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RAPID ACCESS TO PERINATAL PSYCHIATRIC CARE IN DEPRESSION
(RAPPID)

A Master's Thesis Presented

By

NANCY BYATT, DO, MBA

Submitted to the Faculty of the
University of Massachusetts Graduate School of Biomedical Sciences, Worcester
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

APRIL 14, 2015

PERINATAL DEPRESSION

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The signatures of the Master's Thesis Committee signify
completion and approval as to style and content of the Thesis

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The signature of the Dean of the Graduate School of Biomedical Sciences
signifies that the student has met all master's degree graduation requirements of
the school.

Anthony Carruthers, Ph.D.,
Dean of the Graduate School of Biomedical Sciences
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ABSTRACT

Depression is the leading cause of disability among women of reproductive age worldwide. Upwards of 1 in 5 women suffer from perinatal depression. This condition has deleterious effects on several birth outcomes, infant attachment, and children's behavior/development. Maternal suicide causes 20% of postpartum deaths in depressed women. Although the vast majority of perinatal women are amenable to being screened for depression, screening alone does not improve treatment rates or patient outcomes. Obstetrics/Gynecology (Ob/Gyn) clinics need supports in place to adequately address depression in their patient populations. The primary goal of this thesis is to develop, refine, and pilot test a new low-cost and sustainable stepped care program for Ob/Gyn clinics that will improve perinatal women's depression treatment rates and outcomes. We developed and beta tested the Rapid Access to Perinatal Psychiatric Care in Depression (RAPPID) Program, to create a comprehensive intervention that is proactive, multifaceted, and practical. RAPPID aims to improve perinatal depression treatment and treatment response rates through: (1) access to immediate resource provision/referrals and psychiatric telephone consultation for Ob/Gyn providers; (2) clinic-specific implementation of depression care, including training support and toolkits; and (3) proactive depression screening, assessment, and treatment in OB/Gyn clinics. RAPPID builds on a low-cost and widely disseminated population-based model for delivering psychiatric care in primary care settings. Formative data and feedback from key stakeholders also informed the development of RAPPID. Our formative and pilot work in real-world settings suggests RAPPID is feasible and has the potential to improve depression detection and treatment in Ob/Gyn settings. The next step will be to compare

two active interventions, RAPPID vs. enhanced usual care (access to resource provision/referrals and psychiatric telephone consultation) in a cluster-randomized trial in which we will randomize 12 Ob/Gyn clinics to either RAPPID or enhanced usual care.

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PREFACE

Perinatal depression, which is a Major Depressive Disorder occurring during pregnancy or within one year of delivery, is a widespread problem, which in turn, may complicate birth,¹ infant,² and child outcomes.³⁻⁵ While upwards of one quarter of ethnically diverse women suffer from perinatal depression,^{6,7} the vast majority go untreated.⁸⁻¹¹ Depression in pregnancy has deleterious effects on obstetric and birth outcomes including preeclampsia, preterm birth, low birth weight,^{1,12} elective termination of pregnancy,¹³ alcohol/tobacco abuse,¹⁴ and postpartum depression.¹⁵ Postpartum depression is associated with attachment insecurity,³ difficult infant/childhood temperament,^{3,16} and long-term consequences in children, including developmental delay, impaired language development^{4,5} and depressive, anxiety or disruptive disorders.¹⁷ These negative outcomes can be mitigated by leveraging existing resources to bring effective treatment for depression to women receiving care in obstetric settings.

Perinatal depression is increasingly recognized as a major public health problem. Despite the profound negative effects on mother and children, which are mitigated by effective treatment¹⁸ including psychopharmacology and psychotherapy,¹⁹ perinatal depression remains under-diagnosed.^{8-10,20} Acknowledging this lack of detection, several states have mandated screening for postpartum depression.^{21,22} In 2010 the Massachusetts (MA) state legislature created a Special Legislative Commission on Postpartum Depression to consider relevant current research and to recommend screening and treatment policies.²³

The American College of Obstetricians and Gynecologists^{24,25} and other stakeholders²⁶⁻³⁰ recommend strong consideration by obstetricians for depression screening, noting potential benefits to women and their families. Screening for depression is highly accepted by perinatal women and Ob/Gyn providers.^{31,32} However, most efforts to screen have only focused on postpartum depression, which does not detect the 60% of postpartum depression that begins before or during pregnancy.³³ For these reasons, the RAPPID program focuses on the entire relevant perinatal period, rather than just the postpartum period.

Screening for perinatal depression alone does not translate into treatment participation because women and obstetric providers experience multi-level barriers. Perinatal women and their obstetric providers find screening for perinatal depression a futile exercise when done in the absence of trained providers with access to mental health resources and referrals. In our formative studies,³⁴⁻³⁷ and our literature review,³⁸ we identified a number of patient, provider, and systems-level barriers and facilitators to the treatment of perinatal depression and reviewed clinical, programmatic, and systems-level interventions. Provider and systems-level barriers identified included: (1) lack of obstetric provider training in technical aspects of depression care³⁸⁻⁴⁰ and communication skills in this context;⁴¹ (2) absence of standardized processes and procedures for stepped depression care;^{39,40} (3) lack of mental health providers willingness to treat pregnant women;⁴⁰ (4) lack of referral networks;³⁹⁻⁴³ and (5) inadequate capacity for follow-up and care coordination.³⁹⁻⁴³ These barriers are exacerbated

by patient-level barriers. Perinatal women report that they are afraid to disclose mental health concerns due to fears of stigma, losing parental rights, and being judged as an unfit mother.⁴⁴⁻⁶³ Many women perceive obstetric providers and staff as unsupportive, unavailable,^{47,49,50,57,58,61,64-66} and inadequately trained in depression assessment and treatment.^{64,65} The RAPPID program aims to address these critical barriers at the provider, patient, and system level.

Obstetric clinics/practices need supports in place to adequately address depression in their patient populations.³² Despite high acceptance of depression screening by perinatal women, many are not amenable to contact with a mental health provider.^{8-10,11} Less than 30% of women who screen positive for depression attend an initial or subsequent mental health visit^{8-10,11} and less than 10%^{8,11} adhere to a full treatment course. This lack of adherence may be due to unengaged providers and staff⁶⁷ and limited resources to ensure depression evaluation, treatment, and follow-up.^{68,27} Ob/Gyn clinics need a stepped care program such as RAPPID to ensure that they adequately address perinatal depression and improve patient related outcomes.²¹

Translating integrated, stepped-care models to obstetric settings could provide a solution to this critical public health issue. The successful clinical resolution of depression symptoms is uncommon in obstetric settings because major gaps in depression care exist.³² It is well-established that integrated care, such as stepped and collaborative care models and medical homes, effectively integrate depression treatment into primary care settings and improve the quality

of mental health care and depression outcomes.⁶⁹ Such approaches have been introduced and evaluated in Ob/Gyn settings⁷⁰⁻⁷³ but the data in this area remains limited. For example, one study found that a collaborative care approach, which consisted of team management, tracking systems, weekly structured case reviews with a psychiatrist, depression care manager, and co-located clinician, was effective in reducing depression symptoms by at least 50% at 12 months. However, only 7% of the study population was pregnant.⁷⁰ Two other studies that included only postpartum women and women who were not pregnant,^{71,74} emphasize both the promises and limitations of these prior studies.⁷⁴ This shows that there is a need for effective approaches for addressing depression in Ob/Gyn settings. Others are currently testing collaborative care approaches in Ob/Gyn settings but have not yet shown improved depression or treatment outcomes.^{72,73} Since these models have not been fully adapted to, nor evaluated in obstetric settings, there is a considerable unmet need and opportunity to improve and optimize care for pregnant women with depression. As detailed in our conceptual model in Figure II, RAPPID is based on the guiding principles of collaborative care.

Health care reform presents unprecedented opportunities to design and test new integrated care models, such as stepped care, to improve patients' access to services, improve care quality, and lower overall health-care costs. Stepped care models involve initial determination of treatment based on illness severity and intensification of care (such as stepwise increases in dose of

antidepressant medication) for those with persistent illness. Despite treatment success, these collaborative care models depend on care management facets that are not reliably reimbursed and, therefore, their broad implementation, dissemination, and associated treatment improvement are not realized.⁷⁵ The term “voltage drop” has been used to describe the less robust results found when collaborative care approaches are implemented in low resource real-world settings.⁷⁶ Our new stepped care approach, RAPPID, will be cost-effective because it leverages Ob/Gyn providers and staff already working in the Ob/Gyn setting. It will be sustainable because it is modeled on our successful, sustainable, and widely used model that provides psychiatric care for pediatric populations.

The Massachusetts Child Psychiatry Access Project (MCPAP)^{77,78} provides a successful, sustainable, and widely used model for providing psychiatric care in primary care settings that can be translated to Ob/Gyn settings. MCPAP was created and piloted at UMass Medical School in 2005 because children were unable to access psychiatric care. There were not enough child psychiatrists, and pediatricians were not equipped to manage children’s psychiatric needs. While pediatric providers have an essential role in detecting and treating psychiatric concerns in children, children’s needs for mental health care were not being met because pediatricians lacked training and access to necessary resources to help assess and treat these children. The MCPAP program has addressed this problem by delivering telephone psychiatric

consultation and resource provision/referrals to support pediatric providers in MA. Regional teams provide assessment and treatment support, face-to-face consultations, resource provision/referral, and ongoing education for pediatric providers.⁷⁷⁻⁷⁹ MCPAP ensures that the 1.5 million children/adolescents in the state of MA have access to psychiatric care via their pediatrician; currently, 97% of pediatric providers are enrolled (425 practices enrolled; 1,230 of 1,268 MA pediatricians, 323 of 331 of MA pediatric nurse practitioners). The cost of the program, including administrative expenses, is \$2 per child/adolescent per year (\$0.16 per month) or \$3 million for the 1.5 million children in Massachusetts.⁷⁸ Enrolled pediatric providers report a dramatic improvement in their ability to meet the psychiatric needs of their patients.^{77,78} MCPAP is cost-effective because it requires only 6 full time psychiatrists, therapists, and coordinators to serve the entire state. MCPAP has also been utilized in 32 states in the U.S. which led to the establishment of the National Network of Child Psychiatry Access Programs (<http://nncpap.org/>) which promotes the development, sustainability, and quality of child mental health and psychiatry access programs across the country.⁷⁷⁻⁷⁹ Because it is modeled on MCPAP, our RAPPID Program is similarly feasible and sustainable and carries the same potential for widespread dissemination and implementation.

CHAPTER I

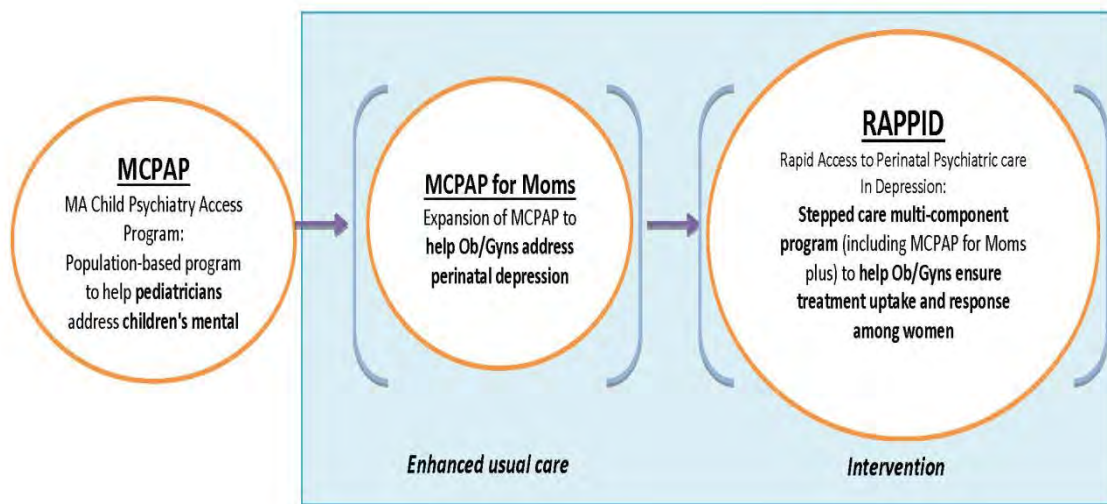
INTRODUCTION

Based on the MA Child Psychiatry Access Project (MCPAP) model, we have created a similar population-based program to help Ob/Gyn providers address perinatal depression – MCPAP for Moms. In 2013, MA passed legislation that increased funding to expand the existing MCPAP, creating MCPAP for Moms to address perinatal depression.⁷⁹ Using the additional resources provided by this funding, our team developed MCPAP for Moms.⁷⁹ MCPAP for Moms aims to ensure that Ob/Gyn providers can detect, assess, treat, and/or refer women with perinatal depression throughout Massachusetts. Similar to MCPAP, our new program MCPAP for Moms provides Ob/Gyn clinics/practices throughout MA with immediate telephonic psychiatric consultation and resources and referrals to women and their providers. This statewide program is staffed with 1 full time equivalent perinatal psychiatrist and 2.3 full time equivalent coordinators. Regional teams provide assessment and treatment support, as needed one time face-to-face consultation, and resource provision/referrals to help providers address perinatal depression.^{78,79} The overall resource demands are low. The cost of the program, including administrative expenses, is \$4.16 per perinatal women per year (\$0.35 per month) or \$600,000 for the 144,000 perinatal women MA has annually. Thus, MCPAP for Moms is within grasp of most Ob/Gyn clinics/practices and health systems because it provides a population-based approach to addressing perinatal depression at a low cost.

MCPAP for Moms now needs to be strengthened to proactively work with Ob/Gyn

clinics to help them develop a systematic stepped care approach to ensure that their patients do not fall through cracks in the depression care pathway. To achieve full remission of depression symptoms, women with perinatal depression must: 1) be recognized via screening; 2) be assessed; 3) initiate treatment; 4) receive adequate treatment; and 5) respond to treatment.⁸⁰ Our pilot work demonstrates that there are still gaps in this depression care pathway because MCPAP for Moms does not include the more intensive implementation and follow-up components that Ob/Gyn practices and their patients need.²¹ Our work indicates that Ob/Gyn practices need additional support and resources to proactively help them implement and sustain depression screening and ensure adequate assessment and treatment of the women they serve. Thus, while our implementation assessment indicates that MCPAP for Moms provides access to invaluable resources that constitutes an enhanced form of usual care, emerging data suggest that additional intervention implementation and components are needed to ensure that women do not fall through cracks in the depression care pathway.

Figure I Progression to RAPPID



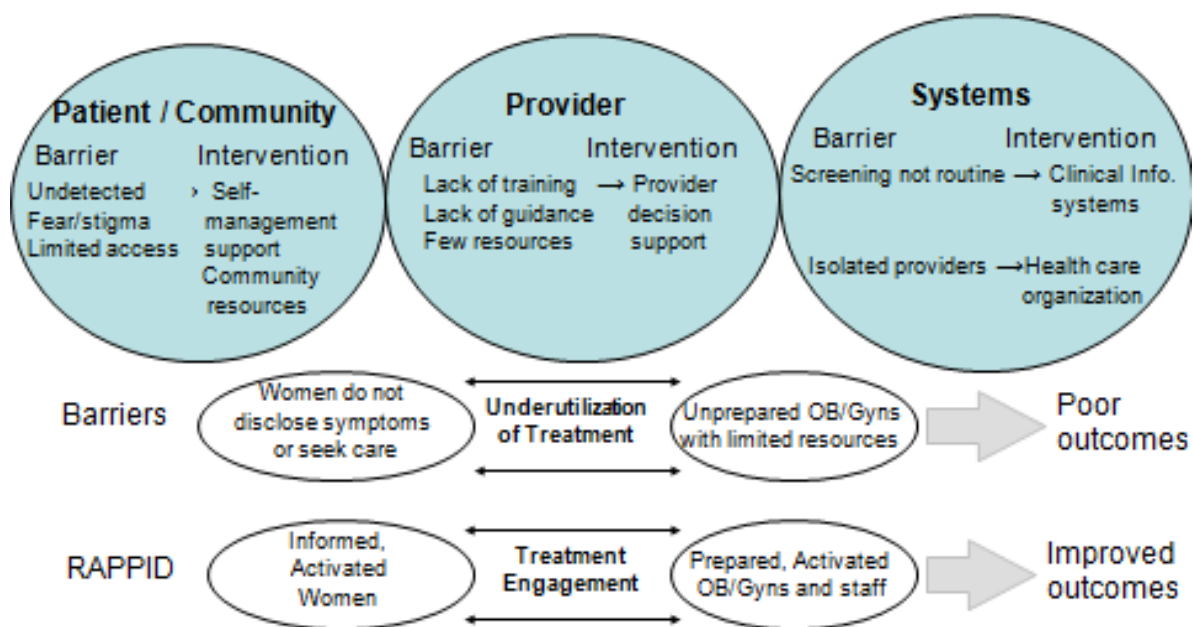
In response, we have built on MCPAP for Moms and developed the Rapid Access to Perinatal Psychiatric Care in Depression Program (RAPPID), a comprehensive and proactive program that could result in improved perinatal depression outcomes and treatment rates perinatal women. In addition to the psychiatric consultation and resource provision/referrals provided by MCPAP for Moms, RAPPID also provides: (1) clinic-specific implementation of stepped care, including training support and toolkits; and (2) proactive patient monitoring, treatment engagement, and stepped treatment response to depression screening/assessment. Drawing on implementation frameworks,⁸¹⁻⁸⁴ RAPPID will provide clinic-specific implementation assistance and step-by-step guidance to help practices systematically recognize, assess, and treat depression in an efficient and sustainable manner.

The stepped care treatment response will provide specific treatment protocols in response to illness severity. This approach will allocate the most intensive resources to

those women with corresponding need. All practice patients who screen positive for depression will be entered into a depression registry to receive close monitoring and engagement strategies to increase treatment initiation, adherence, adequacy, and response. To balance effectiveness, sustainability, and dissemination ability, we have designed RAPPID to leverage and build on MCPAP for Moms along with resources that already exist in Ob/Gyn settings.

RAPPID Conceptual Model: RAPPID aims to improve the delivery of perinatal mental health care at multiple levels.^{85,86} The conceptual basis for RAPPID rests on the Chronic Care Model. Wagner created the Chronic Care Model in response to reviews^{87,88} suggesting that health outcomes were most improved by multi-component practice changes that increase provider expertise and skills, educate and support patients, make health care delivery more team-based and planned, and maximize the use of health information systems. Collaborative care models can improve mental and physical outcomes for individuals with mental illness across a wide variety of care settings, and they provide a robust clinical and policy framework for integrating obstetric and depression care.⁶⁹ Collaborative care models generally focus on chronic illnesses, whereas the majority of perinatal depression is new onset.³³ Thus, we have designed RAPPID to not only detect and treat chronic depression but also to detect/intervene early before chronic depression sets in.

Figure II
RAPPID Conceptual Model Adapted from Chronic Care Model



Our systematic review of perinatal depression treatment in Ob/Gyn settings suggests that RAPPID will seal gaps in care by improving the detection, assessment, referral, and/or treatment of depression in these settings. Systematic reviews performed prior to ours have not found that screening improves depression outcomes in Ob/Gyn settings. Our systematic review examined a wider range of study designs and outcomes to determine whether depression screening in outpatient obstetric settings increases mental health care use. Seventeen articles representing a range of study designs, including 1 RCT and 1 cluster RCT, met our pre-defined criteria and were included. We found that screening alone led to an average 22% participation in ≥ 1 mental assessment among women who screened positive for depression. The rate of attendance of at least 1 mental health assessment doubled when screening was done in conjunction with any of the following: patient engagement strategies (44%), on-site assessment (49%), and provider training (54%). Higher rates of mental health care use (79%) occurred when interventions were combined and included resource combinations provided to women, provider training, on-site assessment, implementation assistance, and access to mental health consultation for perinatal care providers. While screening alone led to only 22% mental health care use during the perinatal period, this rate improved 2-4 fold when intervention programs are in place to ensure that women receive adequate treatment. Our review suggests that screening in conjunction with multi-modal stepped care strategies improves detection, assessment, referral, and/or treatment of depression in perinatal care settings. We designed RAPPID to include the

multi-modal stepped care strategies that our review found increases the frequency of mental health care use.

Formative Work

Our proposed intervention, RAPPID, is designed to overcome several previously identified barriers and leverage facilitators identified in our formative studies. Before developing RAPPID, we conducted 3 formative research studies with obstetric providers and staff, and postpartum and pregnant women, to better understand how to address depression in obstetric settings.^{34,36,37} After screening women for depression (n=110), we identified those with significant depression symptoms (n=46) and conducted semi-structured interviews to better understand how their interactions with health care providers contribute to untreated perinatal depression.⁸⁹ Barriers perceived by these women included providers declining to treat them with medication during pregnancy, and providers' not understanding women's needs and/or available treatment options. We also conducted two qualitative studies, one with postpartum women and the other with obstetric providers, to further investigate barriers and facilitators to perinatal depression care in obstetric settings. Both patients and providers suggested empowering women to seek help through psycho-education, provision of resources, validation of women's experiences, and awareness regarding language and interactions that could be interpreted as stigmatizing.^{34,36,37} Both also recommended that depression care become a routine part of perinatal care via pertinent training for providers/staff and improved collaborations with mental health providers. These formative studies led us to hypothesize that transforming obstetrical practice to include depression treatment would improve women's access to, and engagement in, treatment and, thereby, improve

depression related outcomes.

CHAPTER II

RAPPID DEVELOPMENT AND BETA TESTING

The purpose of our formative research study was to design and beta test the implementation of RAPPID.

Development of RAPPID

Study Setting. Research was conducted in the Ob/Gyn Department of a large tertiary care referral center in an academic medical center in central Massachusetts. The study clinic site has 12 Ob/Gyn attending physicians, 2 nurse practitioners, 20 Ob/Gyn residents that rotate through the clinic, 4 nurses, 1 patient care assistant, and 3 clinical administrative support staff. In fiscal year 2013-2014, the clinic site served 691 obstetric patients; among the prenatal care population, approximately 20.4% are Latina, 13.8% are Black, 53.7% are non-Latina white, 5.7% Asian, and 6.4% are from other race/ethnicities. The clinic population was insured by Medicaid (69%), commercially insured (23%), Medicare (4%), and self-pay/free care (4%).

Work group participants. A multidisciplinary work group consisted of a purposeful sample of perinatal (n=6) and psychiatric health care professionals (n=1) (Table I). Work group participants were recruited via email and direct personal communications at faculty, resident, and staff meetings. Departmental support in the form of release from other clinical or administrative responsibilities was provided for the work group participants.

The multidisciplinary work group provided iterative feedback on the core program components and uncovered barriers and facilitators to the implementation of RAPPID. Nine work group meetings were held over a period of 6 months; each were devoted to reviewing and providing feedback on specific components of the program and the associated products and procedures (Table II). The work group initially identified goals and strategies for addressing perinatal depression in obstetric settings in general and also in their specific clinic. The work group provided iterative feedback as RAPPID components were developed and refined. For example, after the initial treatment protocols proposed were deemed unrealistic and impractical for Ob/Gyn settings by the working group, they were adapted to minimize the time burden for Ob/Gyn providers and staff, while also meeting clinical standards.

Advisory board. A multi-stakeholder advisory board formed and met regularly with the Principal Investigator (PI) (NB) to provide input on acceptability, feasibility, and perceived barriers and facilitators to implementing RAPPID. The board included a woman with a history of postpartum depression (PPD), 3 members from the Massachusetts Legislative Commission on PPD including an Ob/Gyn attending physician, and 3 experts in providing access to psychiatric consultation and care coordination psychiatric telephone consultation to primary care providers. Program components and products were adapted based on iterative feedback from both the work group and advisory board, resulting in a beta version of the RAPPID components ready for beta testing.

Components of RAPPID program

RAPPID (available from first author upon request) consists of: (1) access to the

immediate resource provision/referrals and psychiatric telephone consultation for Ob/Gyn providers; (2) Ob/Gyn clinic-specific implementation of depression screening, assessment and treatment, including training and implementation support and toolkits; and, (3) approaches to facilitating treatment engagement and response to depression screening/assessment.

Table I RAPPID Components

Component	Description
<p>Access to immediate resource provision/referrals and psychiatric telephone consultation for Ob/Gyn providers</p>	<p>Access to mental health consultation with a perinatal psychiatrist to guide treatment provision via email and/or telephone. The consultation may involve diagnostic support, guidance in regards to medication treatment (when indicated), and advice on psychotherapy and community supports, treatment planning, and medication concerns regarding preconception, pregnancy and lactation. The consulting perinatal psychiatrist will work with the provider to assist him/her in addressing their patient's mental health concerns.</p>
<p>Ob/Gyn clinic-specific implementation of depression screening, assessment and treatment, including training and implementation support and toolkits</p>	<p>Step-by-step implementation support is provided to help obstetric clinics/practices implement all the RAPPID components. Several core implementation strategies from Addressing Problems Through Organizational Change (APTOC)⁹⁰ model: (1) engage clinic providers, leaders and staff; (2) identify champion(s) and prepare for change; (3) assess readiness to implement RAPPID; (4) identify steps to achieve goals; (5) implement RAPPID components into the clinic; (6) support, encourage and sustain change.⁹¹</p> <p><i>Engage clinic providers, clinic leaders and staff.</i> Meet with clinic providers and staff and articulate a vision for change. Lead meetings and activities to empower and support Ob/Gyn providers and staff to brainstorm and develop approaches for addressing perinatal depression in their practice and prepare for implementation of RAPPID components.</p> <p><i>Identify champion(s) and prepare for change.</i> Practice champions are identified and a work group will be formed that will implement the practice's change plan and achieve their goals through specific strategies and tactics. A nurse or medical assistant is selected as one of the designated practice champions. The other champion will be a physician serves as a leader and advocate for RAPPID implementation at the practice site. The physician champion works directly with the medical assistant/champion and practice leadership to support and advocate RAPPID implementation.</p> <p><i>Assess readiness to implement RAPPID.</i> A baseline assessment to determine readiness and the best approach for implementing RAPPID will be conducted. The assessment involves detecting early signs of opportunities and threats to implementing RAPPID components and documenting the practice work flow, current screening practices or lack thereof. Implementation strategies are customized to each clinic.</p> <p><i>Identify steps to achieve goals, including policy changes (universal screening).</i> Meet with the work group to identify steps needed to implement RAPPID. Invest in the education, skills training, and tools necessary for Ob/Gyn providers and staff to be effective in implementing RAPPID components.</p> <p><i>Implement RAPPID components.</i> On-site consultation, including work flow assessment and training and ongoing technical assistance with implementation of RAPPID is provided. Work with the clinics/practices to determine the most efficient approach to implementing RAPPID.</p>

<p>Approaches to facilitating treatment engagement and stepped treatment response to depression screening/assessment</p>	<p>Stepped care involves initial determination of treatment based on illness severity followed by intensification of care as necessary (such as stepwise increases in dose of antidepressant medication) for those with persistent illness. The following strategies will be used to implement screening: training, toolkits, systematic screening, patient engagement, and stepped care protocols.</p> <p><i>Training.</i> A total of 3, 2-hour trainings for practice providers and staff. Train and assist the RAPPID clinics to provide care for depression, including systematic screening and monitoring for depression. Providers will be trained how to use to screen and assess depression, to include depression in treatment plans, and to discuss the risks and benefits of antidepressant use during pregnancy and lactation. Providers also receive training in how to de-stigmatize depression and activate women to seek help.</p> <p><i>Toolkits.</i> Practices are provided with screening, referral and treatment protocols. Protocols include specific instructions for specific ranges of scores on the Edinburgh Postnatal Depression Scale (EPDS) to prompt assessment and treatment steps. Psychoeducational resources to give to women are also provided.</p> <p><i>Systematic screening.</i> Work with each practice to develop an individualized approach to depression screening. This will include establishing office procedures for screening. Determine the timing, location, and setting for screening and discussion of screening/treatment/referral. Work with clinic providers/staff to tailor screening procedures to be acceptable and helpful.</p> <p><i>Patient engagement.</i> The Ob/Gyn providers and staff are trained to provide psychoeducation. The medical assistant/champion will deliver psychoeducation when women screen positive for depression as part of the stepped care treatment response and when he/she calls patients to follow-up regarding treatment participation as part of the proactive patient monitoring. During follow-up calls the medical assistant/champion will offer referral to therapy if the patient is not engaged in psychotherapy or behavioral health treatment.</p> <p>Psychoeducation for depression emphasizes instruction and education on a variety of topics relating to depression, including symptoms, the expected clinical course and prognosis, treatment options and strategies, and signs of relapse.^{92,93}</p> <p>We will match the severity and complexity of patients' disorders to the appropriate level of care. Psychopharmacology, when indicated, will be provided by the Ob/Gyn providers and licensed independent practitioners guided by MCPAP for Moms perinatal psychiatry consultation as needed. Psychoeducation and resource provision will be offered during perinatal visits according to the stepped care protocol. Patients with severe, complex, or treatment refractory illness will be referred to a psychiatric provider according to stepped care protocol and</p>
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	<p>clinical judgment of the Ob/Gyn. Referral to psychiatrists or psychiatric nurse will be facilitated by the RAPPID medical assistant/champion. During subsequent follow-ups visits, patients will be stepped up to a higher level of care if there is evidence of clinical deterioration or lack of improvement.</p>
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Beta testing of RAPPID

This study was reviewed by the University of Massachusetts Medical School Institutional Review Board (IRB) and received an exemption because no identifying or demographic data for patient participants was collected. Patients were screened for depression with the Edinburgh Postnatal Depression Scale (EPDS)⁹⁴. Provider and staff participants (Table I) were recruited for the beta testing and focus group evaluation of RAPPID via email and direct personal communications at faculty, resident, and staff meetings. Baseline attitudes toward screening were assessed prior to the study by asking Ob/Gyn providers and staff participants, “Do you routinely screen for perinatal depression using a validated screening tool?” All the Ob/Gyn attending and resident physicians, nursing staff and front desk staff working at the clinic were invited to attend a 1.5 hour training conducted by the PI (NB) and an attending Ob/Gyn from an outside institution. A beta test was then conducted at the study clinic site on Mondays from November - December, 2013. During the period of the beta test, 50 patients were served by the Ob/Gyn providers and staff participating in the beta test.

Table II Beta Testing and Focus Group Participants

Study Phase	Participants	Number of Participants
Working Group	Attending Ob/Gyn physician (n=1) Ob/Gyn nurses (n=1) Ob/Gyn patient care assistant (n=1) Case manager (n=1) Front desk administrative support staff (n=1) Administrative support staff (n=1) Attending perinatal psychiatrist from the outpatient psychiatry department at the academic medical center (n=1)	7
Beta Testing*	Attending Ob/Gyn physician (n=2) Attending Ob/Gyn resident physicians (supervised by the 2 attending Ob/Gyn physicians participating in beta testing) (n=4) Ob/Gyn nurses (n=3) Ob/Gyn patient care assistant (n=1) Case manager (n=1) Front desk administrative support staff (n=2) Administrative support staff (n=1)	14
Focus Group**	Ob/Gyn resident physicians (n=2) Ob/Gyn nurse (n=1) Ob/Gyn patient care assistant (n=1) Case manager (n=1) Front desk and Administrative support staff (n=1) Administrative support staff (n=1)	7

*Except for the perinatal psychiatrist, all beta testing participants were also working group participants

**All focus group participants were also beta testing participants

The Ob/Gyn providers and staff participating in the beta test invited women to participate by being screened for depression. Patient participants were individuals who: (1) were receiving obstetric care at the study clinic site during one of five consecutive Monday clinics during the study period; (2) were receiving care from one of the 4 Ob/Gyn providers participating in the beta test; (3) consented to be screened for depression; (4) were pregnant or postpartum; (5) over 15 years of age; and, (6) English-speaking.

The EPDS is a validated and widely used screening questionnaire that assesses depression during pregnancy and in the postpartum period ⁹⁴. The EPDS is self-administered and consists of 10 multiple-choice items that rate the intensity of symptoms of depression for the preceding 7 days. The total score ranges from 0-30 with higher scores indicating greater severity of symptoms.⁹⁴ The cut-off scores used to indicate possible depression range from 9-13. When using a cut-off of ≥ 9 for “possible” depression, and ≥ 12 for “probable” depression, the EPDS has a sensitivity of 86% and specificity of 78%.⁹⁴ Consistent with prior studies,⁹⁵⁻¹⁰¹ we used a cut-off of 10 to ensure that we captured most or all women with EPDS scores indicating that further assessment for depression is needed. The screening component of the beta testing of RAPPID included having Ob/Gyn provider and staff screen pregnant and postpartum clinic patients with the EPDS. Once the EPDS was completed, providers followed the RAPPID screening protocol and utilized the program components (Table II). The PI (NB) served as the psychiatric consultant.

Table III Provider Toolkit

Toolkit Component	Description
<u>Depression Screening Algorithm for Obstetric Providers</u>	Provides guidance for obstetric providers and clinical support staff on administering the EPDS and next steps depending on the EPDS score. The first side is a simplified version of the algorithm. Side two provides more detailed information including talking points and suggested language re: how to discuss the EPDS and resultant scores with the patients.
<u>Bipolar Disorder Screen</u>	A brief screen derived from the Composite International Diagnostic Interview-Based Bipolar Disorder Screening Scale to be used prior to starting treatment with an antidepressant.
<u>Recommend Steps before Beginning Antidepressant Medication Algorithm</u>	Talking points re: antidepressant use, and the risks of antidepressant use vs. risks of under or no treatment of depression during pregnancy and the postpartum period.
<u>Antidepressant Treatment Algorithm</u>	Provides a step-by-step guide to prescribing antidepressants, with specific first and second line treatment recommendations and guidelines for ongoing assessment and treatment.

Assessment of beta testing. After the beta test, we assessed provider and staff participation in RAPPID and their perceptions of RAPPID components. An attendance log was used to assess training attendance and medical record review to obtain rates of administration and documentation of screening with the EPDS. Utilization of telephone/email consultation and the provider toolkit was assessed via a call/email log and single focus group. The medical records were reviewed by the Research Assistant (RA) to determine rates of screening and documentation of screening results.

After the beta testing, a 90 minute tape-recorded focus group was conducted to identify barriers and facilitators to program implementation of RAPPID. The focus group consisted of a purposeful sample of Ob/Gyn providers and staff who had participated in the beta testing (Table I). Participants responded to open-ended study probes on barriers and facilitators to addressing perinatal depression during the focus group discussions.

The research team debriefed after the focus group to identify general themes and immediate impressions of the focus group. Interview data were coded by the PI (NB) and RA (SH) for concepts and themes. Within this framework, increasingly narrow and specific categories of concepts and themes were defined to condense raw data and to identify common themes. The reliability of findings were enhanced by the coding of data by more than one researcher and comparison of findings with our^{36,102} and others previous research.^{50 103 49 104} RAPPID components were then revised based on focus group feedback and after input from the advisory board.

Screening results from beta testing

The beta testing participants consisted of a multidisciplinary group of 22 Ob/Gyn providers and staff (Table II). Prior to beta testing, 100% of the provider and staff participants answered “no” to the question, “Do you routinely screen for perinatal depression using a validated screening tool?”

Ninety-three percent (13 out of 14) of the providers and staff who practice in the clinic attended the training. Forty out of the 50 women (76%) invited to be screened with the EPDS completed the screen. Ten eligible patients were not screened because: (1) they chose not to be screened; or, (2) consented to screening yet did not understand or complete the EPDS form. The EPDS was documented in the chart in 95% of patients who were screened (n=38). Thirty-five percent (n=14) of patients had an EPDS score of ≥ 10 . No women scored positive on the self-harm question in the EPDS (question 10). Every participating Ob/Gyn provider screened $\geq 50\%$ of their patients, in contrast to baseline reports by participating Ob/Gyn providers that they were not screening systematically with a validated screening tool at all prior to implementation.

During the 5-week study period, the consulting psychiatrist provided four consultations to the obstetric providers, three via email and 1 via the telephone. Three of the four consultations focused on the assessment of depression and use of antidepressants during pregnancy and/or lactation. One consultation asked for assistance with diagnostic clarification and treatment planning.

Table IV Provider Participation in Screening

Provider	Number of pregnant / post-partum patient visits	Patients screened with EPDS (%)	EPDS in chart (%)	EPDS \geq 10 (%)
Provider 1	18	16 (88.8%)	16 (88.8%)	5 (33.3%)
Provider 2	10	5 (50.0%)	5 (100.0%)	1 (20.0%)
Provider 3	15	14 (93.3%)	12 (85.7%)	6 (40.0%)
Provider 4	7	5 (71.4%)	5 (71.4%)	2 (40.0%)
Total	50	40 (75.8%)	38 (95%)	14 (35.0%)

Findings from focus group on beta-testing of RAPPID

RAPPID components need to be enhanced to help patients complete the EPDS screen and engage in mental health care.

Several participants noted that a subset of patients did not complete the EPDS or did not see the value of mental health care and were hesitant to engage in treatment. The clinic social worker found this to be a major barrier to addressing their depression. For example,

“I would get messages and then I would call them and see them at their next visit and they didn’t want help.”

Several participants recommended providing patients with a written and verbal explanation of the EPDS to underscore its importance in obstetric care. They also suggested providing resources to engage patients who screen positive and decline a referral to mental health treatment. A card that includes a link to a website with resources was suggested in order to facilitate them reaching out for mental health care when ready. They also suggested providing psycho-educational materials to patients during nursing intake appointments and also placing these materials throughout the clinic.

Recognizing how common depression is and screening with a validated screening tool reinforces the need to screen with the EPDS.

Provider participants noted that they felt more engaged after having participated in the training and beta testing. Several participants were struck by the fact that depression is twice as common as gestational diabetes. They also reported that the

screening process itself increased patient and provider awareness of perinatal depression. They noted that the EPDS uncovered symptoms that they would not have detected without it, thereby reinforcing the importance of systematically screening for depression with a validated screening tool. One resident noted:

“It’s shocking to me how many people would say [they experience depressed mood] sometimes or every day... I’m shocked that the patient is actually answering that they have those feelings on a regular basis, I would never think that just talking to them.”

Tailoring RAPPID to the clinic setting facilitates providers and staff screening, assessing, referring for treatment, or treating depression.

Participants noted that tailoring RAPPID to the study clinic’s unique setting ensured providers and support staff needs were met during implementation. They noted that screening “no longer felt like they were trying to fit a square peg into a round hole” as it had when they had tried to implement screening in the past. One nurse explained:

“I think it has been totally excellent that you had our input about how the clinic ran before you [implemented screening]... You used us for feedback and input and that was very important.”

Several participants reflected that engaging providers and staff in the depression screening process leads to better obstetric care for women. Several noted that it was “easy” to document the screen and they did not experience it as an “undue burden” because the process was well thought out and designed to be efficient.

Having foundational knowledge and skills and access to consultation with a perinatal psychiatrist provides needed reassurance and expertise and facilitates Ob/Gyn providers and staff screening and managing depression.

The participants noted the training was essential because it equipped them to provide depression care. They particularly appreciated the concrete instructions about how to initiate and titrate antidepressants. Knowing they had access to consultation with a perinatal psychiatrist provided needed reassurance and empowered them to make clinical decisions about their patients' mental health status. One resident noted that she felt much less isolated knowing that she could call the perinatal psychiatrist and thus the screening, assessment, and treatment process felt "easy." Another resident noted:

"...we felt comfortable and we emailed [or called] the RAPPID psychiatrist and said what we want to do, [and] do you think it's reasonable... We also feel like we're supported, so it's easier to start [treatment] when you have someone who is in the specialty that can back you up."

Discussion of RAPPID development and beta testing

Iterative feedback and problem solving with the work group and advisory group resulted in the development of a new program, RAPPID. Beta testing and evaluation of RAPPID was favorable and indicates that it is feasible to use training and implementation assistance to help Ob/Gyn providers and staff implement a multi-component program that incorporates depression screening and treatment into obstetric care.

Our findings from the beta-test build on prior research suggesting that both providers and patients need to be empowered to participate in screening, assessment, and treatment of depression in obstetric settings^{32,36,40,105,106} and , by extension, prevent women in need from falling through the cracks in the depression care pathway. Our beta-test also suggests that RAPPID builds provider capacity to address depression and supports Ob/Gyn providers and staff in taking on screening, assessing, and referring for treatment or treating depression. The most potent facilitators to addressing depression appear to be: (1) clinic specific tailoring of the RAPPID components; (2) knowledge and skills obtained during training; and, (3) access to real-time consultation with a perinatal psychiatrist. The process of screening also appears to increase awareness about the importance of screening with a validated tool.

Our findings are consistent with prior studies suggesting that the capacity of perinatal health care professionals to detect and address depression may be enhanced by providing them with education, resources, and access to mental health consultation^{32,36,40,105,106}. The need to further improve RAPPID to better engage women makes sense given prior studies indicating that empathic depression screening and discussion of mental health concerns is critical to engaging women in mental health care^{32,35,37,49}. Our findings are also consistent with prior studies showing that multi-modal strategies for detecting, assessing, referring and/or treating depression in obstetric settings result in an increase in mental health care use when compared to screening alone^{11,60,74,95,96,106,107,97,105,108}.

Our beta-test has several strengths and weaknesses. One of the strengths is that we were able to develop a new program, RAPPID, using an iterative process in

which we elicited provider feedback and tailored the intervention to work in the “real-world.” Our process of eliciting ideas and feedback from perinatal care professionals as to how the program should be implemented ensured screening was efficient and minimized burden to the providers and staff involved. This led us to refine the implementation process and develop a step-by-step approach to helping Ob/Gyn's integrate depression care into their clinic workflow. In order to be sustainable, RAPPID is designed to utilize existing clinical resources rather than study research-funded resources to screen and address depression, carrying the potential for real-world implementation. We also obtained information that allowed us to enhance RAPPID by integrating proactive patient engagement and monitoring into the existing clinic procedures/operations. This includes training Ob/Gyn clinics to provide Motivational Interviewing to engage patients, proactive tracking of all women in the clinics who screen positive on the EPDS, and a stepped care treatment response to depression screening/assessment.

Our beta-test is limited in that we only worked with one clinic in one academic medical setting, with a subset of motivated providers and staff. However, our study allowed us to develop a critical process for tailoring RAPPID implementation that can be translated to other clinics sites. It is likely that other challenges will occur with different patient populations, providers, and staff clinical settings. We also do not have any follow-up data on the women including adherence to depression care and improvement in depression symptoms; in as much, we are unable to link the screening and referral process to various patient related outcomes. Future studies are needed to evaluate

RAPPID in multiple diverse clinical settings, evaluate patient outcome data, and enrich our understanding of patient perceptions of screening.

Our approach engaged the study clinic site in the process and design of RAPPID. Although further evaluation is indicated, our beta-test indicates RAPPID shows promise in that it may be able to overcome barriers to addressing perinatal depression in obstetric settings.

CHAPTER III

RAPPID PILOT STUDY

With the intention of conducting a large-scale multi-site cluster RCT comparing RAPPID with enhanced usual care, we are currently conducting a pilot cluster RCT (4 sites) to reveal and address feasibility issues. Modeled after Kraemer et al.'s recommendations for performing pilot mental health services studies¹⁰⁹ to guide the design and implementation of larger effectiveness studies, we are evaluating the “feasibility of recruitment, randomization, retention, assessment, procedures, and implementation”¹⁰⁹ of RAPPID. In our pilot study, enhanced usual care consists of screening/referral and access to our statewide population based program, MCPAP for Moms as it is now standard of care in MA. The designation of ‘enhanced’ acknowledges that most Ob/Gyns in other states do not have access to this level of psychiatric consultation and resource provision/referrals (Table I).¹¹⁰ In our pilot cluster RCT, we are comparing 2 clinics in which providers/staff (n=18) and perinatal women (n=30) participate in RAPPID, to another 2 clinics in which providers/staff (n=18) and women (n=30) participate in enhanced usual care.

Table I Characteristics of Intervention and Comparison Group

Enhanced Usual Care/MCPAP for Moms	RAPPID
<p>Access to MCPAP for Moms</p> <ul style="list-style-type: none"> • 30-60 minute presentation on perinatal depression • Access to telephonic psychiatric consultation with MCPAP for Moms perinatal psychiatrist for Ob/Gyns • Access to one-time face-face evaluation with patient by a MCPAP for Moms psychiatrist for assessment and treatment recommendations for Ob/Gyn provider • Access to Provider Toolkit which includes assessment and treatment protocols (available at www.mcpapformoms.org and see Appendix) • Resource provision/referrals 	<ul style="list-style-type: none"> • Access to MCPAP for Moms <ul style="list-style-type: none"> ○ See left column • Provide RAPPID Toolkit with Stepped Care Algorithms • Support clinic specific implementation using the Addressing Problems Through Organizational Change (APTOC) implementation platform^{91,90} <ol style="list-style-type: none"> 1. Engage clinic providers, leaders and staff 2. Identify Champions and prepare for change 3. Assess readiness to implement RAPPID 4. Identify steps to achieve goals 5. Implement RAPPID components into the clinic 6. Support, encourage and sustain change • Develop approach to depression screening customized for each practice. • Proactively engage and track of all women who screened positive on the EPDS • Employ psychoeducation and Motivational Interviewing to engage patients who screened positive on the EPDS • Establish and maintain communication between the medical assistant champion and psychiatrist every two weeks to review cases • Stepped care treatment response to depression screening/assessment

Over a period of 2 months we recruited 4 sites that included 70 Ob/Gyn providers (30 physicians, 1 midwife, 2 nurse practitioners, 6 RNs, 7 PCAs, and 24 administrative

staff); the provider/staff numbers exceeded our calculated needs. We have retained all four clinic study sites and $\geq 98\%$ of our provider and staff participants. Our RAPPID intervention sites are screening $\geq 95\%$ of their patients as compared to pre-RAPPID implementation when there was no systematic screening with validated screening tools. We are also exceeding our patient recruitment goals. Among patient participants from RAPPID clinics screening positive for depression ($n=16$), 81% ($n=13$) have been offered and initiated depression treatment; this finding compares with the rate of 62% ($n=8$) observed in the enhanced usual care group ($n=13$). This suggests that RAPPID has the potential to differentially improve treatment rates as compared with enhanced usual care (access to MCPAP for Moms).

Our ongoing pilot cluster RCT has also uncovered barriers and facilitators to implementing RAPPID and conducting a cluster RCT to test its effectiveness. We have found that clinic characteristics contribute significantly to practice readiness for screening and addressing depression. Challenges include a lack of leadership, high provider and staff turnover rates, high patient volume, and use of multiple electronic medical records. Conversely, RAPPID implementation is facilitated by strong leadership, lower turnover rates, and lower clinic volume. We are using this critical feasibility data to refine the cluster RCT design for this U01. Our pilot study also identified that providers need more robust stepped care approaches to ensure that they screen for and rule-out patients with bipolar disorders prior to referring for or initiating treatment.

We are also currently conducting an additional sub-study to better understand how to screen for bipolar disorder in Ob/Gyn settings. We are recruiting and assessing

perinatal women who screen positive for depression (EPDS ≥ 10) and meet criteria for bipolar disorder based on the Mini International Neurodiagnostic Interview. Thus far, four of six patient participants (67%) have undiagnosed bipolar disorder and three of these four (75%) were being treated with an antidepressant (2 by Ob/Gyn and 1 by PCP). This finding is concerning because treatment with an antidepressant can exacerbate bipolar disorder and increase risk of manic symptoms. To address this critical issue, we have incorporated a well-validated bipolar disorder screen into our stepped care treatment response. The lessons learned from our pilot study will allow us to refine RAPPID to further help Ob/Gyn providers detect, treat, and/or refer women with depression and/or other mental illnesses for ongoing treatment in pregnancy and the postpartum period.

Future directions

As described earlier, our pilot cluster RCT was designed with the a priori intention of performing a larger cluster RCT to test the effectiveness of RAPPID as compared with enhanced usual care. This critical feasibility data will be used to refine the design for a cluster-RCT to test the effectiveness of RAPPID. The lessons learned from our pilot study will also be used to refine RAPPID to further help Ob/Gyn providers detect, treat, and/or refer women with depression. The overall goal of the cluster RCT will be to compare two active interventions, enhanced usual care (access to MCPAP for Moms) vs. RAPPID in a cluster RCT. First, we will further refine RAPPID based on our pilot data. Second, we will test RAPPID in a cluster RCT of Ob/Gyn clinics randomized to either RAPPID or enhanced usual care. More specifically, we will compare depression severity and treatment participation among depressed women that receive

care from enrolled clinics throughout the perinatal period. We will also examine provider/staff fidelity to RAPPID (secondary outcome) and estimate costs of RAPPID and enhanced usual care indicators of potential savings. Third, we will disseminate the trial findings and recommendations.

CHAPTER IV

FINAL SUMMARY AND CONCLUSIONS

Similar to the MCPAP, RAPPID has the potential to spread to other states. Each of the 32 states that have a program modeled on MCPAP **has** unique funding mechanisms including grants from state legislatures, private foundations, or Medicaid funding. In fiscal year 2014, Connecticut, the District of Columbia, New Jersey, Oregon, and Wisconsin passed budgets with funding for new child psychiatry access programs.⁷⁹ **With** movement of health care funding to an accountable care model, some accountable care organizations (ACOs) may also fund their own MCPAP programs. In order to share the program costs with commercial insurers, the Massachusetts legislatures recently added budgetary language stating that as of 2015, commercial insurers will have to pay a surcharge for the program thus enhancing sustainability.⁷⁹ This unprecedented legislative decision provides direct evidence of the power of the MCPAP model to change the regional and national landscape for pediatric mental health care. As evidenced by the support already provided through Legislators and the MA Department of Mental Health, we can replicate this in perinatal mental health. MCPAP was also recently recognized by the Agency for Healthcare Research and Quality (AHRQ) in their Health Care Innovations Exchange initiative to promote diffusion and uptake of innovations.^{79,111} AHRQ noted that MCPAP, “has been broadly accepted by primary care clinicians and enhances their ability to treat children and adolescents with mental health issues.”¹¹¹ This illustrates our potential power to transform Ob/Gyn practice, even within the context of limited resources.

Implementing, testing, and disseminating RAPPID could propel the perinatal mental health field forward. If shown to be effective, RAPPID has the potential to have a tremendous impact on the many mothers, families, and babies affected by depression.

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