Rapid Access to Perinatal Psychiatric Care in Depression (RAPPID)

The primary goal of this K12 award is to provide Dr. Byatt with the advanced research training, protected time, and mentoring she needs to become an independent mental health services researcher committed to improving depression outcomes for pregnant and postpartum (perinatal) women. Her K12 will focus on studying the implementation and effectiveness of interventions that will improve access to and engagement in perinatal depression treatment. Major Depressive Disorder is the leading cause of disability among women of reproductive age and a significant public health issue. Despite routine contact with obstetrical providers, the majority of women with perinatal depression do not receive treatment due to multi-level barriers. There is a critical need to develop and evaluate innovative and practical approaches to perinatal depression care in obstetric settings, which is the focus of this proposal. Dr. Byatt proposes to translate components of the successful Massachusetts Child Psychiatry Access Program (MCPAP), which has transformed the delivery of child mental health services in Massachusetts by making immediate psychiatric consultation available to pediatricians, to address depression in obstetric settings. Dr. Byatt's training and research plan will allow her to obtain expertise in mental health services research and develop and evaluate an innovative perinatal depression program: Rapid Access to Perinatal Psychiatric Care in Depression (RAPPID). RAPPID will build on: (1) her published preliminary work with obstetric providers/staff and perinatal women; (2) the existing infrastructure of the pediatric access program; and, (3) her established relationships with key stakeholders including consumers, obstetricians, and legislators. Dr. Byatt will be guided by her primary mentor, Dr. Ziedonis, and secondary mentors, Drs. Weinreb, Allison, Pbert, Freeman, and consultants, Drs. Barton and Johnson. Aim 1 of her research plan is to create the research infrastructure for her subsequent R01 by developing a procedural manual, training program and fidelity measures for RAPPID. Dr. Byatt and her team will develop and obtain feedback on the feasibility and acceptability of the core components of RAPPID: (1) obstetric provider/staff training in depression screening/management; (2) clinic procedures and office prompts for depression screening/management; and, (3) immediate psychiatric consultation for obstetric providers/staff. Aim 2 is to implement and evaluate the feasibility of RAPPID in a 4 site pilot cluster randomized controlled trial that will compare 2 sites receiving the RAPPID intervention and 2 control sites using the screening/referral approach. Each site will evaluate 9 providers/staff and 15 women. She will also evaluate the preliminary effectiveness of RAPPID to change provider practices regarding depression screening/treatment and improve women's treatment participation and depression severity compared to the screening/referral control. Her K12 will provide an opportunity to develop RAPPID, test its feasibility and preliminary efficacy, and determine an effect size. This will set the stage for her R01 application to conduct a full scale, multi-site implementation and effectiveness study comparing RAPPID to the screening/referral control.

1. SPECIFIC AIMS

The primary goal of the research plan for this K12 Award is to develop and evaluate a low-cost and sustainable program that will improve women's access to and participation in perinatal depression treatment and thereby improve depression outcomes. There is a tremendous public health need for this research. Major depressive disorder continues to be the leading cause of disability among women of reproductive age[1] and major public health concern. Up to 18.4% of women suffer from depression during pregnancy, and up to 19.2% in the postpartum period.[2] Perinatal depression has deleterious effects on birth outcomes,[3] infant attachment, behavior and development.[4,5] Maternal suicide causes 20% of postpartum deaths in depressed women.[6]

Several states have mandated screening for postpartum depression (PPD)[7,8] and MA recently passed legislation recommending screening[9] and created a Special Legislative Commission on PPD.[9] Although 90% of women are amenable to depression screening,[10] it does not improve treatment entry[7,11,12] or outcome.[11,12] Despite the availability of effective evidence-based treatments[13] and frequent contact with obstetric providers, < 30% of women who screen positive for depression receive treatment.[10,14-16] In our pilot work, we found that barriers occurring at the patient, provider, and systems-level prevent perinatal women and obstetric providers from addressing depression. While the majority of obstetric providers want to address depression,[17,18] fear of liability, discomfort, and lack of knowledge/resources present barriers. These barriers are magnified by stigma, fear, and discomfort among mothers.[19] There is a critical need to develop and test new approaches that can be broadly disseminated in low resource real-world settings.[20]

We hypothesize that transforming obstetrical practice to include evidenced-based depression treatment will improve women's access to and engagement in depression treatment and thereby improve depression outcomes. We propose to design and test the Rapid Access to Perinatal Psychiatric Care in Depression (RAPPID) program. RAPPID will leverage existing roles and resources to target patient, provider, and system level barriers to perinatal depression treatment. Our review of the literature[21] and preliminary data suggest that RAPPID will improve perinatal depression treatment participation via: (1) provider/staff training for evidence-based guidelines in depression screening, triage/referral, risks and benefits of medications, and discussion of screening results/treatment options; (2) office prompts and clinic procedures for depression screening/management; and, (3) immediate psychiatric guidance via telephone consultation.

Thus far, statewide PPD screening in the U.S. has not improved treatment rates.[7] The MA PPD Commission has expressed interest in our proposal because they see it as a crucial next step toward successful screening and treatment (*see Letter*). RAPPID will draw upon the successful MA Child Psychiatry Access Program[22,23] created at UMass in response to a crisis in which children needing psychiatric care were falling through the cracks in the health care system. RAPPID has potential because: (1) in our clinics and across the nation, women are requesting to get depression care in obstetric settings;[19] and, (2) in our focus groups,[24] obstetric providers/staff were calling for rapid back up from psychiatry, and evidence-based training/guidelines. In addition, if shown to be effective, the PPD commission is poised to disseminate RAPPID.

The research plan will be conducted in two phases. Phase 1 (Aim 1) will develop the RAPPID manual, training program and fidelity measures. Phase 2 (Aim 2 & 3) will conduct a feasibility test of RAPPID via a pilot cluster randomized control trial (RCT) that will compare 2 clinics in which providers/staff (n=18) and women (n=30) participate in RAPPID to another clinic in which providers/staff (n=18) and women (n=30) participate in screening and referral (control).

Aim 1 (Phase 1) To develop a manual, training program and fidelity measures for RAPPID via iterative feedback from key stakeholders.

Aim 2 (Phase 2) To determine fidelity (primary outcome) to RAPPID (including obstetric provider/staff participation) and change in knowledge, attitudes, and practices toward depression screening and treatment (secondary outcomes) in the RAPPID compared to screening and referral control group.

Aim 3 (Phase 2) To compare perinatal women's treatment participation (primary outcome) and depression severity (secondary outcome) in the RAPPID versus screening and referral control group.

This K12 award will provide the advanced training, mentorship, and protected time I need to become a physician-scientist focused on improving the lives of depressed perinatal women. During years 4/5, I will apply for R01 funding to test the efficacy of RAPPID in a large cluster RCT. Prior training in business (MBA) and perinatal psychiatry, the conduct of pilot studies, and my established relationships with stakeholders uniquely prepares me for this career trajectory. Developing RAPPID, with its products, tools and related interventions will have a tremendous impact on the many mothers, families and babies affected by depression.

2. CANDIDATE'S BACKGROUND

I am committed to becoming an independent mental health services researcher focused on developing innovative ways to improve the implementation and adoption of evidence-based depression treatment for perinatal women, which in turn can improve birth, infant, and child outcomes. I plan to develop and test a new, low-cost and sustainable program that will address barriers to treatment by integrating depression treatment into standard perinatal care. Although I have been successful in the early stages of my research, I need to: (1) further my research skills through mentorship and training in implementation science, biostatistics, research design, and grant writing as it pertains to mental health services research; and, (2) collect pilot data through the proposed research plan. This K12 award will allow me to obtain the skills and data I need to secure R01 funding before its completion.

Due to my clinical experience and training in psychosomatic medicine and perinatal psychiatry, I am acutely aware of the tremendous need to better integrate psychiatric and medical care. My interest in health care systems and organizational change led me to pursue a business administration degree during medical school, which allowed me to understand systems-level complexities in health care organizations and envision ways to improve health care. During my psychiatry residency at UMass Medical School/UMass Memorial Health Care (UMass), I developed a keen interest in improving the assessment and treatment of depression with comorbid medical disorders. This led me to design and conduct a research project on multiple sclerosis and depression and pursue training in psychosomatic medicine. As a Psychosomatic Medicine Fellow at Brigham and Women's Hospital/Harvard Medical School, with a subspecialty focus and liaison with obstetrics, my career goals further crystallized as I worked with many perinatal women whose untreated depression had lasting effects on them and their children. In 2008, I returned to UMass for my first faculty position as an Assistant Professor. During my first 2 years on faculty, I expanded my clinical expertise in perinatal psychiatry and established relationships with obstetric colleagues, which in turn, led me to develop clinically-based research questions. These experiences solidified my commitment to becoming an independent investigator in order to study ways to improve maternal mental health and birth/infant/child outcomes by integrating depression and obstetric care. I have found my passion and mission: to leverage my training in general and perinatal psychiatry, psychosomatic medicine, and business (MBA) to bring low-cost effective depression interventions to "real-world" perinatal care settings.

Determined to make an impact beyond direct patient care, I have obtained research funding to conduct formative studies, published 11 peer-reviewed articles (8 related to this research area), presented oral and poster presentations nationally, and received awards for my work. In the past year, I have published 4 manuscripts as first author (see Biosketch). I am also preparing or revising 5 other manuscripts for submission, and therefore anticipate having at least 16 manuscripts published by 2014, fourteen of which relate to depression and/or perinatal psychiatry. I have also laid the groundwork in my role as PI on two small institutionally-funded pilot studies that evaluated the perspectives of obstetric providers and postpartum women respectively, regarding what can be done to improve depression treatment in the obstetric setting. These studies informed the proposed research to close depression service gaps in obstetric settings.

I have also sought out and established invaluable mentorship relationships and collaborations and established important support from stakeholders, legislators, and colleagues in the MA Department of Public Health. I have been thrilled that several groups of stakeholders have expressed their commitment to partner with me in testing the effectiveness of our proposed program and disseminating our findings (*see Support Letters*). I have also been in continued communication with UMass psychiatric and obstetric clinical and research leaders, and individual providers (*see Support Letters*) and forged an agreement to develop and evaluate my proposed program at UMass. **The proposed research plan is feasible because I have established relationships with and strong support from key stakeholders, including consumers, obstetric providers/staff and policy makers (*see Letters*).**

My ability to make an impact on perinatal women as an independent clinical researcher would increase exponentially with a K12 Award. I am a physician who has not been formally trained in research. Although my high level of commitment and motivation has allowed me to obtain institutional grant funding, conduct and publish pilot studies, and work productively work with my mentors' research teams, my ability to fulfill my research potential is limited without the in depth training outlined in my training plan. The proposed research plan will be a vehicle to apply my new knowledge and skills. The training component will focus on coursework, seminars, mentorship and training in implementation science, biostatistics, research design, and grant writing. I

will commit 75% of my full-time effort (9 calendar months per year) to the K12 grant, including my health services research program and related career development activities. This award will provide the support, time, and training that is essential for me to build a program of research and pursue my mission of improving depression outcomes for perinatal women by expanding access to evidence-based depression treatment.

3. CAREER GOALS AND OBJECTIVES

Although empirically validated interventions for perinatal depression exist,[25] there is a dearth of effective mechanisms to implement these interventions in obstetric settings. My ultimate career goal is to be an independent mental health services researcher focused on using implementation science methods to increase the uptake of evidence-based interventions for perinatal depression. I need mentorship and training to achieve this goal. Designing and testing a new program, the Rapid Access to Perinatal Psychiatric Care in Depression (RAPPID) will be a vehicle to apply the knowledge/skills I gain during coursework, seminars, and mentorship.

3.1 **Primary Training Goal 1:** Obtain focused training in study design, biostatistics, and grant writing.

- I will enhance my knowledge in unique study designs used for effective evaluation in implementation science and effectiveness research. For example, I will develop expertise in cluster randomized controlled trials (RCTs) and stepped wedge design which are commonly used in mental health / health services research to test interventions that occur at the group level (providers or clinics) and observe changes on individuals within the group (patients).
- I will expand my knowledge and skills in biostatistics and epidemiology.
- I will combine advanced grant writing courses with hands-on grant writing guided by mentors.

3.2 **Primary Training Goal 2:** To obtain a firm conceptual foundation and knowledge base in implementation science and effectiveness research.

- I will develop expertise in the frameworks, models and theories that guide approaches to implementing evidence-based programs and practices within organizational systems.
- I will expand my knowledge of the common building blocks of implementation programs including effective components (e.g. training), implementation materials (educational resources, toolkits), techniques for promoting and sustaining behavior and practice change.
- I will expand my knowledge and skills in the use of health informatics for implementation science/mental health services research to learn the role that such applications can play, and the unique issues associated with their implementation and analysis.

3.3 **Primary Training Goal 3**: Develop and apply skills in mental health services research.

- I will develop my expertise in the qualitative and quantitative formative methods that are used during formative health services research including observation, key informant interviews, focus groups, survey methods, and document/artifact analysis.
- I will develop expertise in mixed methods evaluation.
- I will apply knowledge from advanced courses and seminars as I conduct Phase I and 2 of my program of research with mentorship guidance.

4. CAREER DEVELOPMENT / TRAINING ACTVITIES DURING AWARD PERIOD

4.1 TRAINING

Table 4.1 Proposed Time Commitment

Activities	Year 1	Year 2	Year 3	Year 4	Year 5
Coursework/Training	30%	25%	10%	5%	5%
Consultation with Mentors	10%	10%	5%	5%	5%
Research Projects	30%	35%	50%	45%	35%
Manuscript/Grant Writing	5%	5%	10%	20%	30%
Teaching and Clinical Activities	25%	25%	25%	25%	25%

I need to extend my research capabilities via in-depth training. In order to maximize the benefit of the K12 award, I have chosen classes and training activities that are highly related my training and career goals, rather than obtaining a Master's in Clinical Investigation. Table 4.1 outlines my proposed time commitment to training activities. Tables 4.2 and 4.3 provide details on the specific coursework and mentoring activities I will complete to adhere to my primary and secondary training goals respectively.

Table 4.2 Primary Training Goals and Activities

Training goal and activity	K12 Year				
Goal 1: Obtain focused training in study design, biostatistics, and grant writing (& goal 2/3)					
Implementation and Evaluation of RAPPID (Phase 2)		√	√	√	√
Introduction to Clinical Epidemiology* (CTS605A, 3 credits)	√				
Introduction to Biostatistics in Clinical Research* (CTS6112A, 3 credits)	√				
Mixed Models and Analysis of Longitudinal Data (BioEpi 740, 3 credits)	√				
Design of Observational Studies and Clinical Trials* (CTS609, 3 credits)		√			
Applied Biostatistics* (CTS612B, 3 credits)		√			
Grant Writing* (CTS606, 3 credits)		√			
Career Development Institute for Psychiatry: already selected for this competitive 2-yr research training program	√	√			
Independent study in cluster RCTs: Monthly meeting with Dr. Allison to review: Murray D, Design and Analysis of Group-Randomized Trials, Oxford: Oxford University Press, 1998	√	√	√	√	√
Mentorship: guidance from mentors during hands-on practice with ongoing research will reinforce and expand skills learned in formal courses (Ziedonis, Pbert, Allison, Weinreb, Freeman, Barton, Johnson)	√	√	√	√	√
Goal 2: To obtain a firm foundation and knowledge base in implementation science (& goals 1/3)	**1**	**2**	**3**	**4**	**5**
Innovative strategies for implementing evidence-based practices and new developments in implementation theory hosted by VA Quality Enhancement Research Initiative (QUERI) Enhancing Implementation Science (EIS)	√				
Annual training meeting of VA QUERI Enhancing Implementation Science (EIS) VA	√	√			
Independent Study: Monthly Meeting with Drs. Allison and Pbert to review Brownson R et al (eds), Dissemination & Implementation Research in Health: Translating Science to Practice, Oxford Univ. Press, NY, NY	√				
Mentorship: guidance during ongoing K12 real-world study (Ziedonis, Pbert, Allison, Weinreb). Will include further learning of the Getting to Outcomes implementation platform and other organizational change models	√	√	√	√	√
Attend Annual NIH Conference on the Science of Dissemination and Implementation		√		√	
Apply for the Implementation Research Institute (IRI) training hosted by the Center for Mental Health Services Research at Washington Univ. in Missouri. 8 fellows/year are appointed and receive mentoring and collaboration. Alternatively, I will apply to attend the NIH Dissemination and Implementation Research conference	√	√			
Goal 3: Develop and apply skills in mental health services research (& goals 1/2)					
Understand research infrastructure development: RAPPID Intervention (Phase 1) and Implementation and Evaluation (Phase 2)	√	√			
Center for Mental Health Services Research Group weekly meetings at UMass	√	√	√	√	√
Implementation Science Academic Research Group monthly meetings at UMass	√	√	√	√	√
Reproductive Psychiatry Academic Research Group monthly meetings (co-chair: Byatt) at UMass	√	√	√	√	√
Independent study in organizational change: Monthly meeting with Dr. Ziedonis to review: Beitler M, Strategic Organizational Change, Greensboro, NC: Practitioner Press Intl., 2006	√	√			
Community and Stakeholder Advisory Board: Biannual meetings	√	√	√	√	√

*Offered via Masters of Science in Clinical Investigation (MSCI)/UMMS Graduate School of Biomedical Sciences (GSBS)
**Offered via Biostatistics and Epidemiology Program at UMass, Amherst

Table 4.3 Secondary Training Goals and Activities

Goal	Training activity
Improve manuscript writing skills via 5 publications per year	I will work with my mentorship team to refine my manuscript writing skills. Yrs 1-2: publish 1 review paper. Yrs 1-5: publish data from ongoing/completed studies (PI: Byatt) and 2 data papers in collaboration with mentors/colleagues. Yrs 3-5: publish 1-2 RAPPID data papers.
Improve presentation skills via presentations at 2-3 meetings per year	As I prepare presentations, my mentors will guide me and provide feedback on performance. Yrs 1-5: platform and poster presentation at the Acad. of Psychosomatic Medicine. Yrs 1, 3 and 5: poster presentation at The Marcé Society for Perinatal Mental Health and National Assoc. of Psychosocial Ob/Gyn. Yrs 2 & 4: poster and platform presentation at Postpartum Support International.
Establish/maintain collaborations	Collaborate with other investigators in submitting grants, papers, and abstracts.
Improve mentoring skills	UMMS course, "Entering Mentoring", adapted from a research mentor training seminar series developed by the Wisconsin Program for Scientific Teaching.[26]
Improve grant writing skills and prepare R01 proposal	Attend monthly UMMS R01 writing group. In year 4/5, prepare R01 for large multi-site cluster RCT to test the efficacy of RAPPID.
Non-K12 activities (25% effort)	Continue teaching and clinical work in perinatal psychiatry.

4.2 MENTORING

The mentors below each offer a specific area of expertise within mental health services/implementation science including organizational change, integrated care, women's behavioral health, intervention design/implementation, clinical trial design, and statistics. The Community and Stakeholder Advisory Board will provide key input to ensure that RAPPID is sustainable and tailored to meet the needs of consumers. Various organizational systems and stakeholders involved in perinatal depression. I will have extensive contact and access to my mentoring team. I will meet with Drs. Ziedonis, Allison, Weinreb, Pbert, Freeman (by phone)

during a monthly group mentoring meeting. In addition, I will meet: 1) with Dr. Ziedonis 3 times a month; 2) with Drs. Allison, Weinreb, and Pbert monthly; 3) with Dr. Freeman monthly (phone) and quarterly in person; 5) with consultants Drs. Johnson and Barton every 3-6 months; and, 6) with Community and Stakeholder Advisory Board every 6 months. We will also have RAPPID Development Research Group meetings every 3 months. My mentoring team will meet quarterly via phone or in person to review my progress, outline future changes, and identify training and research needs and other opportunities. Progress on any identified "action items" will be reviewed at the next meeting. Progress will be tracked using the timetables in Tables 4.2, 4.3, and 11.7, evaluation forms, and annual faculty review.

Primary Mentor: Douglas Ziedonis, MD, MPH (Mental Health Services Research and Organizational Change): Dr. Ziedonis is a Professor with tenure and Chair of the UMass Psychiatry Department. He has extensive mentoring experience, including being the primary mentor for 5 NIH K23 awardees who are successful academics. His mental health services/implementation science research includes developing, implementing, and evaluating innovative programs/system changes and other organizational change platforms, including efficacy and effectiveness studies of psychosocial treatment interventions. **Role:** He will provide overall academic/research mentoring guidance, assurance of institutional support, and review future grant proposals and manuscripts. **Working relationship:** Primary mentor on 2 funded grants (see 5A Prelim. Data) and co-author on 3 published articles and 2 manuscripts that are in preparation.

Health Behavior Change, Health Care Integration and Intervention Design/Implementation Team:

Secondary Mentor - Linda Weinreb, MD (Women's Mental Health and Integrated Care): Dr. Weinreb is a Professor and Vice-Chair of the Department of Family Medicine and Community Health at UMMS. She has a broad background in health services research focused on integrating mental health care for women and mothers into primary care settings. **Role:** She will provide guidance on how to successfully conduct our proposed study that integrates depression care into obstetric settings and troubleshoot issues specific to integrated care research that may arise. **Working relationship:** She has been a mentor on several of my grant applications and formative studies (see 5A Prelim. Data) and is co-author on 2 manuscripts.

Secondary Mentor - Lori Pbert, PhD (Intervention Design/Implementation and Health Behavior Change): Dr. Pbert is a Professor and Associate Chief of the Division of Preventive and Behavioral Medicine, Dept. of Medicine at UMMS. She is a Clinical Psychologist with expertise in the design, implementation, and evaluation of clinic-based interventions for health behavior change in primary care settings. **Role:** She will provide guidance/direction in the design and implementation of RAPPID and review future grant proposals and manuscripts. **Working relationship:** We meet regularly and she is co-author on a manuscript in preparation.

Clinical Trial Design and Statistics Team:

Secondary Mentor - Jeroan Allison, MD, MS (Implementation Science and Methods): Dr. Allison is a Professor and Vice-Chair of the UMMS Department of Quantitative Health Sciences. His health services research spans the areas of implementation research, health informatics, and health disparities. **Role:** He will provide oversight on implementation science and methodology training, with a focus on pilot studies and cluster RCTs and will review methodology for future grant proposals and manuscripts. **Working relationship:** He mentored 2 funded grant applications (see 5A Prelim. data) and is co-author on 2 manuscripts.

Consultant - Bruce Barton, PhD (Statistics): Dr. Barton is a UMMS Research Professor in Quantitative Health Sciences, Dir. of the Quantitative Methods Core, and expert in clinical trials statistics, especially mixed effects models. **Role**: He will provide tutoring in statistics for clinical trials and guidance in analyzing Phase 2 data and developing my R01 proposal. **Working relationship:** He provides statistical guidance in grant writing.

Perinatal Depression and Obstetric and Gynecology Team:

Secondary Mentor - Marlene P. Freeman, MD (Perinatal Depression): Dr. Freeman is an Assoc. Professor, Harvard Medical School, and Dir. of Clinical Services of the Perinatal and Reproductive Psychiatry Program at MA General Hospital. Her research focuses on perinatal mood disorders and the development of efficacious and accessible interventions. **Role:** She will guide the development of RAPPID components, review grant proposals and manuscripts, and help me network with national/international perinatal depression experts. **Working relationship:** She has guided me in writing this proposal and we are co-authors on 2 manuscripts.

Consultant - Julia Johnson, MD (Obstetrics and Gynecology): Dr. Johnson is a Professor and Chair of the UMMS Department of Ob/Gyn. Her expertise in organizational change and clinical system management are critical to my developing and evaluating integrated services for perinatal depression. **Role**: She will provide guidance, direction, and leadership as I develop and test RAPPID and apply for future grants. **Working relationship:** We have laid the groundwork for this research plan and are co-authors on a manuscript.

Community and Stakeholder Advisory Board: We have formed an advisory board of providers and

consumers who have and will continue to provide input on acceptability, feasibility, and perceived barriers and facilitators to implementing RAPPID. The board will provide real-life input and guidance on: (1) acceptability of RAPPID versus control by providers and consumers; (2) translating the pediatric access program to obstetric settings; (3) tailoring RAPPID to be sustainable and transportable to other settings; (4) managing issues that arise during implementation; and, (5) help in interpreting study findings and implications. Several individuals have graciously agreed to be on the board and committed to bimonthly meetings in years 1-5. The board will include a consumer who experienced PPD (Liz Friedman), a family member of a consumer who experienced PPD (to be identified) a PPD Commissioner (Janice Goodman, PhD), and an expert in psychiatric telephone consultation to primary care providers, and the statewide medical director for the Massachusetts Child Psychiatry Access Program (Barry Sarvet, MD).

5. RESEARCH STRATEGY

A. SIGNIFICANCE

Perinatal depression (Major Depressive Disorder occurring during pregnancy or within one year of delivery) is a widespread problem, which in turn, may complicate birth,[3] infant,[27] and child outcomes.[4,5,28] While 1 in 8 women[2] and as many as 36% of ethnically diverse women suffer from perinatal depression,[29] the vast majority go untreated.[10,14-16] Depression in pregnancy has deleterious effects on pregnancy and birth outcomes;[3] it has been associated with preeclampsia, preterm birth, low birth weight,[3,30] elective termination of the pregnancy,[31] alcohol / tobacco abuse,[32] and postpartum depression (PPD).[33] PPD is associated with attachment insecurity,[28] difficult infant/childhood temperament,[28,34] and long-term consequences in children, including developmental delay, impaired language development[4,5] and depressive, anxiety or disruptive disorders.[35] We aim to mitigate this negative impact by bringing effective treatment for depression to women in obstetric settings.

Perinatal depression is increasingly being recognized as a major public health issue and there is a growing sense of urgency to identify approaches to better manage it. In spite of the profound negative effects on mother and child, which are mitigated by effective treatment,[13] including psychopharmacology and psychotherapy,[25] perinatal depression remains under-diagnosed and under-treated.[10,14,15,36] Recognizing this gap, several states have mandated screening for PPD[7,8] and in 2010 the MA state legislature recommended screening[9] and created a Special Legislative Commission on PPD to consider current PPD research and recommend policies to promote screening and treatment.[9] The American College of Obstetricians and Gynecologists[37,38] and others[39-43] also advocate that obstetricians screen for depression every trimester. However, most efforts to intervene have only focused on PPD, which does not address depression that begins in pregnancy. We will build a program that addresses depression throughout the perinatal period.

Despite high acceptance of depression screening by perinatal women, many are not amenable to contact with a mental health provider.[10,14,15,16] Less than 30% of women who screen positive for depression attend an initial or subsequent mental health visit[10,14,15,16] and as few as 0-6%[14,16] adhere to a full treatment course. This lack of adherence may be due to unengaged providers and staff[44] and limited resources to ensure depression evaluation, treatment, and follow-up.[24,40] The MA PPD Commission, for example, has not mandated screening because screening does not work without a program in place to secure adequate assessment, treatment, and follow-up.[7] Consequently, MA State Rep. Ellen Story (PPD Commission Chair) and individual PPD Commissioners including legislators, colleagues in the Department of Public Health, and obstetric and psychiatric physician leaders have expressed a keen interest in our proposal. Key stakeholders (see *Support Letter)* indicate that if RAPPID is shown to be successful, they are committed to implementing it statewide, as done with the Massachusetts (MA) Child Psychiatry Access Program (MCPAP). Our established link with these stakeholders enhances the potential for widespread dissemination and implementation.

Screening for perinatal depression does not translate into treatment participation because women and obstetric providers experience multi-level barriers. Perinatal women and their obstetric providers find screening a futile exercise when done in the absence of trained providers with access to mental health resources/referrals (See Prelim. Data). In our recent literature review[21] we identify patient, provider, and systems-level barriers and facilitators to the treatment of perinatal depression and review clinical, program, and systems-level interventions. Identified provider and systems-level barriers included: (1) lack of obstetric provider training in technical aspects of depression care[38-40] and communication skills in this context;[41] (2) absence of standardized processes and procedures for depression care;[45,46] (3) lack of mental health providers willing to treat pregnant women;[46] (4) lack of referral networks;[45-49] and, (5) inadequate capacity for follow up and care coordination.[45-49] These barriers are exacerbated by patient-level barriers. Perinatal women report they are afraid to disclose mental health concerns due to fears of stigma, losing parental rights, and being judged as an unfit mother.[19,50-68] Many women perceive obstetric providers and staff as unsupportive,

unavailable,[19,53,55,62,63,66,69-71] and inadequately trained in depression assessment and treatment.[69,70] RAPPID will overcome these barriers via provider training in depression screening/management, standardized [72]processes and procedures for screening/management, informal mental health consultation, and a centralized telephonic mental health care coordination/consultation service. RAPPID components have been thoughtfully proposed based on data suggesting that perinatal depression screening is feasible[73,74] and increases detection and treatment rates[75-77] when coupled with systematic changes to ensure women receive appropriate care.[73-77] RAPPID could optimize perinatal depression treatment through patient, provider, and system-level changes.

Successful integrated care models need to be translated to obstetric settings. It is well-established that integrated care models, such as collaborative care and medical homes, effectively integrate depression and primary care and improve clinical outcomes.[72] However, there is an unmet need because these models have not been fully adapted to obstetric settings. Health care reform presents an unprecedented opportunity to leverage the success of integrated care models to enhance patients' access to services, improve the quality of care and lower overall health-care costs. Perinatal depression represents a missed opportunity because depression is only just beginning to be addressed in obstetric settings. We hypothesize that integrated care models can be adapted to obstetric settings to enhance women's access to services and improve quality care and depression outcomes. Our proposed approach, RAPPID, will build on the established success of integrated care models by using existing roles and resources to support obstetric providers/staff in helping women access and engage perinatal women in depression treatment.

Preliminary data: Our proposed research plan is designed to overcome the barriers and leverage the facilitators we identified in our preliminary studies. The lack of timely diagnosis and treatment for perinatal depression is a major concern for perinatal women and their obstetric providers. The Departments of Psychiatry and Ob/Gyn at UMass have deemed it a priority to develop an integrated approach to perinatal depression. As demonstrated by the enthusiastic support letters, we have forged an agreement with the Department of Ob/Gyn to develop, implement, and test our proposed RAPPID program at UMass. To inform this proposal, we conducted 3 formative research studies with obstetric providers and staff (PI: Byatt), postpartum (PI: Byatt) and pregnant women (Co-I Byatt) respectively.

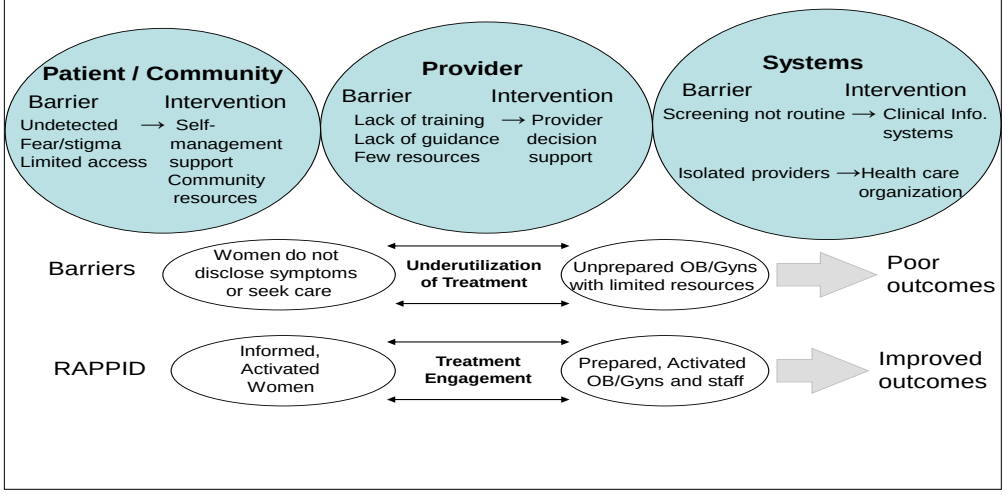
To better understand how women's interactions with health care providers contribute to untreated perinatal depression, we conducted **study 1** (Co-I: Byatt). We screened women for depression (n=110) and conducted semi-structured interviews with women that reported significant depression symptoms (n=46). We found that 35.3% of women that either sought (n=8) or were receiving depression care (n=17) at the point they learned of their pregnancy were not in mental health treatment at the time of screening. Women perceived a multitude of barriers to depression treatment including providers declining to treat them during pregnancy and providers' not understanding women's needs and/or the available treatment options. This data suggests that transforming obstetrical practice to include perinatal depression will help women access treatment.

To investigate barriers and facilitators to addressing perinatal depression in obstetric settings, we conducted 2 additional studies with postpartum women and obstetric providers respectively.[78,79] In **study 2**, we conducted four, 90 minute focus groups with UMass obstetric residents (n=6), attending physicians (n=8), advance practice nurses (n=4), nurses (n=4), registration staff (n=3), patient care assistants (n=2), and social work staff (n=1) (PI: Byatt). In **study 3**, we assessed the perceptions of perinatal women by conducting four, 90-minute focus groups with women 3 - 36 months postpartum (n=27), who experienced symptoms of perinatal depression (PI: Byatt). Both study 2 and 3 identified limited access to depression treatment, limited ability of obstetric/providers staff to help, and shortage of psychiatric specialists as barriers to addressing depression in obstetric settings. Both studies also noted that lack of training, time and resources to address depression among obstetric providers/staff results in undetected perinatal depression. Both women and professionals recommended depression care become a routine part of perinatal care via depression training for obstetric providers/staff and improved collaborations with mental health providers. Both groups suggested empowering women to seek help through psycho-education, provision of resources, validation of women's experiences, and attention to language and interactions that could be interpreted as stigmatizing.[78,79] Obstetric providers/staff also recommended immediate psychiatric back up via the telephone. Our preliminary data supports our hypothesis that transforming obstetrical practice to include depression treatment will enhance women's access to and engagement in treatment and thereby improve depression outcomes. As we develop RAPPID, we will incorporate the strategies we identified: (1) obstetric provider/staff training; (2) structured screening/referral processes and resource guides; and, (3) immediate psychiatric back up via telephone consultation.

RAPPID Conceptual Model: RAPPID will aim to improve the delivery of health care at the patient/community, practice (provider), and organization (systems) levels.[80,81] The conceptual basis for RAPPID rests on the Chronic Care Model. Wagner created the Chronic Care Model in response to reviews of

interventions[82,83] that showed 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). As described in Section 5C and illustrated in Figure 5.1, RAPPID will rely on the key areas of the Chronic Care Model: (1) self-management support for women via screening, psychoeducation, and resources/referral guide; (2) provider decision support via immediate psychiatric telephone consultation and provider toolkit; (3) delivery systems design via screening/referral protocols and office prompts to screen for depression and document treatment plan; (4) health care organization via procedures for depression screening and management and, (5) community resources via a resources/referral guide, telephonic care coordination and educational resources.

FIGURE 5.1
RAPPID Conceptual Model Adapted from Chronic Care Model



The Rapid Access to Perinatal Psychiatric Care in Depression (RAPPID) Program may provide a feasible and sustainable solution. The design of RAPPID will also draw upon the successful outcome of the MA Child Psychiatry Access Program (MCPAP),[22,23] created at UMass 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. MCPAP supports pediatricians in diagnosing and treating patients with mental health issues. Regional teams provide assessment and treatment support, face-to-face consultations, care coordination and ongoing education for pediatric providers.[22,23] This program secures access to psychiatric care for >90% of children/adolescents in the state of MA because currently 97% of pediatric providers are enrolled (425 practices enrolled; 1230 of 1268 MA pediatricians, 323 of 331 of MA pediatric nurse practitioners). This is accomplished by employing only 6 full time psychiatrists and care coordinators for the whole state. MCPAP was recently recognized by AHRQ in their Health Care Innovations Exchange initiative to promote diffusion and uptake of innovations.[84] AHRQ noted that the MA Child Psychiatry Access Program, "has been broadly accepted by primary care clinicians and enhances their ability to treat children and adolescents with mental health issues."[84]

Translating this approach to obstetric settings is promising because even solo practitioners and community clinics with few resources could utilize the training and centralized referral and consultation system. Due to its remarkable success and the nationwide shortage of child psychiatry care, the MA Child Psychiatry Access Program has expanded to become the National Network of Child Psychiatry Access Programs. This illustrates the potential power of RAPPID to transform practice, even within the context of limited resources.

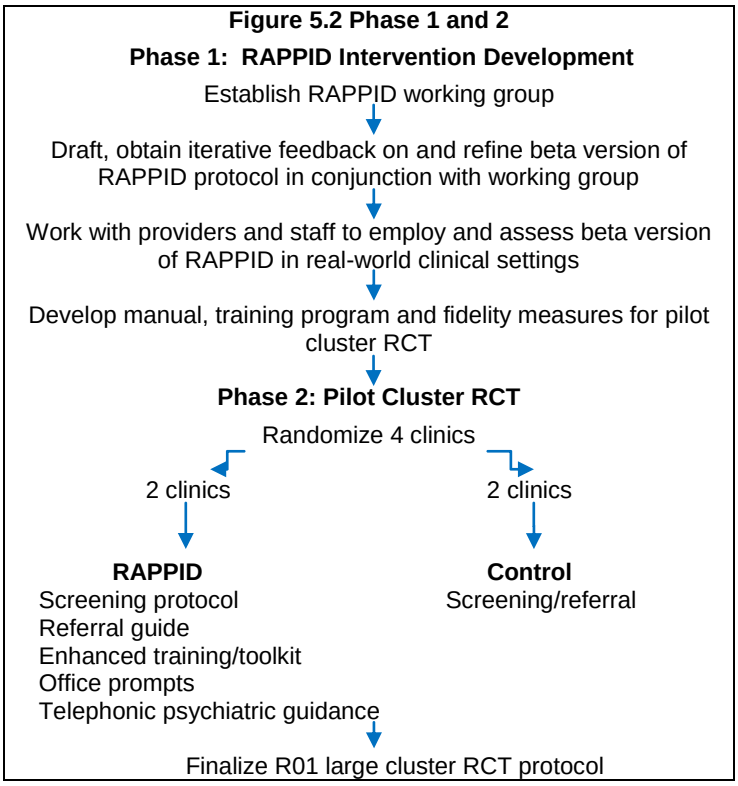
B. INNOVATION

- We will adapt models that effectively integrate depression and primary care,[72] to address an unmet need among perinatal women by incorporating depression treatment into obstetric settings.
- We seek to transform current perinatal depression practice paradigms by developing RAPPID, a site-level intervention that will overcome patient, provider and systems-level barriers to treatment.
- The formative phases of RAPPID will incorporate real-life input from consumers, obstetric providers/staff and policy makers to purposefully tailor RAPPID to be sustainable and transportable to other real-world settings.
- RAPPID will be a distinct, generalizable and cost-effective program because it will leverage existing roles and resources to enhance access to perinatal depression services and thereby improve depression outcomes.
- Due to our established relationships with consumers, obstetricians, and legislators and the applicability of RAPPID to diverse settings, we will be poised for widespread dissemination and public health impact, with the potential for implementation at the policy level.

C. APPROACH

Overview: We will set the stage for our R01 application in year 4 by developing and pilot testing the elements needed to test the efficacy of RAPPID in a large cluster RCT. Phase 1 (Aim 1) will develop the RAPPID

manual, training program and fidelity measures. Phase 2 (Aim 2 & 3) will conduct a feasibility test of RAPPID via a pilot cluster randomized control trial (RCT) that will compare 2 clinics in which providers/staff (n=18) and women (n=30) participate in RAPPID and 2 clinics in which providers/staff (n=18) and women (n=30) participate in screening/referral control.



Phase 1 → RAPPID Intervention Development

Overview: We will establish a working group to design and obtain feedback on RAPPID components **(Aim 1),** uncover barriers and facilitators to implementation, and develop the protocol and products for the Phase 2 pilot cluster RCT.

1. Establish RAPPID Working Group. The group will consist of obstetric physicians (n=2), licensed independent practitioners (n=2), nurses (n=2), a patient care assistant (n=1), administrative support staff (n=1) from the Community Women's Care clinic at UMass (all recruited, *see Support Letters*) and the consulting psychiatrist (n=1). Guided by her mentors, Dr. Byatt (PI) will coordinate and meet with the working group.
2. Establish, obtain iterative feedback on, and refine an initial version of RAPPID. Dr. Byatt will: (1) meet with the working group to elicit their opinions on what will hinder and facilitate participation and adherence to RAPPID components; (2) assimilate the existing literature, our preliminary data and the opinions of the working group to develop the initial version of RAPPID; and, (3) present the initial version of RAPPID (screening/referral procedures and protocols, telephone consultation) and products (training curriculum, resource/referral guide) to the working group and elicit their opinions.
3. Implement and Beta-test RAPPID components and products in one clinic site. The RAPPID components will be: (1) two, 2-hour trainings for obstetric providers/staff, and evidence-based screening/referral protocol and resource/referral guide (toolkit); (2) office prompts and procedures for depression screening/management; and, (3) immediate guidance via psychiatric telephone consultation. The working group members will each individually test the RAPPID components and complete a process checklist for each component. Using individual tape recorded in-depth interviews. Dr. Byatt will explore barriers and facilitators to employing components. Guided by her mentors, Dr. Byatt will review, segment, and code interviews to identify emerging themes and recurrent patterns. Increasingly narrow and specific categories of concepts and themes will be defined to condense raw data and identify common themes.
4. Develop and finalize RAPPID manual, training program and fidelity measures and protocol for Phase 2 pilot cluster RCT. Other products will include screening/referral protocol and resource/referral guide.

Phase 2 → RAPPID Program Implementation and Evaluation

Overview and Rationale for Design: In Phase 2 we will implement and evaluate the feasibility and preliminary effectiveness of RAPPID to change obstetric provider practices regarding perinatal depression and compare treatment participation and depression severity among perinatal women in the RAPPID and screening/referral control group. We propose to pilot test a cluster RCT, rather than a traditional RCT, because cluster RCTs are the "gold standard" for examining the effect of programs, such as RAPPID, that are delivered to large groups.[85] To reveal and address feasibility issues specific to cluster design, we designed Phase 2 to mirror the R01 proposal we will submit in years 4/5. Modeled after the recommendations of Kraemer et al. for pilot studies in mental health services research[86] to guide the design and implementation of a larger effectiveness study, we will "evaluate the feasibility of recruitment, randomization, retention, assessment, procedures, and implementation"[86] of RAPPID. To set the stage for our R01 we need multiple sites to uncover barriers and facilitators to implementation and estimate the intra-class correlation (ICC) within groups.[85]

RAPPID Program:

1. Deliver evidence-based guidelines in depression screening, triage/referral, medication use and discussion of screening results and treatment options to providers (obstetric faculty, nurses/patient care assistants) and

clinical administrative support staff via Training and a Toolkit.

a. *Training:* Each provider group (obstetric faculty, nurses/patient care assistants) will receive two, 2-hour trainings respectively, to total 4 hours per provider group. The clinical administrative support staff group will also receive two-hour trainings. The curriculum will be tailored to meet the needs of each group. Providers will be trained to screen and assess depression, include depression in the treatment plan, and discuss the risks and benefits of using antidepressants during pregnancy/lactation. All groups will review the screening and referral protocol and resources and referral guide and receive training in how to de-stigmatize depression and activate women to seek help. All groups will also be given tools to encourage help-seeking, including fact sheets on depression, strategies to address depression, and resource guides.
b. *Toolkit: A*ll providers and staff will be provided with a screening and referral protocol, resource and referral guide and website with resources. The screening protocol will have specific instructions for specific ranges of scores on the Edinburgh Postnatal Depression Scale (EPDS), a ten-item patient-completed scale validated for rating postpartum and non-postnatal depression.[87] Women who score >10 on the EPDS will be offered referrals for depression. To link women and providers with community resources, we will develop a resource and referral guide that includes information about resources in the community and at UMMHC. Providers will also be equipped with verbal and written materials and web-based educational resources about perinatal depression to use during feedback interventions.

2. Establish office prompts and procedures for depression screening/management. We will determine the timing, location, and setting for screening and discussion of screening/treatment/referral. We will work with clinic providers/staff and the Community and Stakeholder Advisory board to tailor screening procedures to be acceptable and helpful to women and providers. We will work with providers/staff to establish office prompts for depression screening, discussion of screening results and treatment/referral.
3. Provide immediate psychiatric back up via a Centralized Psychiatric Telephone Consultation Service. A care coordinator and consulting psychiatrist team will support obstetric providers in detecting and addressing depression. The team will provide assessment and treatment support, face-to-face consultations, care coordination and ongoing education for obstetric providers. The consultant(s) will provide telephone consultations during visits and follow-up and face-to-face consultation as needed. They will educate providers during the telephone consultations by discussing practice guidelines, interviewing/assessment methods and relevant research. If needed, the care coordinator will help to secure and coordinate additional mental health treatment such as psychotherapy or ongoing medication management.

   To build relationships with the obstetric providers/staff, the team will conduct an onsite orientation to RAPPID and provide case-based consultation to demonstrate its value, and provide bimonthly educational sessions with providers/staff. Using this approach, the MA pediatric access program (MCPAP) successfully fosters relationships with pediatricians.[23] The telephone consultation service will be located in the regional pediatric access program (MCPAP) hub at UMass (*see Letter*) and the care coordinator will be trained in how to triage for perinatal depression. The existing pediatric access program care coordinator will be used because it is inexpensive and exportable to other settings; there are emerging or established pediatric access programs in 28 states in the U.S.[88]

Screening and Referral Control Group: We chose a screening/referral control group to provide: (1) attention control;[89] (2) critical screening data for comparing depression severity among groups; and, (3) the ability to provide referral information to women, which is essential to maintain ethical standards. Although an active control group, we do not expect screening/referral to change our outcome measures because screening and/or offering resources/referrals alone does not improve treatment entry[7,11,12] or outcomes[11,12] among perinatal women. This is an attention/active control group[89] because many obstetricians are not screening and referring for depression (see Prelim. Data).[90] The screening/referral control group will consist of an instructional session, screening protocol, and resource/referral guide (see Figure 5.2 for differences between RAPPID and control group). Each obstetric provider/staff in the control group will: (1) attend a 2-hour instructional session on how to use the screening tool (EPDS); (2) screen women for depression using the EPDS and screening protocol; and, (3) have access to the resource/referral guide.

Phase 2 Methods, Procedures and Data Analysis

Study Setting: Four UMMHC Ob/Gyn practices: (1) Generalist OB/Gyn Clinic; (2) Maternal-fetal Medicine Clinic; (3) Women's Health of Central MA; and, (4) Central MA OB/Gyn Associates. To allow each study group to have 1 UMMHC and 1 UMMHC- affiliated practice, we will randomize 2 UMMHC and UMMHC-affiliated practices respectively. RAPPID will be designed for a broad spectrum of women and all clinics serve a socioeconomically and ethnically diverse population.

Recruitment of Provider/Staff Subjects: Due to the pressing need for a program like RAPPID, we had no difficulty with provider/staff recruitment. We have already recruited 36 obstetric providers/staff for Phase 2 (see Table 5.1 and support letters from clinic directors).

Table 5.1 Recruited Provider and Staff Subjects

Subjects	Per clinic	Per group	Total
Providers and staff	9	18	36
Obstetric faculty: physicians, licensed independent practitioners, & midwives	5	10	20
OB/Gyn nursing staff	2	4	8
Patient care assistants	1	2	4
Administrative staff	1	2	4
Perinatal women	15	30	60

Recruitment of Women: All women attending the participating clinics (see Table 5.2) will be screened by their providers as per the RAPPID or screening/referral protocols before 22 weeks gestational age (GA). Eligible perinatal women will then be identified by research staff via the electronic medical records to assess if they meet inclusion criteria: female, age 18-45 years, English speaking, and 4-22 weeks GA. Conservatively assuming 8-12% of women will score ≥10 on the EPDS,[2,91] we will identify at least 60 women with depression from the 4 clinics and recruit them into the study over a year. Our screening and recruitment process is carefully designed based on our team's experience with this strategy. We do not anticipate recruitment difficulties given the available number of women to recruit (see Table 5.2) and our research team's previous success recruiting from these clinical sites. Recruitment rates will help determine how many clinical sites will be needed to power the large cluster RCT.

Table 5.2 Women Available to Recruit

Ob/Gyn Clinic	Available Prenatal women*
Generalist	584
Maternal-fetal Medicine	165
Women's Health of Central MA	1260
Central MA Ob/Gyn Assoc.	601

*Based on FY 2012

Sample size: As Leon, Davis, & Kraemer (2011) and others[86,92] recommend, we based the sample size of 60 women on pragmatics of recruitment and the necessities for examining feasibility. Our study will provide critical feasibility data to support an R01 application to test the efficacy of RAPPID in a large cluster RCT. We will identify modifications required to implement the large cluster RCT[86,93] by obtaining data about the feasibility of recruitment, retention, assessment procedures and acceptability of RAPPID. We set the acceptable percentage of participation/acceptability at 80% and have powered the study to keep our confidence interval (CI) 0.80 +/-0.155. Because estimates from pilot studies alone tend to be underpowered due to the variability in estimated standard errors,[86,93] we will combine our results (including the ICC) with clinically meaningful effect and results of previous adequately-powered interventions to calculate sample size requirements for our large cluster RCT.

Retention and Attrition: Based on our research team's prior studies[94-96] we expect attrition rates of 10% among providers and women. Intent-to-treat and completer analyses will be performed. To reduce attrition and enhance retention in providers we will use well-established[97,98] approaches. For women, we will establish ≥2 contact numbers, offer incentives, and conduct assessments after clinic visits.

Evaluation Design and Measurement: Using a mixed-methods approach (see Table 5.3), we will assess **Aim 2** primary outcome (provider and staff participation/fidelity to RAPPID), **Aim 2** secondary outcomes (knowledge, attitudes, and practices toward depression), **Aim 3** primary outcome (women's treatment participation) and **Aim 3** secondary outcomes (depression severity). Our prior studies have used these specific assessment measures, except the Barriers to Access to Care Evaluation scale (BACE) and Likert Scales.

Table 5.3 Phase 2 – Experimental Design and Assessment Schedule

Week/visit		4-22 wks Gestational Age GA)	28-40 wks GA	2-12 wks postpartum
Enrollment		Enroll Women/Informed consent		
Implementation	Training, implement screening protocol / medical record prompts	← Implement RAPPID →		
Assessment of Providers/Staff	Baseline assessment: S-KAP, Likert scale (see Table 5.3), semi-structured interview	Longitudinal assessment: participation, adherence, fidelity via training log, consultation log, medical record chart review, procedure checklist		Post assessment: S-KAP, Likert scale, semi- structured interview
Assessment of Women		Baseline assessment: EPDS, BACE, S-KAS, semi-structured interview	EPDS	Post assessment: EPDS, BACE, S-KAS, semi-structured interview

Procedures for Providers and Staff: As outlined in Table 5.3, participation data, adherence, and fidelity will be collected longitudinally. All other provider / staff and systems-level data will be collected at baseline and after RAPPID participation (12-14 months after initiation of Phase 2). We will obtain pre- and post-intervention data through individual surveys and semi-structured interviews to evaluate depression screening practices, acceptability of screening, perceived gaps in screening/referral supports, and attitudes, and practices towards perinatal depression. The post-implementation interviews will measure acceptability of RAPPID components.

Table 5.4 Provider/staff and Systems-level Measures (Aim 2)

Outcome/endpoint	Measure	Administration
PARTICIPATION	Obstetric provider and staff participation in Training Curriculum, Telephone Consult service.[99]	Training log, consult log, and chart review (RA to collect)
ADHERENCE AND FIDELITY	Appropriateness of telephone consultation, screening and referral rates, medication prescription rates, documentation of depression in plan. Procedure checklist: clinic policies/procedures, environmental scan.	Consult log (nature of calls), medical records, procedure checklist (RA to collect)
ACCEPTABILITY	Five-level Likert Scale for obstetric providers/staff (Find the telephone consults useful, Adequate access to depression care, Able to consult with psychiatrist in a timely manner, Able to meet the mental health needs of women). Likert Scale for psychiatric consultant (Adequate expertise to provide consultation, Able to help OB providers). Semi-structured interview assessing barriers and facilitators to RAPPID vs. screening/referral.	OB/Gyn provider and staff and consultant self-administered online survey and 15-minute semi-structured interview (RA to collect)
KNOWLEDGE, ATTITUDES, AND PRACTICES	Knowledge, Attitudes, and Practices Instrument (S-KAP):[100] 46 items adapted for depression in obstetric settings.	OB/Gyn provider and staff online survey

Procedures for Perinatal Women: Assessments will be collected at baseline and post intervention except the EPDS which will be collected longitudinally. Assessments will be pre-tested to ensure the time burden is < 60 minutes. At 2-12 weeks postpartum, we will repeat the EPDS and collect data regarding knowledge and attitudes toward depression, treatment participation, help-seeking, and stigma (see Table 5.5). We will also do post assessments to examine socioeconomic factors and other variables associated with treatment engagement including affordability, health insurance, childcare, transportation, and illness course. We will assess acceptability of RAPPID or screening/referral via semi-structured interviews. Our team's previous tracking methods[94-96] that have yielded 80 and 90% follow-up will be used.

Table 5.5 Patient Level Measures (Aim 3)

Outcome/endpoint	Measure	Administration
DEPRESSION SEVERITY	Edinburgh Postnatal Depression Scale (EPDS): 10 items that assess depression severity during the perinatal period.[101]	Self-administered survey at 4-22, 28-40 wks GA & 2-12 wks PP (collected by providers/staff)
KNOWLEDGE, ATTITUDES, AND TREATMENT PARTICIPATION	Five-level Likert Scale (e.g. Willing to engage in treatment, Adequate access to perinatal mental health care, Able to discuss depression with my OB/Gyn provider).[99] Semi-structured interview assessing utilization of depression treatment and barriers and facilitators to treatment participation. Knowledge, Attitudes, and Services Instrument (S-KAS):[102] 40 items adapted for depression in obstetric settings.	Self-administered surveys, 15-minute semi-structured interview, structured interview for women 4-22 wks GA & 2-12 wks PP (RA to collect, total time < 60 minutes)
HELP-SEEKING	Barriers to Access to Care Evaluation scale (BACE): 30 items assessing barriers to access to mental health care, includes a 'treatment stigma' subscale.[103]	

Rationale for Feasibility of Conducting Phase 2: We have carefully constructed the pilot cluster RCT and allocation of the K12 resources to ensure that Phase 2 is feasible to implement. Enthusiastic about our proposal, the UMass MCPAP hub has offered to expand its clinical services to include care coordination for obstetric providers/staff and perinatal women without additional funding (see Letter). Also enthusiastic and committed, adult psychiatrist Dr. Rebecca Lundquist has offered to expand her practice and fill the role of the RAPPID psychiatric consultant without additional funding (see Letter). These generous offers will allow us to leverage the K12 resources to hire a 0.5 FTE research assistant during year 3 and 4 (Phase 2) to conduct the assessments and assist with recruitment and retention. We have also mapped out our implementation and evaluation protocol to provide needed data for the R01 while staying within the scope of a K12 award. We will enroll and conduct pre-assessments on 4-5 providers/staff per week over 8 weeks. Longitudinal and post-assessments will be conducted with 2 providers/staff per month over 1 year. We will recruit, enroll, and perform pre-, post- and longitudinal assessments on 1-2 women per week (see Table 5.3). This protocol is feasible because 0.75 FTE of Dr. Byatt's time and 0.5 FTE of an RA's time will be dedicated to carrying out Phase 2.

Data Analysis Aim 2: To determine fidelity (primary outcome) to RAPPID (including obstetric provider/staff participation) and change in knowledge, attitudes, and practices toward depression screening and treatment (secondary outcomes) in the RAPPID compared to screening/referral control group. We will use 4 assessment points with 18 providers/staff and 60 women. For the primary outcomes of fidelity and participation in the RAPPID group, we will calculate proportions of providers who document/screen properly at each visit (fidelity) and who have participated in training and call the telephone consultation service at each visit (participation) for each woman. This will be compared to the proportions of providers in the screening referral control group who have documented/screened properly at each visit (fidelity), and who have participated in training and referral for each woman using a standard chi-square comparison of proportions. For these outcomes, it is unlikely that we will have much power to detect significant factors in a model. However, as preliminary investigations and to gather information for future studies, we will use longitudinal logistic models to assess differences between

RAPPID and control over the duration of the study through non-linear mixed effects models. The analysis of the secondary outcome (adapted S-KAP) will be an initial comparison of the change in S-KAP score from baseline between treatment groups at each visit, using a non-parametric (Wilcoxon rank-sum test) due to the small sample size. Given the small sample size, to inform future studies, we will use a linear mixed effects model, to investigate the effect of the RAPPID on depression knowledge, attitudes and practice compared to the control group, adjusting for inherent correlations. The adapted S-KAP score will be the outcome with treatment group, visit, and baseline EPDS as predictors.

Data Analysis Aim 3: To compare perinatal women's treatment participation (primary outcome) and depression severity (secondary outcome) in the RAPPID versus screening and referral control group. For the primary outcome of treatment participation, a binary outcome at each visit, we will use approaches similar to those for the fidelity and participation outcomes for Aim 2. For the secondary outcome of depression severity (EPDS), we will use analysis approaches similar to those for the adapted S-KAP in Aim 2. Due to the exploratory nature of the analyses, we will conduct all tests of inference at the standard alpha level of 0.05. All analyses will use the latest version of SAS (SAS Institute, Cary, NC).

Table 5.6 Time Table for Phase 1 and 2

	Year 1				Year 2				Year 3				Year 4				Year 5			
Quarter	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
RAPPID manual and adherence measure development	**P**	**H**	**A**	**S**	**E**	**1**														
Develop, employ & assess beta version of RAPPID																				
Develop adherence/competence measures																				
Conduct Cluster RCT							**P**	**H**	**A**	**S**	**E**	**2**								
Baseline assessment of providers and staff																				
Provider/staff training																				
Implement RAPPID and screening and referral control																				
Recruit and enroll women																				
Conduct longitudinal and post assessments																				
Analyze data; write outcome data papers																				
Disseminate, write, submit and resubmit NIMH R01																				

Products: Phase 1 and 2 will produce a RAPPID manual, provider/staff training program, fidelity measures and provider/staff toolkit. It will also provide critical information on the feasibility and acceptability of RAPPID and insights into participant recruitment rates, randomization, retention, assessment, procedures, estimate of intra-cluster correlation coefficient (ICC). At the end of Phase 2 we will have: (1) a refined recruitment and retention protocol; (2) estimate of effect size; (3) estimates of the effort required to recruit and retain providers/staff and women; (4) data for determination of sample size required for large R01 cluster RCT; and, (6) data that will disseminated in scientific meetings and publications (see Table 4.2). Phase 1 and 2 will provide critical information needed to refine and finalize the large R01 cluster RCT protocol.

Study Strengths and Limitations: Because of the limited data available on this type of intervention, we must begin with intervention development and feasibility testing. This K12 feasibility trial is designed to mirror the larger R01 in order to determine barriers and facilitators to and feasibility of engaging clinics, and recruiting participants. Rather than estimating clinically meaningful differences in the K12, due to the small sample size, we will use descriptive statistics to look at differences in terms of estimates. We will examine the differences of point estimates between groups using the CI. As recommended by Leon et al. (2011) and others,[79,87] we will combine the pilot study point estimate with reported assessments of clinically meaningful differences to determine the sample size for the R01. In the K12, we propose to work with 4 clinics that are either at or affiliated with UMMHC, which may not be a representative sample. We will address this limitation in our R01 by comparing 16 clinics with a larger sample size of women and providers. In the R01, we will achieve balance by pair matching of site characteristics such as practice size, provider/staff characteristics, urban vs. non-urban and academic affiliation. When recruiting sites, we will leverage our links with Ob/Gyn practices across MA.

Impact and Future Directions: This K12 Award will set the stage for her R01 by providing critical information on feasibility of RAPPID and determination of sample size for her R01 application in year 4 to conduct a full scale, multi-site implementation and effectiveness study in which RAPPID will be compared to screening/referral in a large cluster RCT. Our long-term plan also includes translating RAPPID components and/or products to family practice, pediatric and community mental health settings. We will also use our data on factors that impede and facilitate treatment participation to inform the development of additional approaches to helping women access perinatal depression treatment. Our phase 3 translation (T3) research program will address a major public health issue by developing and testing a new approach to depression care in obstetric settings that can change the whole landscape for depressed perinatal women and their families and children.

6. TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH

I understand the importance of and am committed to knowing the current ethical standards and methods in research conduct, particularly in vulnerable populations such as pregnant women. Since 2006, I have trained in the responsible conduct of research by completing the Collaborative Institutional Training Initiative (CITI) online Responsible Conduct of Research (RCR) course at least every 3 years as required by UMMS. My most recent certification was on December 27, 2010. The CITI course includes several modules for self-study that are followed by quizzes that assess comprehension and retention. Modules include: history and ethical principles; IRB regulations and review processes; informed consent; social and behavioral research for biomedical researchers; records-based research; genetic research; and several modules pertaining to research with vulnerable populations including prisoners, minors, and *pregnant women*. I have also completed the Key Personnel CITI Financial Conflict of Interest (COI) Training (CITI) Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules on August 23, 2012.

During the 5 year award and during every stage in my research career, I will seek out and complete in depth educational opportunities in ethics and the responsible conduct of research. My goals are to: (1) advance my knowledge of research ethics in clinical research; (2) obtain expertise in the regulations and resources for safe and efficient conduct of research. As demonstrated in Table 6.1, I will achieve these goals via formal UMMS coursework, seminars, online CITI trainings, and regular meetings with mentors. My proposed research plan will be a vehicle to apply the knowledge and skills I gain during coursework and seminars, particularly as it relates to conducting research with perinatal women. I will obtain guidance regarding ethical issues that arise during regular meetings with my mentors and quarterly meetings with Dr. Chuck Lidz (expert in Research Ethics in the UMMS, Department of Psychiatry).

Table 6.1 Training in Responsible Conduct of Research

Training activity	**K12 Year**				
Goal 1: Advance my knowledge of research ethics in clinical research (and Goal 2)	**1**	**2**	**3**	**4**	**5**
Research Ethics for Clinical Research* (CTS702; 2 credits/16 hours): Weekly fall semester course instructed by Dr. Charles Lidz, PhD on specific topics including IRBs, human subjects, data handling, and NIH guidelines through didactics, small group discussion of cases and online exercises. Addresses dilemmas of informed consent, potential scientific contribution, and issues for *special populations including pregnant women.* Covers fraud, misrepresentation, conflict of interest (personal, professional, financial), peer review, and authorship guidelines. Provides instruction on ethical research design, evaluation of treatment risk, utilization of a placebo control, and recruitment.	√				
UMMS Center for Mental Health Research Ethics Core and UMMS CTSA Ethics Core (Non-credit; 4 hours/year): Quarterly face-to-face meetings with Dr. Lidz to discuss topics such as informed consent and ethical research practices. The Ethics Core is available for ongoing consultation.	√	√	√	√	√
Mentorship: During regularly scheduled meeting (see Section 4 Mentorship Plan), my mentors will provide guidance and on the current ethical standards and responsible conduct of research.	√	√	√	√	√
Goal 2: Obtain expertise in the regulations and resources for safe an efficient conduct of research (and Goal 1)					
Principles and Practice of Clinical Research* CTS-715; 3 credits/24 hours): Weekly summer semester course on the regulations and resources needed to support safe and efficient conduct of research, especially intervention studies. The shared responsibilities of sponsors (biotech, drug and device), investigative sites, physician investigators and professional research staff will be analyzed within the current regulatory climate. Topics of public trust, patient perceptions and research integrity as a common thread throughout the semester are weaved in via case studies and contemporary media.	√				
CITI online Responsible Conduct of Research course: Basic Course for Biomedical Researchers and Key Personnel (Non-credit; 2 hour recertification course every 3 years): Covers: history and ethical principles; IRB regulations and review process; informed consent; social and behavioral research; records-based research; genetic research in human populations; *research with protected populations—vulnerable subjects such as pregnant women and fetuses in utero*; group harms—research with culturally or medically vulnerable groups; FDA regulated research; and workers as research subjects. Includes didactics/case presentations on: responsible conduct of research; research misconduct; data acquisition and management; responsible authorship; peer review; mentoring; COI; collaboration.	√		√		
CITI Financial Conflict of Interest Training (CITI) Financial COI: Overview, Investigator Responsibilities, and COI Rules (Non-credit; 1 hour recertification course every 4 years): Covers: how federal regulations relate to financial COI; forms of financial COI in research; research team members who are required to disclose financial conflicts of interest; significant financial interests that investigators are required to disclose to their institutions; ongoing obligations that investigators have relating to financial COI.		√			√

*Offered through UMMS Graduate School of Biomedical Sciences

8. DESCRIPTION OF INSTITUTIONAL ENVIRONMENT

The institutional environment at **University of Massachusetts Medical School (UMMS)** will provide the ideal setting to launch Dr. Byatt's proposed K12 project and early research career because it has strong, well-established programs of research in the domains of implementation science/health services, health behavior change and women's mental health. UMMS is an institution with the active ingredients for Dr. Byatt's success and the right mentors to provide her access to the best UMMS has to offer.

UMMS in Worcester houses the University's academic medical center, including the Graduate School of Nursing, Graduate School of Biomedical Sciences, Clinical and Population Health Research PhD program, and Master's in Clinical Investigation program. Established in 1962, UMMS is the only public medical school in the state and one of 28 university-based academic health science centers in the country. UMMS has experienced substantial and sustained growth in its research enterprise over the last 20 years. From FY'94 to FY'98, NIH funding of UMMS researchers has more than tripled ($35 million to $128 million), and from FY '02 to FY'08, total research and development expenditures at UMMS have increased 43 percent ($133 million to $190 million). In 2011, extramural research funding rose to more than $307 million. As the only state-funded medical school in MA, UMMS is committed to preparing faculty to understand and address the needs of vulnerable populations. The Master's in Clinical Investigation is one of a few programs in the U.S. that trains students with an advanced degree in order to bring evidence-based care to patients (see courses in Table 4.2, fee waived).

Multiple clinical research support facilities exist at UMMS. In 2010, the NIH awarded UMass a prestigious, 5-year, $20 million **Clinical and Translational Science Award (CTSA)** to establish the **Center for Clinical and Translational Science (UMCCTS).** Dr. Byatt's research and training plan are supported by the unique resources/training opportunities offered by the CTSA. The UMCCTS provides an academic home for investigators across campuses and has greatly enhanced the UMMS research infrastructure by developing innovative core facilities, training programs, and pilot funding. The **Department of Quantitative Health Sciences (QHS)** (Vice-chair: J. Allison, MD, MS, secondary mentor) houses a **UMCCTS Quantitative Methods Core** (Director: B. Barton, PhD) which provides biostatistical, epidemiological, and methodological consultation and technical support. QHS also houses a **UMCCTS Biomedical Informatics Core** which provides informatics consulting and development support. QHS also provides training in common, emerging, and novel methodologies in clinical trials, informatics and health services research.

At UMMS, the **Office of Faculty Affairs (OFA)** offers outstanding resources for promoting faculty development through its Junior Faculty Development Program (JFPD), and for which Dr. Byatt was chosen in 2010 to cultivate promotion and advancement to become an academic leader (J. Allison, MD, MS, JFPD Mentor & secondary mentor), leadership and promotion series, and Women's Faculty Committee, which Dr. Byatt was appointed to in 2009. Her academic home**,** the **Department of Psychiatry** offers guidance and resources via its **Career Development & Research Office** (**CDRO)**, Career Development and R01 grant writing groups (led by Drs. Rothschild & Ziedonis), Academic Research Group in Reproductive Psychiatry (co-chair: Byatt)**,** and research career development workshops. Health services research is conducted at the **Center for Mental Health Services Research** (Assoc. Director: K Biebel, PhD, significant contributor) in the Dept. of Psychiatry and the Bedford VA Health Services Research Center resources. The **Division of Preventive and Behavioral Medicine** (Assoc. Chief: L. Pbert. PhD, secondary mentor) in the Dept. of Medicine is starting an Academic Interest Group in Implementation Science which will bring together UMMS implementation science experts to provide opportunities for mentorship, peer-supervision, and collaboration across the institution. UMass' **National Network of Depression Center** is 1 of 21 centers in the U.S.; it excels at integrating depression treatment and research in traditional and non-traditional settings, including OB/Gyn.

UMassMemorial Health Care (UMMHC) is the clinical partner of UMMS and the largest health care system in Central MA. With its referral region extending to the borders of New Hampshire, Connecticut, and Rhode Island, UMMHC has an effective catchment area of nearly 1 million individuals. The Dept. of Psychiatry at UMass is the largest provider of psychiatric services in Central MA, including over 300 faculty and 2000 staff. The Dept. has a busy Ambulatory Psychiatry Clinic with over 45,000 annual visits. The clinic houses a Women's Mental Health Clinic that specializes in reproductive psychiatry. The Dept. of Ob/Gyn (Chair: J. Johnson, MD, consultant) at UMass includes 4 UMMHC clinics and 5 UMMHC-affiliated clinics specializing in providing Ob/Gyn care.

In summary, the unique training and resources provided by the Academic units and affiliated faculty at UMass are ideally suited to the innovative work Dr. Byatt proposes.

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