the Center for Epidemiologic Studies Depression Scale (CES-D-8), with women reporting a score of 8 or more identified as depressed [38]. Antidepressant use was based on a woman's self-report of current use of these medications for the treatment of depression.

# Menopausal and Hypoactive Sexual Desire Disorder Classifications

Menopausal status was classified into one of four categories: premenopausal, perimenopausal, naturally menopausal, and surgically menopausal. Self-reported information on timing of last menstrual period, recent or current pregnancy, reproductive surgeries (bilateral oophorectomy or hysterectomy), hormone use, and age were used in the classification process; details of this algorithm are provided elsewhere [11]. For the purposes of these analyses, we examine only women who have undergone natural (n = 552) or surgical (n = 637) menopause, where surgical menopause was defined as bilateral oophorectomy with or without a hysterectomy. We excluded 636 premenopausal women, 206 perimenopausal women, 24 pregnant women, and 33 women with unknown pregnancy or menopausal status.

HSDD is characterized by low sexual desire with concomitant personal distress resulting from low sexual desire [1,4,5,7]. We used clinically validated thresholds for desire and distress using the PFSF and PDS, respectively [22,23,28]. As such, we defined HSDD as a PFSF desire domain score <40 and a PDS® score <60; women meeting these criteria would have indicated that, on average, they "seldom" or "never" felt sexual desire and experienced significant concern or distress about this lack of sexual desire.

#### Comorbidities

The women were asked whether a physician or health professional had ever told them that they had one of the following 23 comorbidities—heart disease, high blood pressure, high cholesterol, stroke or transient ischemic attack, heart attack, arthritis or joint pain, depression, diabetes, obesity, polycystic ovary syndrome, thyroid problems, urinary incontinence, osteoporosis, cancer (other than breast or cervical), noncancerous breast

lumps, breast cancer, cervical cancer, headaches or migraines, fatigue, back pain, insomnia or sleep disturbances, memory problems, or loss of sexual desire. These conditions were selected for query because low levels of estrogen and/or testosterone may influence their occurrence, either by their potential mutagenicity, altering a women's cardiovascular or neurotransmitter profile, or affecting other interrelated factors. Data are not presented for comorbidities for which the observed prevalence was not significantly different from zero.

#### Statistical Analysis

Means, proportions, and associated standard errors are reported for continuous and categorical variables. Student's *t*-test and analysis of variance were employed to evaluate mean differences between the menopausal and HSDD groups and to compare survey means to published norms. The Rao–Scott designadjusted chi-square test [39–41] was used to evaluate differences in categorical outcomes among the groups.

To examine factors predicting health status and HRQOL, we conducted survey-weighted regression analysis using the EQ-5D index and the SF-12 physical and mental component summary scores, respectively, as the dependent variables. Menopausal status and the presence of HSDD were the independent variables of interest. To test the combined effects of HSDD and menopausal status and/or depression, we included interaction terms; nonsignificant interaction terms were subsequently deleted from the model specification. The presence of comorbid conditions and demographic characteristics, including age, race/ethnicity, marital status, income, educational attainment, and obesity were included to control for factors previously shown to be associated with HSDD [10]. Three variables capturing family stress and physical and emotional satisfaction with the current sexual partner were added to evaluate the effects of relationships on health status and perceived quality of life [42].

All analyses were conducted using SAS statistical software, version 9.1 (SAS Institute, Cary, NC). Survey procedures were employed to correct for the complex sampling design. Subgroup analyses were adjusted for variation that may be unrelated to the survey sampling process [43]. Differences are considered statistically significant if the *P*-value is less than 0.05, and corrections are not made for multiple comparisons.

#### **Results**

A total of 1189 naturally and surgically postmenopausal women completed the survey (Table 1). On average, our respondents were 57 years old, 87% were white, and 81% were married or living with a partner. Nearly 61% had less than a college education, with approximately 16% having a high school diploma or less. Slightly more than 9% reported HSDD. Based on the CESD-8 administered during the interview, 11% of the postmenopausal women exhibited depressive symptoms. Regardless of symptomatology, about 15% of the postmenopausal women included in our study were treated for depression. In total, 98% of women reported at least one comorbidity, with a mean of 5.2 (standard error [SE] = 0.2) conditions. Nearly 10% of the women reported 10 or more comorbidities with a maximum of 16 conditions reported.

Compared with women without HSDD, women with HSDD were more likely to be depressed, whether or not they reported current antidepressant use (P = 0.006), and to express dissatisfaction with their home life (P = 0.039) and with the emotional (P = 0.002) and physical (P < 0.001) relationships with their sexual partner. They also were slightly younger although the

**Table I** Comparison of demographic and clinical characteristics $^{\ddagger}$  of postmenopausal women by HSDD status (n = 1189)

Characteristic	All	HSDD	No HSDD
Mean age, years	56.9 (0.6)	54.0 (1.3)	57.2 (0.7)
Age category (%)			
30–39	2.0 (0.6)	4.6 (1.9)	1.8 (0.6)
40–49	14.9 (2.6)	21.5 (5.6)	14.3 (2.9)
50–59	43.5 (3.0)	48.7 (7.8)	43.0 (3.2)
60–70	39.5 (3.1)	25.2 (9.3)	40.9 (3.4)
Menopausal status (%)			
Surgical <sup>9</sup>	42.4 (3.3)	58.3 (8.4)	40.8 (3.6)
Natural	57.6 (3.3)	41.7 (8.4)	59.1 (3.6)
Race/ethnicity (%)			
White, non-Hispanic	86.9 (2.1)	89.9 (4.3)	86.6 (2.3)
Black, non-Hispanic	6.4 (1.5)	8.1 (4.2)	6.2 (1.6)
Hispanic	4.4 (1.4)	0.23 (0.15)	4.8 (1.6)
Other/multiracial	2.3 (0.7)	1.7 (0.9)	2.3 (0.8)
Educational attainment (%)	15.0 (2.2)	15.2 (4.2)	140(04)
<high high="" or="" school="" school<="" td=""><td>15.9 (2.2)</td><td>15.3 (4.2)</td><td>16.0 (2.4)</td></high>	15.9 (2.2)	15.3 (4.2)	16.0 (2.4)
diploma	440 (2.5)	F42 (77)	43.0 (3.0)
Vocational/2-year degree	44.8 (3.5)	54.2 (7.7)	43.8 (3.8)
4-year college degree	24.3 (3.1)	22.0 (5.8)	24.5 (3.4)
Graduate degree	15.0 (2.3)	8.4 (5.4)	15.7 (2.4)
Married or living together (%)	81.2 (3.1)	89.7 (4.2)	80.4 (3.3)
Income ≤\$60,000 (%)	53.7 (3.6)	48.3 (8.2)	54.2 (3.8)
Body mass index (%) <25	39.2 (3.4)	27.4 (5.7)	40.4 (3.7)
25–<30	29.2 (3.1)	41.0 (7.9)	28.0 (3.3)
30+	31.5 (3.4)	31.6 (8.4)	31.5 (3.7)
Reported comorbidity <sup>†</sup> (%)	31.3 (3.1)	31.0 (0.1)	31.3 (3.7)
Fatigue	41.4 (3.4)	67.5 (7.2)***	38.8 (3.6)
Back pain	43.2 (3.4)	60.9 (7.6)*	41.5 (3.6)
Arthritis or joint pain	55.1 (3.4)	55.9 (7.7)	55.0 (3.7)
Insomnia	39.4 (3.2)	54.3 (8.1)	37.9 (3.6)
Memory problems	28.6 (3.1)	46.1 (8.0)*	26.9 (3.3)
Depression	26.2 (2.8)	43.5 (7.6)*	24.5 (7.6)
Current depressive symptoms and	( ' ' )	( )	( , , ,
antidepressant use (%)			
Symptomatic and treated	4.3 (0.9)	9.0 (2.3)**	3.8 (6.0)
Symptomatic and untreated	6.6 (1.6)	16.1 (5.2)	5.6 (1.7)
No symptoms and treated	11.4 (2.2)	16.7 (6.2)	10.8 (2.3)
No symptoms and not treated	77.8 (2.7)	58.0 (7.6)	79.7 (2.9)
Satisfaction with home life (%)	, ,	` '	, ,
Very satisfied	63.0 (3.4)	44.0 (8.1)*	64.8 (3.6)
Somewhat satisfied	28.2 (3.2)	38.0 (7.6)	27.2 (3.4)
Somewhat dissatisfied	6.8 (1.6)	13.8 (4.7)	6.1 (1.6)
Very dissatisfied	2.0 (0.6)	4.2 (2.6)	1.8 (0.7)
Satisfaction with emotional			
relationship with partner (%)			
Very satisfied	63.6 (3.2)	41.6 (8.2)**	65.8 (3.4)
Somewhat satisfied	23.4 (2.6)	38.2 (7.4)	21.9 (2.8)
Neither	2.8 (1.0)	5.2 (3.8)	2.5 (1.0)
Somewhat dissatisfied	4.9 (1.2)	12.9 (4.1)	4.1 (1.2)
Very dissatisfied	5.3 (1.9)	2.2 (0.9)	5.6 (2.1)
Satisfaction with physical relationship			
with partner (%)	()		
Very satisfied	58.5 (3.3)	34.0 (6.9)***	62.0 (3.5)
Somewhat satisfied	30.0 (3.0)	48.0 (8.0)	28.2 (3.2)
Neither	1.6 (0.5)	5.0 (3.0)	1.3 (0.4)
Somewhat dissatisfied	6.6 (1.6)	10.2 (3.2)	6.2 (1.8)
Very dissatisfied	3.2 (0.7)	12.8 (4.7)	2.2 (0.6)

†Statistical significance designated as \*P<0.05; \*\*P<0.01; \*\*\*P<0.001. There were no differences by hypoactive sexual desire disorder (HSDD) status for: heart disease, high blood pressure, high cholesterol, stroke or transient ischemic attack, heart attack, diabetes, obesity, polycystic ovary syndrome, arthritis or joint pain, insomnia or sleep disturbances, thyroid problems, urinary incontinence, osteoporosis, cancer other than breast or cervical, non-cancerous breast lumps, breast cancer, cervical cancer, and headaches or migraines. \* $^{4}$ Standard errors are reported in parentheses.

 $\S{\sf Removal}$  of both ovaries (with or without concomitant hysterectomy) before natural menopause.

difference fell just short of statistical significance (P = 0.059). Surgically menopausal women were slightly more likely to report HSDD than naturally menopausal women (12.5% vs. 6.6%, P = 0.059). Women with HSDD reported significantly more comorbidities than women without HSDD (P < 0.001). They

were significantly more likely to report back pain (P = 0.022), fatigue (P < 0.001), memory problems (P = 0.018), and depression (P = 0.012). For each of these conditions, women with HSDD were nearly twice as likely to report the condition as women without HSDD. They also were more likely to report insomnia and migraines or headache, though these differences had borderline statistical significance.

Several of these differences remained after we accounted for menopausal status (i.e., surgical vs. natural). Among surgically menopausal women, those with HSDD were more likely to report symptoms of depression (P = 0.032), and to be less satisfied with home life in general (P = 0.049), and with their emotional (P < 0.001) and physical (P < 0.001) relationships with their primary partner. Naturally menopausal women with HSDD were more likely to have depressive symptoms with or without antidepressant treatment (P = 0.005) than those without HSDD. Regardless of menopausal status, women with HSDD were more likely to report comorbidities than women without; however, differences attained statistical significance only for fatigue (surgically menopausal women, P = 0.003) and depression (naturally menopausal women, P = 0.008). Although there were some differences between naturally menopausal women with and without HSDD in terms of their satisfaction with home life, and emotional and physical relationships with their partners, none of these reached statistical significance.

#### Health Status and Health-Related Quality of Life

There were substantial differences between women with and without HSDD in health status and HRQOL as measured by the SF-12 (summary and domain scores) and EQ-5D (index and individual dimensions) instruments (Tables 2 and 3, respectively). Women with HSDD reported poorer health status as evidenced by lower SF-12 summary and domain scores (Table 2). Statistically significant differences were observed for the mental summary score (P = 0.033), and the BP (P = 0.025), MH (P = 0.006), VT (P = 0.004), and SF (P = 0.025) domain scores. These differences suggest that women with HSDD experience substantial decrements to their health status and HROOL.

When we disaggregate by menopausal status, this disparity in health status persists. Surgically menopausal women with HSDD reported lower scores across all measures with the differences in the MCS-12 (P = 0.011), GH (P = 0.027), MH (P = 0.016), and VT (P = 0.026) scores attaining statistical significance. A similar pattern was observed for naturally menopausal women with HSDD who reported significantly more pain than their counterparts without HSDD (P = 0.027).

Women with HSDD reported lower EQ-5D index scores than women without HSDD (0.76 vs. 0.84, P < 0.010) (Table 3). They also were more likely to report difficulties for each of the five dimensions although only two dimensions were statistically different: pain and discomfort (P = 0.017) and anxiety and depression (P < 0.001). Among naturally menopausal women, those with HSDD reported lower EQ-5D index scores (P = 0.002) and more difficulty with self-care (P < 0.001) and more anxiety and depression (P = 0.006) compared with their counterparts without HSDD.

Factors predicting EQ-5D index and SF-12 physical and mental summary scores are presented in Table 4. After controlling for several factors, both HSDD and surgical menopause were associated with lower EQ-5D index scores. Only surgical menopause was associated with lower HRQOL as measured by PCS-12 scores. Neither HSDD nor surgical menopause predicted MCS-12 scores, which were predicted primarily by current

Table 2 Differences in SF-12 mental and physical composite scores and domain scores for postmenopausal women† by HSDD and menopausal status

			Surgical m	Surgical menopause <sup>‡</sup>		Natural menopause	
SF-12 scores HSDD	No HSDD	HSDD	No HSDD	HSDD	No HSDD		
Composites							
PCS-12	45.0 (2.3)	47.3 (0.8)	44.6 (2.3)	45.1 (1.3)	45.6 (4.8)	48.8 (1.1)	
MCS-12	47.3 (2.1)*	52.0 (0.6)	44.7 (2.1)*	50.6 (1.3)	51.1 (3.2)	53.0 (0.8)	
Domains							
GH	46.2 (1.9)	49.3 (0.8)	43.1 (2.3)*	48.9 (1.1)	50.6 (2.7)	49.6 (1.1)	
PF	44.9 (2.1)	48.8 (0.8)	45.0 (2.3)	46.9 (1.2)	44.7 (3.8)	50.1 (1.0)	
RP	46.4 (1.5)	47.6 (0.8)	45.7 (1.7)	45.6 (1.4)	47.5 (2.8)	49.0 (1.0)	
RE	46.6 (1.7)	49.8 (0.7)	44.6 (2.6)	48.8 (1.0)	49.5 (1.4)	50.4 (1.0)	
BP	41.4 (2.2)*	46.7 (0.9)	41.7 (2.7)	43.1 (1.4)	40.9 (3.5)*	49.2 (1.2)	
MH	45.4 (1.9)**	51.0 (0.6)	43.1 (2.2)*	49.1 (1.0)	48.9 (2.7)	52.4 (0.8)	
VT	47.7 (1.3)**	52.0 (0.7)	45.9 (1.6)*	50.2 (1.1)	50.2 (2.0)	53.3 (1.0)	
SF	47.3 (1.4)*	50.9 (0.7)	45.5 (I.8)	48.6 (1.2)	49.7 (1.8)	52.5 (0.7)	

Statistical significance designated as \*P < 0.05; \*\*P < 0.01.

depression and antidepressant use. The interaction between HSDD and surgical menopause was not statistically significant in any of the models and thus was eliminated from the model specification.

### Health-Related Quality of Life Comparison by Age

Figure 1 shows SF-12 summary and domain scores for women with HSDD compared with US norms by age for all women [29]. Survey results and norms for women ages 30-34 and 65-70 are not shown because of insufficient numbers of women with HSDD. Women with HSDD generally report lower scores for both composites and all domain scores when compared with the age-specific US norms for women. In results not shown, we compared scores for women with HSDD to their age-matched norm (i.e., women age 35-44 with HSDD vs. the US norms for all woman age 35-44). For each age group, women with HSDD reported greater impairment in all HRQOL domains than the population-based norms. Women age 35-44 with HSDD reported significant impairment in physical aspects of HRQOL (PCS-12, P = 0.008; GH, P = 0.011; PF, P = 0.002; RP, P < 0.001; and BP, P < 0.001). Among women with HSDD age 45-54, the differences were statistically significant for both physical (PCS-12, P = 0.008; RP, P = 0.042; and BP, P < 0.001) and emotional aspects of HRQOL (RE, P = 0.034 and MH, P = 0.024). Only BP (P = 0.002) and MH (P = 0.010) attained

statistical significance for women age 55-64 with HSDD. Similar results were observed when comparing to Hanmer and colleagues' [36] age-based US population norms.

## Health-Related Quality of Life Comparison between **HSDD** and Selected Chronic Diseases

To place HSDD into context with other health conditions, we compared the SF-12 scores of women with HSDD to available norm scores for the general population (i.e., "healthy" population without chronic disease) and for adults with various chronic conditions (Fig. 2). Compared with the "healthy" population, women with HSDD reported more HRQOL impairments (all domains; P < 0.001). Although women with HSDD reported fewer impairments in psychosocial aspects (MCS-12, RE, MH, VT, SF; P < 0.001) than individuals with depression, they were very similar in their report of physical impairment and GH. Women with HSDD experienced similar HRQOL when compared with individuals with back pain and diabetes. Nevertheless, they did report better GH (P = 0.013) and physical role functioning than individuals with diabetes (P = 0.013).

Table 5 presents the mean, median, and quartiles for EQ-5D scores of women with HSDD compared with conditions in Sullivan and Ghushchyan's [37] catalogue of nationally representative, community-based preference scores. The norm value

Table 3 Differences in EQ-5D. index scores and proportion of postmenopausal women reporting difficulties with individual dimensions by HSDD and menopausal status

EQ-5D		No HSDD	Surgical menopause <sup>‡</sup>		Natural menopause	
	HSDD		HSDD	No HSDD	HSDD	No HSDD
Index score	0.76 (0.03)*	0.84 (0.02)	0.74 (0.04)	0.78 (0.04)	0.78 (0.03)**	0.88 (0.01)
Dimensions (% reporting any difficulty)	, ,	` ′	` ′	` ′	, ,	` ,
Mobility	45.4 (8.2)	31.2 (3.7)	44.5 (8.5)	38.6 (5.6)	46.7 (15.5)	26.1 (4.8)
Self-care	13.2 (5.2)	4.1 (2.1)	15.6 (7.2)	8.9 (4.9)	9.8 (6.8)***	0.79 (0.34)
Usual activity	38.4 (8.3)	27.4 (3.5)	34.3 (8.0)	37.3 (5.6)	44.2 (15.6)	20.5 (4.3)
Pain/discomfort	70.3 (6.3)*	51.8 (3.8)	70.2 (7.4)	60.1 (5.5)	70.4 (11.0)	46.2 (5.2)
Anxiety/depression	47.8 (7.9)***	21.7 (2.9)	45.1 (8.2)	29.8 (4.8)	51.6 (15.1)**	16.2 (3.6)

<sup>†</sup>Standard errors are reported in parentheses.

<sup>‡</sup>Removal of both ovaries (with or without concomitant hysterectomy) before natural menopause.

BP, bodily pain; GH, general health; HSDD, hypoactive sexual desire disorder; MCS-12, mental component summary score-SF-12; MH, mental health; PCS-12, physical component summary score-SF-12; PF, physical functioning; RE, role emotional; RP, role physical; SF, social functioning; SF-12, Short Form 12; VT, vitality.

Standard errors of mean and proportion are reported in parentheses.

<sup>‡</sup>Removal of both ovaries (with or without concomitant hysterectomy) before natural menopause.

EQ-5D, EuroQol 5-D index; HSDD, hypoactive sexual desire disorder.

Table 4 Predictors of EQ-5D index and SF-12 composite (PCS-12 and MCS-12) scores in postmenopausal women

	EQ-5D index		PCS-12		MCS-12	
Characteristic	В	SE (B)	В	SE (B)	В	SE (B
Constant	0.98	0.04	56.64	2.48	54.46	2.17
HSDD	-0.07*	0.03	-1.64	2.14	-1.55	1.34
Surgical menopause	-0.03*	0.02	-2.90**	1.08	-0.06	0.88
Current depressive symptoms and antidepressant use						
No symptoms and not treated			Reference	category		
No symptoms and treated	-0.01	0.03	0.38	1.67	<del>-4</del> .72***	1.06
Symptomatic and untreated	-0.06*	0.03	1.06	1.94	-II.25***	1.50
Symptomatic and treated	-0.20***	0.06	-6.90**	2.35	-14.47***	2.26
Age						
40–59			Reference	category		
50–59	-0.05	0.04	-1.41	1.86	-0.11	1.12
60–69	-0.01	0.02	-0.33	1.21	0.07	0.98
Race/ethnicity						
White, non-Hispanic				category		
Black, non-Hispanic	0.08**	0.03	2.80	2.31	0.06	2.31
Hispanic	0.00	0.04	-3.09	2.02	1.11	2.28
Other/multiracial	-0.01	0.06	- <del>4</del> .73**	1.82	3.33*	1.55
Educational attainment						
<high diploma<="" high="" school="" td=""><td></td><td></td><td></td><td>category</td><td></td><td></td></high>				category		
Vocational/2-year	-0.03	0.03	2.36	1.68	1.81	1.21
4-year college degree	-0.0 I	0.03	2.05	1.72	1.23	1.40
Graduate degree	-0.02	0.03	2.02	1.83	1.95	1.41
Married or living together	0.04	0.03	1.08	1.62	0.30	1.20
Income ≤\$60,000	-0.01	0.02	0.15	1.12	-0.89	0.98
Current smoker	-0.05*	0.02	-2.49*	1.15	-1.88	0.98
BMI			ъ.			
<25	0.01			category	1.44	
25-<30	0.01	0.02	-2.84* 4.05*	1.29	1.44	1.05
30-<35	-0.01	0.03	-4.85*	1.90	1.65	1.30
35-<40 40+	-0.01 0.02	0.03 0.04	-7.90*** -7.55**	2.07 2.29	3.80** 2.42	1.38 1.95
	0.02	0.04	-/.55 <sup>n-n</sup>	2.29	2.42	1.75
Reported comorbidity Cardiac	-0.11*	0.05	-0.87	1.62	-2.49	1.92
Hypertension	-0.11· -0.01	0.03	-0.67 -3.15**	1.18	-2. <del>49</del> -1.00	0.88
Hypercholesterolemia	0.01	0.02	-0.25	0.94	1.17	0.88
Diabetes	-0.04	0.02	-5.09*	2.14	0.33	1.53
Thyroid condition	0.02	0.02	-1.52	1.45	0.05	1.18
Urinary incontinence	-0.02	0.02	2.43*	1.43	-0.70	1.10
Osteoporosis	0.00	0.03	-3.65*	1.44	-0.43	1.03
Migraine	-0.04	0.03	2.56*	1.15	-0.73	0.96
Fatigue	0.01	0.03	-4.67***	1.16	-2.28*	1.09
Back pain	-0.02	0.02	-2.33	1.24	-0.38	0.89
Arthritis	-0.09***	0.02	−3.64**	1.24	0.12	1.03
Insomnia	0.01	0.02	-0.37	1.12	1.56	0.90
Memory problems	-0.06	0.03	-1.36	1.21	-1.26	0.96
Satisfaction with:						
Home life: very satisfied			Reference	category		
Home life: somewhat satisfied	-0.02	0.02	-1.31	1.21	-3.64***	1.06
Home life: dissatisfied	-0.06	0.03	2.19	1.96	-3.92*	1.53
Emotion: very satisfied				category		
Emotion: somewhat satisfied	-0.02	0.02	-1.22	1.40	-1.02	1.05
Emotion: dissatisfied	0.04	0.04	3.97	3.10	0.10	1.80
Physical: very satisfied			Reference	category		
Physical: somewhat satisfied	0.05*	0.02	2.34	1.12	0.42	1.06
Physical: dissatisfied	0.04	0.03	-2.63*	3.62	0.59	1.50
F	26.99 (P < 0.0001) 23.61 (P < 0.0001)				25.88 (P <	0.00017
Adjusted R <sup>2</sup>	0.4955		0.4620		0.4858	2.0001)

Statistical significance noted as: \*P < 0.05; \*\*P < 0.01; \*\*\*P < 0.001.

BMI, body mass index; Emotion, emotional relationship with partner; EQ-5D, EuroQol 5-D Index; HSDD, hypoactive sexual desire disorder; MCS-12, SF-12 mental health component summary score; PCS-12, SF-12 physical health component summary score; Physical, physical relationship with partner; SE, standard error; SF-12, Short Form 12; Surgical menopause, removal of both ovaries (with or without concomitant hysterectomy) before natural menopause.

they report for menopausal disorder (International Classification of Disease, Ninth Clinical Modification [ICD-9] 627) of 0.817 is significantly higher than the values we found for women with HSDD (0.758), with the largest difference observed compared with surgically menopausal women with HSDD (0.745). Compared with women with other chronic conditions, those with HSDD report similarly low EQ-5D index scores.

#### **Discussion**

Our results offer a systematic evaluation of health status and HRQOL in women with HSDD. Women with HSDD experience greater health burden in terms of comorbidities, and were nearly twice as likely to report depression, fatigue, back pain, and memory problems compared with women without HSDD. They also reported poorer health status as reflected by lower

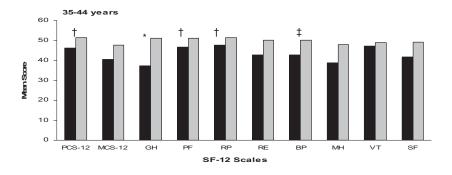
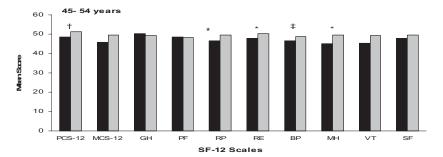
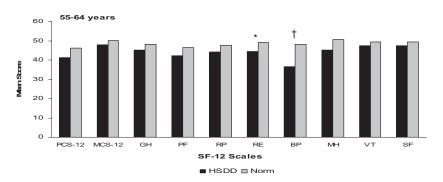


Figure I HRQOL comparisons between women with HSDD and US norms for women by age. For each age group (i.e., age 35-44, 45-54, 55-64), women with HSDD reported greater impairment in all HRQOL domains than the population-based norms. Women age 35-44 with HSDD reported significant impairment in physical aspects of HRQOL (PCS-12, P = 0.008; GH, P = 0.011; PF, P = 0.002; RP, P < 0.001; and BP, P < 0.001). Among women with HSDD age 45-54, the differences were statistically significant for both physical (PCS-12. P = 0.008; RP. P = 0.042; and BP. P < 0.001) and emotional aspects of HRQOL (RE, P = 0.034 and MH, P = 0.024). Only BP (P = 0.002) and MH (P = 0.010) attained statistical significance for women age 55-64 with HSDD. Statistical significance designated as \*P < 0.05; †P < 0.01; ‡P < 0.001. BP, bodily pain; GH, general health; HRQOL, health-related quality of life; HSDD, hypoactive sexual desire disorder; MCS-12, mental component summary score-SF-12; MH, mental health; PCS-12, physical component summary score-SF-12; PF, physical functioning; RE, role emotional; RP, role physical; SF, social functioning; SF-12, Short Form 12; VT, vitality.





SF-12 scores with 4-point to 6-point differences in GH, BP, MH, VT, and SF domain scores, and a 5-point difference in the MCS-12 score. These differences generally persisted after stratification for menopausal status, with statistically significant differences observed for surgically menopausal women. Differences for physical domains and summary scores were on the order of 2 to 3 points, and were not statistically significant.

EQ-5D results present a similar pattern, reinforcing the finding that women with HSDD have poorer quality of life than women without. Women with HSDD reported significantly lower EQ-5D index scores than women without, experiencing a decrement of 0.08 points (on a scale from 0 to 1), with a 0.1-point decrement for naturally menopausal women with HSDD. Women with HSDD reported more difficulties in general than those without. They were 35% more likely to report pain and discomfort and twice as likely to report pain and anxiety compared with women without HSDD.

The availability of population-based norm scores for the SF-12 [29,36] and the recent EQ-5D catalogue of preferences scores [19,37] provide a context for evaluating the health burden of HSDD. Compared with healthy adults without chronic diseases, women with HSDD demonstrated significantly poorer

HRQOL across all dimensions as measured by SF-12 scores. This finding is not surprising given that women with HSDD were 10 years older (54 years vs. 44.8 years) and reported an average of 6.6 (vs. 5.1) chronic conditions compared with women without HSDD. Women with HSDD reported similar profiles of impairment when compared with the SF-12 norm scores for diabetes, hypertension, back pain, and arthritis. These patterns are echoed in the comparison of EQ-5D results with Sullivan and Ghushchyan's [37] catalogue of EQ-5D index scores, with our score for HSDD being significantly lower than the estimate for menopausal disorders (ICD-9 627) and comparable to various chronic conditions.

In findings consistent with ours, Leiblum and colleagues [8] report significant decrements in HRQOL using data from 952 premenopausal and postmenopausal women. Reporting un-normed SF-36 scores, which are neither comparable to normed SF-12 scores or to the available norms for SF-36 scores [29], they demonstrate that women with HSDD score consistently lower (i.e., 5 to 16 points lower) on the eight SF-36 domains (summary scores are not reported), with smaller differences for domains that capture aspects of physical health. As well, our prevalence results [11] correspond to those reported by Dennerstein and colleagues [9] and Leiblum and

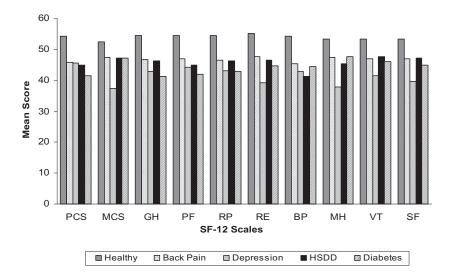


Figure 2 SF-12 score comparisons among women with HSDD, a healthy population, and adults with selected chronic diseases. Compared with the "healthy" population, women with HSDD reported more HRQOL impairments (all domains; P < 0.001). Although women with HSDD reported fewer impairments in psychosocial aspects (MCS-12, RE, MH,VT, SF; P < 0.001) than individuals with depression, they were very similar in their report of physical impairment and general health. Women with HSDD experienced similar HRQOL when compared with individuals with back pain and diabetes. Nevertheless, they did report better general health (P = 0.013) and physical role functioning than individuals with diabetes (P = 0.013). BP, bodily pain; GH, general health; Healthy = "healthy" adults with no chronic conditions; HRQOL, health-related quality of life; HSDD, hypoactive sexual desire disorder; MCS-12, mental component summary score-SF-12; PH, mental health; PCS-12, physical component summary score-SF-12; PF, physical functioning; RF, role emotional; RP, role physical; SF, social functioning; SF-12, Short Form 12; VT, vitality.

colleagues [8], which both used validated instruments of sexual function and distress (i.e., the PFSF and PDS).

Our study design has several advantages over existing research. First, our data come from a population-based survey derived using a probability-sampling frame of US households with telephone access, thus allowing us to make inferences at the national level. Previous studies of sexual desire disorder have employed clinical trial participants, small convenience samples, or, in the case of the only study providing preliminary HRQOL data, were derived from consumer marketing databases. Additionally, we assessed sexual desire and distress using instruments

Table 5 Comparison of EQ-5D index scores for HSDD and selected chronic conditions

	EQ-5D index score					
Condition*	Mean	25%ile	Median	75%ile		
HSDD	0.758	0.761	0.800	0.844		
Surgically menopausal with HSDD	0.745	0.708	0.800	0.860		
Naturally menopausal with HSDD	0.775	0.761	0.778	0.844		
Angina pectoris (ICD-9 413)	0.695	0.517	0.768	0.827		
Osteoarthritis (ICD-9 715)	0.703	0.689	0.778	0.816		
Neurotic disorders (ICD-9 300)	0.739	0.506	0.778	0.844		
Adjustment disorder (ICD-9 309)	0.739	0.597	0.800	0.844		
Obesity (ICD-9 278)	0.744	0.708	0.800	0.844		
Diabetes mellitus (ICD-9 250)	0.751	0.708	0.800	0.844		
Gastritis and duodenitis (ICD-9 535)	0.765	0.708	0.800	0.844		
Essential hypertension (ICD-9 401)	0.789	0.761	0.816	1.000		
Asthma (ICD-9 493)	0.797	0.761	0.827	1.000		
Breast cancer (ICD-9 174)	0.803	0.708	0.816	1.000		
Migraine (ICD-9 346)	0.806	0.778	0.827	1.000		
Menopausal disorders (ICD-9 627)	0.817	0.778	0.827	1.000		
Acquired hypothyroidism (ICD-9 244)	0.821	0.778	0.827	1.000		
Benign mammary dysplasia (ICD-9 610)	0.852	0.810	0.827	1.000		

\*Data for conditions other than HSDD obtained from Sullivan and Ghushchyan [37]. EQ-5D, EuroQoL 5-D; HSDD, hypoactive sexual desire disorder; ICD-9, International Classification of Diseases-Ninth Clinical Modification; 25%ile, 25th percentile (i.e., lower quartile); 75%ile, 75th percentile (i.e., upper quartile).

that were validated in a postmenopausal population [22,23,28]. We also employed well-validated health status and HRQOL instruments used extensively for population-based surveys of various health conditions and calculated norm-based scores [19,29–32,34,36,37,44,45]. By doing so, we were able to compare our results directly with the population norms provided and to provide nationally representative estimates of SF-12 and EQ-5D index scores for HSDD.

Several limitations of our study should be noted. First, based on the known prevalence of oophorectomy in young women, we anticipated having difficulty identifying enough women age 30-39 years who had their ovaries removed. In addition, although we had conducted an earlier pilot of our survey and sampling approach, we had difficulty accruing the desired sample size of women age 60-69 and had to modify our sampling frequencies midsurvey. This modification resulted in a final survey population that was heavily weighted towards women 50-59 years of age. In addition, we interviewed only 25% of the women aged 60-70 that we had proposed, which affected our power in analyses for this subgroup. In particular, we were unable to compare SF-12 scores for women with HSDD ages 30-34 or 65-70 to age-specific population norms, and therefore cannot draw with confidence conclusions as to the comparative severity of HSDD in these groups.

Second, telephone surveys although efficient are subject to the whims of technology; bias is a function of telephone coverage and characteristics of nonrespondents. The advent of caller ID, voicemail, and answering machines has contributed to declines in telephone survey response rates [46]. During our survey period, 93.5% to 94% of households in the US had landline telephones [47]. Individuals less likely to have a telephone include racial and ethnic minorities, individuals with less education, who live in rural areas, and who are more likely to report worse self-rated health [48]. As well, renters and unemployed individuals are less likely to have telephones [47,49,50]. The increase in cell phone subscribership from 195 million to 207 million wireless tele-

phones in use in 2005 [47] also may result in bias. Studies suggest that the cell phone only group is demographically distinct from individuals with landlines [46]. These individuals are either young (age 18–30), relatively wealthy renters, or poor ethnic minorities who have cell phones for economic reasons [47,51]. Surveys, including ours, are typically weighted to account for nonresponse from landline coverage [52,53]; reweighting for cell phone coverage has been suggested but is not commonly implemented [54]. Blumberg et al. [54] further has suggested that excluding these individuals may not result in large bias and has shown that they generally resemble individuals with landlines in terms of health-risk behaviors.

As well, our survey response rate (56.7%) was somewhat lower than the rates reported by other studies evaluating sexual function in women; differences may be due to the sample selected and survey administration approach. Dennerstein and Lehert [54] reported a rate of 71% from a convenience sample of women recruited through their physicians, offices; the women also completed written questionnaires. Leiblum and colleagues [8] employed a mail survey (77% response) of women selected from a marketing research pool. These women may have been more likely to respond to surveys in general than the women who participated in our national telephone survey. Differences in survey administration may account for our lower response rate. Our response rate, however, was similar to that of the 2004 Behavioral Risk Factor Surveillance System (BRFSS) (median response rate 47.2%), which asks data about sensitive topics, including HIV testing, drug use, and binge drinking. Recent studies suggest that the BRFSS yields results that are similar to those of national in-person surveys such as the National Health Interview Survey and National Health and Nutrition Surveys. which have higher response rates [55,56]. We were unable to collect any data from nonresponders in the current study because of institutional review board restrictions and thus do not know whether women who declined to participate in the survey were systematically different from women who did participate in the survey. As well, we are unable to determine whether nonresponders were similar to individuals who typically do not respond to surveys.

An additional concern is that the PFSF and PDS instruments were validated for self-administration, whereas, in our study, the instrument was administered by a female interviewer. It is unclear whether this difference changed how women answered the questions. Nevertheless, when we compared our results to those of Leiblum and colleagues [8] who used self-administration of the PFSF and the PDS, we saw little difference when evaluating the correlations across the sexual interest, arousal, and orgasm domains [11]. In addition, the prevalence of HSDD was similar between the two studies. Thus, we feel that mode of administration did not affect our survey results.

#### **Conclusions**

Using a nationally representative sample, this study shows that postmenopausal women with HSDD report poorer health status and HRQOL than women without HSDD. These impairments, though apparent in all aspects of quality of life, are particularly pronounced for BP and MH and psychosocial aspects of quality of life, including SF and VT. When compared with national norms, our results indicate a degree of impairment comparable to that observed for common chronic conditions such as hypertension, diabetes, osteoarthritis, and asthma. Given recent estimates of the prevalence of HSDD [8,11], HSDD affects a significant

number of women [11]. Taken together, these results suggest that HSDD represents a significant and clinically relevant problem rather than a disorder "medicalised" for its pharmaceutical market potential.

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