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CLINICAL ARTICLE

Development of a screening and recruitment registry to facilitate perinatal depression research in obstetrics settings in the USA

Lucy J. Allbaugh [a,*], Sheila M. Marcus [b], Eleanor C. Ford [c], Heather A. Flynn [b,d]

[a] Department of Psychology, Miami University, Oxford, OH, USA
[b] Department of Psychiatry, University of Michigan Medical School, Ann Arbor, MI, USA
[c] Department of Psychology, Teachers College at Columbia University, New York, NY, USA
[d] Department of Behavioral Sciences and Social Medicine, The Florida State University College of Medicine, Tallahassee, FL, USA

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ABSTRACT

Objective: To create a multi-site registry to enable future large-scale studies of perinatal depression among women attending obstetrics clinics in the USA. *Methods:* A screening and recruitment registry was developed that included women aged at least 18 years who attended seven obstetric clinics in the University of Michigan Health System (Ann Arbor, MI, USA) for prenatal care between September 8, 2008, and June 9, 2011. Participants completed depression screening and research recruitment materials. *Results:* Of 4745 women who returned a screening form, 2983 had completed it, giving an overall agreement rate of 62.9%. A total of 630 participants were enrolled into ten research studies via the registry. Among the 2982 women for whom scores on the Edinburgh Postnatal Depression Scale were available, 494 (16.6%) fell within the at-risk range or had scores suggestive of clinical depression. *Conclusion:* The present registry could improve detection of perinatal depression symptoms and potentially serve as a model for dissemination and implementation at other sites with an interest in studying factors linked to perinatal depression.

1. Introduction

Worldwide, major depressive disorder is one of the main causes of disability-adjusted life years (years of healthy life lost), with women disproportionately affected [1,2]. The peak prevalence for depressive disorders among women occurs during the childbearing years [3,4], with the recorded prevalence as high as 22.2% in pregnancy and the postpartum period [5,6].

Depression during pregnancy—which has been variously defined—has been linked to negative birth outcomes [7] and effects on the infant's temperament [8]. Prenatal care settings provide an ideal opportunity for intervention, but most women who present with symptoms of depression at such centers in the USA do not receive adequate treatment. One study evaluating the ability of US obstetrics clinics to detect symptoms of depression [9] found that just 14% of women with an elevated score on the Edinburgh Postnatal Depression Scale (EPDS) [10] were receiving any kind of mental health care, such as antidepressant medications or psychotherapy.

Therefore, screening for depression has been widely supported as part of routine obstetric care [11]. Nevertheless, recommendations published in 2010 by the American College of Obstetricians and Gynecologists [12] cautioned that screening alone is insufficient to address perinatal depression and that this approach offers potential benefit only when closely linked with appropriate intervention. Systematic screening is not routinely associated with adequate follow-up and improved clinical outcomes in the USA [13,14]. Furthermore, intervention research can be limited by difficulties in recruitment. This difficulty might be related to a lack of coordinated recruitment efforts and/or to the length of time required to identify a large number of participants who meet study criteria [15].

Some studies have reported on rates of agreement to participate in intervention trials among women already screened for perinatal depression [16,17], but few have recorded rates of agreement to screening procedures themselves among women attending obstetrics clinics who are approached to participate in research [18–20]. Consequently, the findings of research studies that target pregnant women who are experiencing depression (particularly untreated major depressive disorder) are often limited by small or homogeneous sample populations [21,22].

The development of screening procedures that are both feasible within clinic settings and efficient as research recruitment tools is an important step toward improved screening, detection, and intervention research. Although many investigators already use screening tools for research recruitment in obstetrics settings, standardized, multicenter screening efforts are urgently needed to enable large-scale recruitment while minimizing the burden on clinical staff and their patients. Australia, Canada, the UK, and several Scandinavian countries benefit

* Corresponding author at: Department of Psychology, Miami University, 90 North Patterson Avenue, Oxford, OH 45056, USA. Tel.: +1 734 417 3073; fax: +1 513 529 2420.
E-mail address: allbaulj@miamioh.edu (L.J. Allbaugh).

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from the availability of national healthcare or population-based registries that make the process of conducting research with large, representative cohorts easily accessible [23,24]. No such standard registries currently exist in the USA; guidance on implementation and acceptability of such procedures could help to accelerate the pace of US-based research. Importantly, assessing large and diverse samples of patients attending obstetrics services could allow researchers to characterize phenotypes of perinatal depression outside of specialty psychiatric care.

The present study aimed to develop a screening and recruitment registry of women interested in research participation to be used in obstetric clinics at multiple centers in the USA. The first goal was to provide instruction and guidance on optimizing screening and recruitment registry procedures across multiple settings. The second goal was to provide data on how the screening process could enhance recruitment to multiple research studies by streamlining the process to minimize burden on clinic staff and patients.

2. Materials and methods

A screening and recruitment registry was developed using data provided by women who attended one of seven obstetrics clinics within the University of Michigan Health System (Ann Arbor, MI, USA) between September 8, 2008, and June 9, 2011. All procedures were approved by the institutional review board of the University of Michigan Medical School.

The present study commenced with consultations with obstetrics clinic stakeholders regarding the feasibility of developing a registry. Full support for the project was crucial at all stages to ensure that the registry could be embedded within existing systems (e.g. in other healthcare screening or during regular prenatal care visits). The concerns of clinic staff mainly related to the potential time required to administer screening, return forms to research staff, and enter additional information (e.g. EPDS score) into medical records. Therefore, research staff offered a menu of procedures to each clinic from which to customize registry operations (e.g. options on how to administer EPDS). Connection with clinical trials was an integral part of the registry for those agreeing to participate. Additionally, clinics were aided in referring women to existing mental health services. Staff members at participating clinics were instructed on EPDS scoring and interpretation. Clinics were provided with a comprehensive list of mental health services available to women found to have significant depressive symptoms.

After consultation, consent forms (to establish willingness to be included in the registry) and screening forms (to gather information about depressive symptoms and other eligibility criteria) were developed and iteratively updated. Pregnant women aged at least 18 years who presented for prenatal care at one of the participating obstetrics clinics were eligible for inclusion in the registry. The consent and screening forms were attached to the EPDS test administered by clinic staff. The women were provided with a brief description of the registry and informed about the need for ongoing research; however, in view of the changing nature of research within the psychiatry department, a description of the specific studies recruiting was not provided. They were also advised that should they be deemed eligible to participate in a specific study, they would be contacted by a member of the relevant research team, that they could decide at that time whether they would like to participate in a trial, and that no cost would be associated with such participation. Three options were provided for level of participation in the registry: (1) complete both the consent and screening forms to enter the registry and potentially be contacted for participation in specific research projects (participants); (2) check an "opt out" box on the consent form to provide anonymous data to the registry only at the time of screening (anonymous participants); or (c) decline participation by leaving the consent form blank (refusers).

Version 1 of the screening form was concise and did not require a separate consent form because it was intended solely to recruit for an existing project [25] within the University of Michigan Health System, which had its own consent process. Version 2 included a consent form and was also longer than version 1 to accommodate inclusion criteria for additional studies. The final screening form (version 3) was the shortest because it streamlined the consent and screening forms and removed items that could easily be found in medical records (Supplementary Material S1). The consent process allowed for examination of the medical records to determine eligibility for specific studies. Two versions of the screening and recruitment system indicated that psychoeducational materials about perinatal depression could be provided to women by the research team upon request, and this offer was made irrespective of participation in the registry.

As noted, three versions of the registry screening form were used to gather information not found in the medical record. Lifetime depression and episodes of depression within the past 6 months were assessed using depression-focused items derived from the Diagnostic Interview Schedule, Version Three, Revised [26]. The sensitivity of these items to screen for depression was found to range between 0.83 and 0.94 in a community sample of adults in three major cities in the USA [27]. Current symptoms of depression were assessed by the EPDS [10]. This tool is a widely used, reliable, and validated 10-item measure of perinatal mood symptoms; the EPDS was approved by the obstetrics clinics participating in the present study as the standard screening tool to be used for the registry. Total EPDS scores range from 0 to 30, with high scores indicating increased symptoms of depression [10]. A score at or above nine indicates a risk of major depressive disorder, whereas a score at or above 12 indicates that the diagnostic criteria have probably been met [10].

The EPDS was scored, reviewed, and entered into the medical record by a nurse, medical assistant, or obstetrician who addressed the EPDS results, including indicated risk (e.g. suicide), and provided standard care, including referral to mental health resources. EPDS and screening forms were returned to the research staff and data entered into an SPSS (version 20; IBM, Armonk, NY, USA) tracking database by the registry coordinator who determined eligibility for participation in ongoing clinical research programs; eligible participants were referred to the relevant investigators for enrollment. The prevalence of depression symptoms among the registry population was also evaluated as part of the present study.

Data were analyzed using SPSS version 20 (IBM, Armonk, NY, USA). Agreement rates were determined by dividing the number of women who completed the forms by the number eligible to undergo screening. Frequency data were calculated to describe eligibility for, and participation in, individual research studies. The mean total EPDS score, frequency of endorsement of individual EPDS items, history of depression, and current use of psychotherapy or psychopharmacological treatment were calculated.

3. Results

A total of 4745 screening forms were collected during the present study period. The mean age at the time of screening was 30.3 ± 5.0 years (range 18.0–46.0) and mean gestational age was 24.2 ± 9.1 weeks (range 0.0–40.0).

Of the women screened, 2259 (47.6%) provided screening data and agreed to be contacted for potential enrollment in research studies (participants), 724 (15.3%) declined future contact for research studies but provided anonymous screening data (anonymous participants), and 1762 (37.1%) refused to participate under any circumstances. Thus, 2983 women completed the screening form, giving an overall agreement rate of 62.9%. Rates of agreement varied over the course of the present study (Table 1), potentially owing to differences in the length of the various versions of the registry form. Versions 2 and 3 included an option to receive an information packet about perinatal depression. However, of the 2535 women who completed these two versions, only 87 (3.4%) requested the material.