

Women and Mood Disorders Task Group

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The Women & Mood Disorders Task Group

Goals Overview

- ***Near term goal:*** To build a research network infrastructure and specifically to establish, develop and demonstrate collaborative research capacity. The first step is a focused research agenda that may be strengthened by the diversity and interdisciplinary nature of the group.
- Research Agenda based on (1) clear gaps in knowledge, (2) high public health importance and (3) need for a network-based approach.
- ***Longer term goal:*** We will be a national resource for research on women's depression and sex differences and will serve the community through education, research and improvements in clinical care and influence on public policy.

W&MD Infrastructure and Collaborative Capacity

- Assistance with amending all parent study Human Use Approval protocols
- Data Sharing / authorship agreements
- Consensus on data elements and process for central repository
- Transmission and handling of data
- Databases codebook templates
- Protocol and Manual of Procedures templates
- Warehousing, cleaning / aggregation of databases
 - Decision rules about standardizing different data elements (e.g assessment time frames; use of different measures)

Brief W&MD Accomplishments

- numerous presentations at scientific conferences
- three publications
- two funded NIH grants, and two additional grants under review
- Recently completed Phase I of a pilot aimed to demonstrate the feasibility of utilizing standard assessment of mood and related clinical factors across multiple sites and settings

Flynn, H., Spino, C., Guille, C., Deligiannidis, K., Maki, P., Jahnke, J., Rosenblum, K., Epperson, N., & Weiss, S. (2017). A collaborative, network-based approach to advance women's depression research in the U.S.: Preliminary findings. Journal of Women's Health.

Institution	Setting	Data Collection Process*	Sample Size (%)
University of Michigan	Obstetrics	Clinicians administered	67 (5%)
UMASS	Reproductive Psychiatry Clinic	Clinicians administered	159 (12%)
University of Pennsylvania	Reproductive Psychiatry Clinic	Clinicians administered	46 (3%)
Florida State University	Obstetrics and Gynecology Clinic	Research staff administered	596 (45%)
MUSC	Obstetrics and Gynecology Clinic	Clinicians administered and research staff collected	356 (27%)
UIC	Women's Health Outpatient Clinic	Research staff administered	49 (4%)
UCSF	Neonatal Intensive Care/Obstetrics	Research staff administered	60 (5%)

**Phase 1
Multi-Site Pilot**

N= 1316

Selected Results

Variable	%
Lifetime history of depression	46%
PHQ9 ≥ 10	14%
GAD7 ≥ 10	15%
Ever diagnosed with depression	31%
Ever diagnosed with anxiety	24%
Most common symptoms of depression	tired/little energy, trouble sleeping, and poor appetite/overeating
Most common symptoms of anxiety	becoming easily annoyed/irritable, worrying too much, and feeling nervous or on edge

Feasibility Results: Facilitators

- Achieved target of ≥ 50 forms per site
- involving students as recruiters
- incorporating the forms into an ongoing study or as part of standard clinical care
- having funding available for research assistants
- centralized infrastructure for the overall project: trouble-shooting by the study's Co-Investigators, access to the detailed procedural manual provided to each site, and the flexibility and ease with which data could be transferred to the central coordinating center

Feasibility Results: Barriers

- reliance on busy clinic staff to engage women and distribute questionnaires
- lack of resources to pay clinical research coordinators and RAs for recruitment and data entry
- lack of resources to reimburse women for their time in completing forms
- lack of and instant data upload program

Phase II

Women's Mood & Screening Project

- **Overall Goal**
 - **Refine and test a validated screening questionnaire that can be used for network-based grants and provide valuable data for testing of research questions**

Aims of Phase II

- **Revise components of the core screening questionnaire where needed**
- **Develop supplemental assessment modules based on individual site interests and need**
- **Pilot the new version, including more sites than were originally involved**

Core Questionnaire Data

Demographics

Menstrual History & Status

Brief Family Psychiatric History

-Depression, Bipolar, Anxiety, Other

Patient Psychiatric History

Psychiatric Treatment : Current & Past

Suicide Attempts

Depression & Anxiety Screens

- PHQ-9

- GAD-7

Revisions Based on Phase 1 Analysis

- **Data Collection Procedures**
 - Reconsidering the option for anonymous data collection versus informed consent (missing data & lack of follow-up)
 - Expanding settings beyond those with a perinatal population
 - Expanding settings that are non-psychiatric

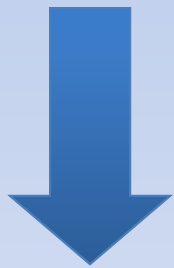
Revisions Based on Phase 1 Analysis

- **Data Being Collected**
 - Added History of Personal/Family Bipolar Illness
 - Modified and Simplified Section on Menstrual History/Status
 - Clarified Questions on Work History
 - Added Questions on Access to Treatment
 - Added Specific Question on a Suicide Attempt
 - Expanded Choices for Types of Treatment Use (eg. telepsychiatry)
 - Added Basic Classes of Medication Use

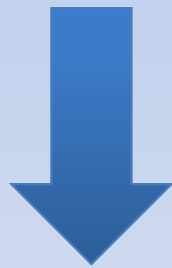
Core Screening Questionnaire



Supplemental Modules



**Stress
Exposure**



**Reproductive
Status**



**Substance
Abuse**



**Social & Health
Context**



**Treatment
Use/Response**

14 Participating Sites

- **University of Pennsylvania**
- **Emory**
- **University of Texas**
- **University of Michigan**
- **Mayo Clinic**
- **University of California, San Francisco**
- **Medical University of South Carolina**
- **University of Iowa**
- **University of Massachusetts**
- **Florida State University**
- **Ohio State University**
- **Hofstra Northwell Health, NY**
- **Virginia Commonwealth**
- **Brigham & Women's Hospital**

Central Infrastructure Support

- **Manual of Instructions and Procedures**
- **Consultation on Administration/Staff Engagement**
- **Consultation on IRB Documents & Approval**
- **Consultation on Data Entry**
- **Aggregation and Analysis of Preliminary Data**
- **Arrangement of Procedures for Data Access & Use**

Deliverables

- **Preliminary Data for Grant Submission**
- **Submission of at Least 2 Research Applications for Funding**
- **Publication of a Least 2 Manuscripts from the Data**

Deliverables

- **Testing of Specific Research Questions**
- **Further Mining of the Data based on Unique Questions Posed by Investigators**
 - **from Core Screening Questionnaire & Supplemental Modules**

Ultimate Mission

- **Advance screening for women's mood problems in a variety of health care settings**
- **Improve assessment methods for diagnosing mood disorders among women**
- **Improve understanding of the unique nature of mood problems among women at various stages of the lifespan**
- **Advance the best possible treatment approaches for addressing mood problems among women**
- **Reduce the incidence of mood disorders among women worldwide**