

The HSDD Registry for Women: Design and Methods

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INTRODUCTION

Hypoactive sexual desire disorder (HSDD) is defined in the DSM-IV as a deficiency or absence of sexual fantasies and desire for sexual activity, which causes marked distress or interpersonal difficulty and cannot be better accounted for by another non-sexual Axis I disorder or result solely from the direct physiological effects of a substance or medical condition, in the judgment of the clinician.

HSDD is a clinically challenging disorder. Little is known about risk factors and predictors of HSDD or the long-term consequences and natural history of the disorder. A well-designed, longitudinal registry can address these and other clinically-important needs. We describe the design and implementation of a large-scale registry study of HSDD in women, **The HSDD Registry for Women**.

METHODS

Registry Design

A longitudinal registry study of women with HSDD was initiated at clinical sites throughout the U.S. Recruitment of 1000 women with a new diagnosis of HSDD as determined by clinician assessment is scheduled to occur over 18 months at 40 sites.

An organizational chart appears in **Figure 1**.

Inclusion and Exclusion Criteria

- Women aged 18 years or older with a confirmed diagnosis of HSDD by a qualified clinician within 3 months of enrollment.
- Women are excluded if they are currently enrolled in a clinical trial, have a chronic medical or psychiatric condition that is likely to interfere with their participation in the opinion of the clinical site investigator, or are non-English speaking.

HSDD Diagnosis: Role of the Decreased Sexual Desire Screener (DSDS)

The HSDD diagnosis required for eligibility in the Registry is determined by in-person administration of a validated diagnostic instrument, the Decreased Sexual Desire Screener (DSDS), administered by a qualified clinical investigator.

Recruitment

Recruitment occurs primarily at Sexual Medicine and Obstetric/Gynecological clinic sites throughout the U.S.

Monitoring and Follow-Up Procedures

- The Registry is designed to follow each individual participant for approximately two years, using both in-person follow-up at clinic visits and remote monitoring via web-based, mail, or telephone communication.
- The first (baseline) assessment occurs in person at the clinical site upon enrollment. After the baseline visit, follow-up occurs at approximately 3-monthly, 6-monthly, and yearly intervals (**Figure 2**).

Registry Measures

(1) Participant Self-Administered Questionnaire

The questionnaire includes previously validated scales and measures (select measures are listed in **Figure 2**), as well as questions designed and validated for the Registry, or based on other ongoing epidemiologic surveys.

(2) Medical History Review

A medical history form is completed by the clinical site staff. The information collected on the medical review form includes: HSDD status, treatments and referrals, prevalent and incident comorbidities and prescription medications.

Data Coordinating Center

New England Research Institutes, Inc. (NERI, Watertown, MA) is the Data Coordinating Center for the Registry.

Figure 1. Organizational Chart

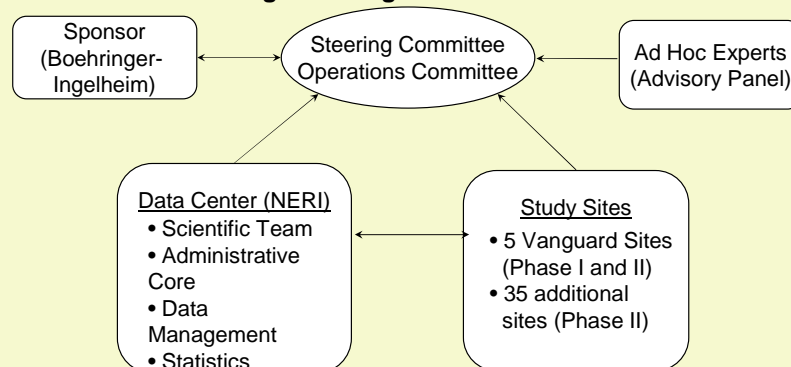
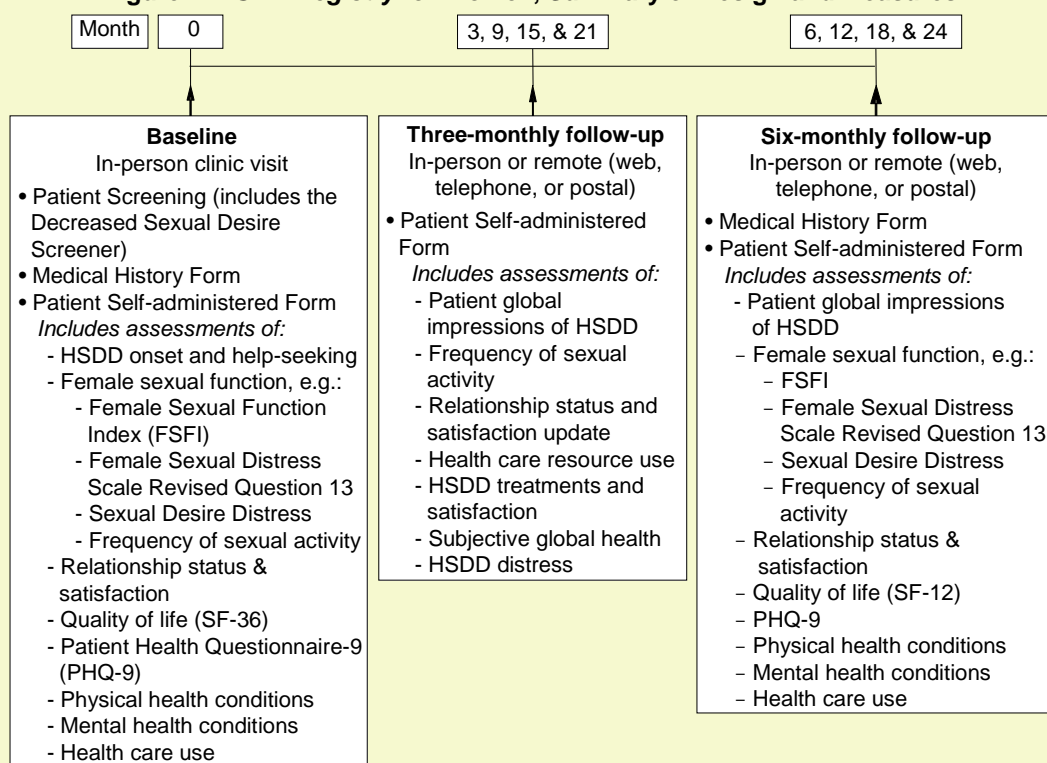


Figure 2. HSDD Registry for Women, Summary of Design and Measures



INTERIM RESULTS

Registry Implementation – Progress to Date

A total of 290 women (ages 19-80) including 209 pre-menopausal and 81 post-menopausal have been recruited as of February 12, 2009. Demographic characteristics of these women are provided in **Table 1**. As mandated by the Registry follow-up schedule, 150 women have completed 3-month follow-up visits and 22 women have completed 6-month follow-up visits. As of February 12, 2009, 15 clinical sites were actively participating in the Registry. The clinical sites are located across the U.S. (**Table 2**). Additional sites are in preparatory phases (e.g., pending IRB approval) of participation. Results of the feasibility phase indicated that the Registry protocol was implemented successfully and the data collection instruments performed well, resulting in minimal missing data. The initial feasibility sample showed that the sample was socioeconomically diverse.

Table 1: Characteristics of 290 participants recruited into the HSDD Registry as of February 12, 2009

Age, mean years ± sd, range	41.9 ± 12, 19-80
Menopausal status, n (%)	
Premenopausal	209 (72)
Postmenopausal	81 (28)
Relationship status, n (%)	
Married	189 (65)
Living with partner, unmarried	42 (14)
Divorced/separated	18 (6)
Widowed	3 (1)
Single, never married	33 (11)
Other	5 (2)
Highest Education Level, n (%)	
High School or less	129 (44)
College degree	106 (37)
Post-College degree	55 (19)
Race/ethnicity, n (%)	
White	221 (76)
Black	39 (13)
Hispanic	22 (8)
Asian	3 (1)
Other	5 (2)

Table 2: Locations of the first 15 clinical sites participating in the HSDD Registry and characteristics of the first 290 participants recruited at each site as of February 12, 2009

	N	Mean Age	Pre-menopausal N (%)	Post-menopausal N (%)	Married N (%)
Northeast #1	15	44.4	9 (60)	6 (40)	12 (80)
Northeast #2	8	41.4	6 (75)	2 (25)	4 (50)
Mid Atlantic #1†	30	39.2	24 (80)	6 (20)	17 (57)
Mid Atlantic #2†	34	42.9	26 (76)	8 (24)	23 (68)
Mid Atlantic #3	6	43.3	4 (67)	2 (33)	4 (67)
Mid Atlantic #4	11	44.1	7 (64)	4 (36)	5 (45)
Southeast #1†	43	41.8	31 (72)	12 (28)	31 (72)
Southeast #2	34	37.3	27 (79)	7 (21)	19 (56)
Southeast #3	6	54.2	1 (17)	5 (83)	4 (67)
Southeast #4	18	44.9	12 (67)	6 (33)	7 (39)
Midwest #1	10	44.2	6 (60)	4 (40)	8 (80)
West Coast #1†	24	43.3	19 (79)	5 (21)	13 (54)
West Coast #2†	19	47.1	13 (68)	6 (32)	16 (84)
Southwest #1	2	31.0	2 (100)	0 (0)	2 (100)
Southwest #2	30	38.5	22 (73)	8 (27)	24 (80)
Total	290	41.9	209 (72)	81 (28)	189 (65)

† Site participated as one of the five Vanguard Phase I clinical sites, which began recruitment on June 27, 2008. All other sites began recruitment after August 28, 2008.

CONCLUSIONS

The *HSDD Registry for Women* is the first registry in female sexual dysfunction. Longitudinal analyses will be used to assess natural history and clinical course of HSDD in a well-characterized sample of 1000 women.

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