An Analysis of Social Media and Web-Based Recruitment Strategies and Sociodemographic Representation for a Nationwide Preeclampsia Postpartum Lifestyle Intervention Trial

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I. LITERATURE REVIEW

Preeclampsia

Preeclampsia is a hypertensive disorder of pregnancy that is reported in 2-8% of pregnancies, and is one of the leading causes of maternal and fetal morbidity and mortality worldwide, with the majority of disease burden in developing countries (Ghulmiyyah & Sibai, 2012). Between roughly 10% to 15% of maternal deaths are directly associated with preeclampsia and eclampsia, the latter which is defined by the onset of seizures in women with preeclampsia. Eclampsia is associated with a higher mortality rate (Al-Jameil, Khan, Khan, & Tabassum, 2013; Duley, 2009). In order to halt this progression and enhance the likelihood of a safe delivery, magnesium sulfate is usually administered for seizure prophylaxis and delivery is often induced or a cesarean section is performed. After delivery, preeclamptic women will typically return to a normotensive state (Sheth & Chalmers, 2002).

Several risk factors for preeclampsia are well documented in the literature, including primiparity, which is defined as giving birth for the first time, diabetes, obesity, family history, fertility procedures, as well as preexisting hypertension (English, Kenny, & McCarthy, 2015). Preeclampsia is one of four hypertensive disorders of pregnancy. The other three are gestational hypertension, chronic hypertension, and superimposed preeclampsia on chronic hypertension. Preeclampsia is typically characterized by a new onset of hypertension and proteinuria after 20 weeks of gestation. However, other specific manifestations of multisystem disease have been highlighted as potential alternatives to proteinuria including thrombocytopenia, renal insufficiency, impaired liver function, pulmonary edema, or cerebral or visual symptoms ("Hypertension in Pregnancy- ACOG," 2013). Women with preexisting hypertension may develop superimposed preeclampsia with the presence of protein in their urine or other systemic

manifestations. Gestational hypertension differs from preeclampsia in that it has only the increase in blood pressure and no proteinuria or other systemic manifestations (Mustafa, Ahmed, Gupta, & Venuto, 2012; Sibai, 2008).

Pathophysiology

The pathophysiology behind preeclampsia is still not well understood. Combinations of immune, placental, and vascular factors have been recognized as essential components; however, strong evidence has suggested that an abnormally implanted placenta is a major cause of the disorder (Steegers, Dadelszen, Duvekot, & Pijnenborg, 2010). As a result of poor placental implantation, restricted blood supply frequently leads to intrauterine growth restriction (IUGR) and thus low birth weight (Srinivas et al., 2009). For the mother, there is current debate as to whether placental abnormalities in the event of preeclampsia may cause damage to endothelial cells, or if there is an underlying feature of the women who develop preeclampsia that predisposes them to the disease (Sánchez-Aranguren, Prada, Riaño-Medina, & Lopez, 2014). As for the latter explanation, pregnancy has been suggested as a physiological "stress test" that has the potential to reveal underlying chronic disease.

Future Cardiovascular Disease Risk

Following a preeclamptic pregnancy, women face an increased risk of developing a variety of chronic conditions including cardiovascular disease (CVD), kidney disease, and hypothyroidism (Williams, 2011). In recent years, strong evidence has shed light on the increased risk of CVD for women who have had preeclampsia compared to women who have had normal pregnancies. Women with preeclampsia have a two-fold increase in risk of developing

CVD and a four-fold increased risk of developing chronic hypertension in the years after pregnancy (Bellamy, Casas, Hingorani, & Williams, 2007). The American Heart Association (AHA)'s effectiveness-based guidelines for the prevention of CVD in 2011 specified that clinicians consider a history of preeclampsia as a CVD risk factor in women (Mosca et al., 2011). Despite current AHA lifestyle intervention guidelines geared to prevent CVD in women, the effectiveness of a cardio-protective lifestyle in reducing CVD risk among preeclamptic women has yet to be discerned (Celi et al., n.d.).

Although the exact pathophysiology between pregnancy complications and chronic disease remains unclear, it is thought that an event like preeclampsia may serve an important indicator for future CVD risk (Maas, van 't Hof, & de Boer, 2007). Thus, the postpartum period following preeclampsia can provide an important opportunity for timely intervention to mitigate future cardiovascular risk in otherwise "silent early adult years" in which the trajectories of chronic disease are cemented (Rich-Edwards, McElrath, Karumanchi, & Seely, 2010). Moreover, the post-partum period has been identified as a window and teachable moment for behavior change for new mothers. In the transition from pregnancy to motherhood, especially in the context of a complicated pregnancy, new mothers may experience a greater level of motivation to take steps to maintain control of their health (Beckles, Thompson-Reid, (U.S.), & Translation, 2001). However, to date, few studies that focus on postpartum intervention for women with preeclampsia have been conducted (Berks et al., 2013).

Recruitment in Clinical Research

Because postpartum women who have experienced preeclampsia are in need of an intervention to help mitigate future CVD risk, it is important that the effectiveness of lifestyle

modification interventions be discerned through clinical trials. For many clinical trials, one of the major challenges investigators face is participant recruitment. In an analysis of 2579 recently completed trials, approximately 19% were either discontinued due to failed recruitment, or completed recruitment with less than 85% of their target population size (Carlisle, Kimmelman, Ramsay, & MacKinnon, 2015). Insufficient participant recruitment can lead to a host of potential threats to internal and external validity. First, researchers may face loss of statistical power in their analyses if recruitment goals are not met. For example, if the target sample size is not reached, studies may face the possibility of committing a Type II error (i.e. incorrectly concluding that there is no significant difference between treatment groups). Additionally, if participant recruitment takes longer than anticipated, researchers may face increased costs to extend the recruitment period and the efficacy of the interventions being assessed may not be determined if studies ultimately cannot be completed (Thoma, Farrokhyar, McKnight, & Bhandari, 2010)

In addition to a lack of negative results reported by clinical trials, difficulties encountered in participant recruitment are not often reported (Matosin, Frank, Engel, Lum, & Newell, 2014). There is a dearth of studies that examine the effectiveness of various recruitment strategies. In four recent systematic reviews, investigators examined methods to increase recruitment in 33 unique clinical trials. These reviews suggest that although many published studies describe individual recruitment strategies, there are few published studies that evaluate the utility and success of specific recruitment approaches or strategies. Across the few existing studies that have been published, conclusions made regarding the most effective recruitment strategies are inconsistent. The aforementioned reviews have found that strategies such as telephone reminders to non-respondents, financial incentives for participants, and interventions that are culturally

relevant such as translations and language appropriate measures, may enhance recruitment (Bryant & Powell, 2005; Mapstone, Elbourne, & Roberts, 2007; Mc Daid, Hodges, Fayter, Stirk, & Eastwood, 2006; J. M. Watson & Torgerson, 2006).

Recruitment and Generalizability

In addition to the difficulties of meeting recruitment targets, many studies face the challenge of recruiting samples that accurately reflect the population of those affected by the disease of interest. Regardless of study type, socially disadvantaged groups are consistently underrepresented in research (Heller et al., 2014). Likewise, the failure to recruit subjects that reflect the entirety of a population poses a threat the external validity or generalizability of any research findings (George, Duran, & Norris, 2013). Under-represented groups, such as those from socially disadvantaged or racial/ethnic minority communities are often considered "hard-to-reach" due to a variety of barriers to participation (Bonevski et al., 2014). For African American populations specifically, mistrust of academic and medical institutions and research has been reported as the most significant barrier to participation in clinical trials (Farmer, Jackson, Camacho, & Hall, 2007; Sengupta et al., 2000; Shavers, Lynch, & Burmeister, 2002). Reasons for this mistrust are largely due to a plethora of historical mistreatment in health care or clinical trials, and continued socioeconomic and health inequities have been shown to magnify the barriers to participation for social disadvantaged groups (Scharff et al., 2010).

In qualitative studies, patients often report that they are unaware of opportunities to participate in clinical trials, and even if they are aware, it is often difficult to find a trial that is geographically accessible. Geographic distance from academic medical centers can introduce significant costs in terms of time and travel which may be particularly burdensome for some

groups. Moreover, many studies have strict eligibility criteria excluding large portions of potential participants due to compounding health issues, disease progression, and exposure to certain medications (IOM, 2010). Because disadvantaged groups often have a higher prevalence of co-morbidities such as chronic hypertension, the ability to participate in clinical trials for many members of these groups is further restricted (Opara et al., 2013). Furthermore, minorities disproportionately face system-level barriers to access of clinical trials as they are often the recipients of a care at under resourced clinics and healthcare systems, which lack resources and efforts for community engagement (Hamel et al., 2016). However, a recent assessment of over 4000 racially diverse cancer patients found that racial and ethnic minorities were just as likely as their white counterparts to consent to participation in clinical trials if they were made aware and offered the opportunity to participate in a trial (Langford et al., 2014). Although this may be true for cancer patients, the application of this finding may be limited due to the life-or-death nature of many cancer clinical trials.

Recruitment of Postpartum Women and Representative Samples

When recruiting special populations, such as postpartum women with a recent history of preeclampsia, great attention must be paid to the unique barriers to participation that individuals may face. It is important to recognize that new mothers, and parents in general, often prioritize the health of their child over their own health (Rodger et al., 2003). Furthermore, new parents face many practical issues including work and childcare commitments, transportation issues (Tooher, Middleton, & Crowther, 2008; van Delft, Schwertner-Tiepelmann, Thakar, & Sultan, 2013). One descriptive study that examined the success rates of different recruitment strategies over a 4-year period in a clinical trial of postpartum mental health found that mass media

presentations by the investigators on morning television talk shows, as well as cable news, radio, and newspaper advertising helped reach a wide audience and enroll many participants (Peindl & Wisner, 2003). However, it is important to note that these strategies are often expensive and time consuming, despite the wide reaching potential (Feman et al., 2008).

With very little population-level data on the demographic characteristics of women who experience preeclampsia in the United States, it is difficult to gauge if clinical trials on preeclampsia have successfully recruited representative samples. However, in general, it has been well documented that racial and ethnic minorities are regularly underrepresented from clinical trials, and are quite often difficult to recruit, even after initial contact. Health professionals have been highlighted as gatekeepers to the participation of minorities in research due to paternalistic beliefs in that those of lower socioeconomic status have poor communication skills and do not have the time or interest in participating (Bonevski et al., 2014). A recent weight loss trial from 2012 reported a descriptive analysis of their recruitment of postpartum women from areas of social disadvantage. This particular study focused their recruitment efforts in a variety of physical locations that low income mothers of young children were likely to visit including pharmacies, libraries, nurseries, child and family centers, supermarkets, and shopping centers. The most successful strategy to identify eligible participants for this study was visiting community groups with over one-third of eligible women by this effort. However, this study found that over half of the women screened were excluded due to a high self-reported BMI, suggesting that exclusion criteria played a significant role in recruiting from this population (Macleod et al., 2013).

Thus, it is important for studies, especially those that aim to include socio-demographically diverse populations, to incorporate strategies that have been successful in recruiting traditionally "hard-to reach" populations. Suggested strategies to overcome some of the barriers to recruitment of racial/ethnic minority and low-income women have included the use of community-engaged research, making interpreters and linguistically appropriate materials available, and the provision of financial incentives to boost participation (Homer, 2000; Moore, 1997). Likewise, a recent review from 2014 examining strategies for improving research with socially disadvantaged groups, highlighted several studies that have improved inclusion of linguistically diverse and low literacy groups by reading age simplification and the use of bilingual research assistants. Other suggestions from this review that have been shown to be successful in reaching desired populations include the use of media and social marketing tailored to the target audience, and cultural competency education of research staff members (Bonevski et al., 2014).

Social Media and Web-Based Recruitment

According to a survey conducted in 2015 by the Pew Research Center, approximately 84% of Americans, are readily accessing the internet. Of women in the range of women recently postpartum between the ages of 18 and 49 years of all demographics, it has been documented that 93-96% of women access the internet ("Americans' Internet Access," 2015). Not only is the internet highly utilized by women in this age group, but many specifically rely on internet technology for health information and connection with online communities that share health related concerns (Fox, 2011). Due to the wide accessibility of health information via the internet and social media, it has been suggested that today's potential participants in clinical trials are

both more aware of their health and personally involved in their healthcare (Shere, Zhao, & Koren, 2014). It has been suggested that volunteers who participate in clinical trials can, in many cases, are highly "informed health-care consumers" (Omurtag, Jimenez, Ratts, Odem, & Cooper, 2012).

With the rapid rise of internet technology and widespread adoption of social media, the utilization of social media and web-based channels to disseminate recruitment materials may be a key step towards the refinement of effective recruitment strategies. However, to date, few studies have implemented social media and web-based tools for recruitment, and even fewer have compared the relative success of these recruitment tools to conventional recruitment methods (Shere et al., 2014). In recent years, social media has made it feasible to provide access for millions of individuals to a plethora of "user-centric spaces" that can be used to generate content and can be linked together forming internet-based social networks. Although the definition and conceptualization of social media is evolving, the basis lies in user generated content, user-specific profiles, and the development of social networks by connecting profiles through various platforms. These principles, for the purpose of clinical trial recruitment, differentiate social media from other conventional modalities that may be utilized such as telephone calls, emails, and letters (Obar & Wildman, 2015). Of the studies that have utilized social media and web-based strategies, several have indicated that such tools can be effective in not only reducing costs, but also reaching a larger number of potential subjects. One such study in Tasmania exploring the viability of using social media advertisements for a smoking cessation trial found that those recruited by social media were significantly younger, but found no difference in socioeconomic status compared to those recruited by traditional methods (flyers, word of mouth, newspaper advertisements. With a population size of 266 participants, 52% of

the population was recruited by targeted Facebook advertisements (Frandsen, Walters, & Ferguson, 2014). Other study which investigated the role of social media in recruiting for clinical trials in pregnancy, with a population size of 56 women over a recruitment period of 6 months, found that recruitment by social media was 12-fold compared to solely healthcare-based sources. Interestingly, this study utilized two phases in which social media was added as a supplementary tool in the second phase with posts on various web-based platforms such as craigslist and pregnancy specific websites, in addition to Facebook and Twitter. The study found no significant sociodemographic differences between the two groups; however, because of the small sample size, the investigators noted that further research will be necessary to determine potential bias in the population recruited from social media (Shere et al., 2014).

Although the population that may be recruited from social media into clinical trials has yet to be thoroughly investigated, a survey conducted by the Pew Research Center found that traditionally 'difficult to reach' groups, specifically African Americans and Latinos, were reported to more heavily rely on smartphones and internet enabled mobile devices for health information compared to other racial groups (Anderson, 2015). In some cases, social media and web-based recruitment has been shown to reach a wider audience than traditional recruitment, often reaching traditionally "difficult to recruit" populations including racial and ethnic minorities and young adults. Another study using Facebook advertisements targeted towards females located in a 50-mile geographic radius of 17 cities in Victoria, Australia, found that women from regional and lower socioeconomic areas were well represented that countered their initial predictions. Likewise, the average Facebook charge was relatively cheap with only $0.67 per click which amounted to roughly $20 per compliant participant (Fenner et al., 2012).

Previous studies that have investigated the health of postpartum women have relied

heavily on hospital and newborn/maternal clinics for participant recruitment, which is often time consuming for research staff (Leach, Butterworth, Poyser, Batterham, & Farrer, 2017). In an intervention that aims to recruit women who are recently postpartum with young children, social media may provide a unique recruitment avenue to alleviate many of the barriers this population may face to study participation. Postpartum women are often socially isolated at home as well as restricted in their mobility and free time due to childcare demands (Drentea & Moren-Cross, 2005). Although these factors may be significant drawbacks for many recruitment methods, such factors may explain an increase internet use among this population (Maloni, Przeworski, & Damato, 2013). In a first of its kind study from 2012, researchers examined internet usage among new mothers on average 7.9 months postpartum and found that the population appears to be on the computer approximately 3 hours per day, with a significant portion using social networking sites and blogs. Although limited by a sample consisting of mostly white and highly educated women, the researchers suggested that internet usage, especially frequency of blogging among this population, may be correlated with feelings of connectedness to family and friends, which may be driven by isolation due to caregiving demands (McDaniel, Coyne, & Holmes, 2012).

Partnerships in Recruitment

In addition to utilizing social media and web-based platforms as a means of broadcasting a study to potential participants, partnering with patient advocacy groups (PAGs) has been shown to significantly improve recruitment of target populations in a timely manner. PAGs have been shown to positively influence recruitment for clinical trials, particularly in the case of rare diseases, by using online and in-person patient support meetings and networks. Disease specific organizations can also provide a platform for advertising clinical trials directly to patients in the

target population, and allow for the education of potential participants about the value of clinical studies (Forsythe et al., 2014). In one study that examined the Rare Diseases Clinical Research Network (RDCRN) partnerships with PAGs , both representatives from PAGs and RDCRN investigators ranked "communication and outreach" among the most impactful aspects of their partnerships (Merkel et al., 2016). Not only do disease advocacy organizations connect investigators to potential participants, but PAGs can also be involved in financial support, study design, data collection and analysis. In an analysis of disease advocacy organization participation in genetic clinical research, 91% of organizations surveyed collaborated on recruitment efforts in clinical trials. In addition, 75% of organizations had aided in data collection, 45% had supported a research registry, and 60% had reported that they provided financial support to one researcher in the previous two years (Landy et al., 2012).

Although disease-specific partnerships may help connect patients to clinical studies, especially in the case rare diseases with a limited time frame for recruitment, the characteristics of patients engaged with PAGs are often not well known. A target disease population may be a heterogeneous group of affected individuals in terms of economic, social, racial, and ethnic diversity. Often times, an advocacy organization's decisions in how they attract subscribers and serve their population can have a significant impact on who is ultimately engaged (Dresser, 2003). In a systematic review of approaches for engaging patients, many authors of clinical studies on rare diseases expressed concerns about the potential for bias among patients enrolled. This concern stemmed from the observation that engaged participants are often more likely to be highly motived, have higher levels of education, and are more likely to subscribe to platforms utilized in recruitment methods such as website use and attendance to meetings (Forsythe et al., 2014). When partnering with a disease specific organization for recruitment efforts, it may be

important to keep in mind what populations are reached and engaged in the organization's efforts, which can have the potential for selection/ response bias and thus impact the quality and legitimacy of research representation.

II. SPECIFIC AIMS

This senior honors thesis will investigate the recruitment methods of the Heart Health 4 Moms Study (HH4M), a randomized controlled trial that investigates the efficacy of a web-based lifestyle intervention for women with a recent history of preeclampsia designed to increase cardiovascular disease risk knowledge and self-efficacy in relation to nutrition and physical activity. The HH4M study focused the majority of their recruitment efforts on social media and web-based recruitment channels, in addition to some more traditional institution-based methods. This thesis will focus specifically on the success of the methods employed to recruit postpartum women. Specifically, this thesis aims to:

1. Identify which recruitment outlets utilized in the HH4M study were reported by participants as sources of recruitment for those who filled out the initial survey and those who were ultimately enrolled.

2. Examine the socio-demographic characteristics of the sample enrolled in the study.

II. METHODS

Heart Health 4 Moms Study Design

The HH4M study is an ongoing nationwide randomized control trial led by researchers at Brigham and Women's Hospital in Boston, Massachusetts and funded by the Patient Centered Outcomes Research Institute (PCORI). Because women who have experienced preeclampsia have an increased risk in developing CVD later on in life, the HH4M study is investigating whether a web-based lifestyle intervention for women with a recent history of preeclampsia can increase CVD risk knowledge and self-efficacy in relation to nutrition and physical activity. The overall aims of the HH4M study are as follows: 1) to improve patient ratings of their self-efficacy to achieve a healthy lifestyle through healthy eating and increased physical activity, 2) to improve patient behavioral risk factors by increasing adherence to the Dietary Approaches to Stop Hypertension (DASH) diet, increase physical activity, and reduce physical inactivity, 3) to improve patient ratings of their self-efficacy to promote healthy lifestyle for their families, 4) improve patient knowledge of CVD risk and prevention options, and 5) to test the extent to which the program will improve clinical risk factors for CVD at 3 and 9 months after baseline including lower postpartum weight retention and blood pressure.

In the control arm of the study, enrolled participants receive access to a website page containing links to online information pertaining to the AHA Class I Lifestyle recommendations for women with a history of preeclampsia. In the intervention arm, participants are given access to a customized patient-informed online program with modules and phone meetings with a lifestyle coach who was a registered dietician on how to achieve the AHA recommendations for diet, activity, and weight management.

Inclusion and Exclusion Criteria

The HH4M study aimed to recruit a cohort of postpartum women from across United States who had recently experienced preeclampsia. Women who were enrolled in the study were required to: be healthy and capable of giving consent, have had a live birth within the past 5 years during a pregnancy complicated by preeclampsia, be residents of a US state/territory, between 18-44 years of age, and have a BMI between 18.5 and 40 kg/m^2 to exclude women who fit the WHO definition of underweight and morbid/ grade III obesity.

Due to the nature of the intervention in which the modules focus on the context of new motherhood, the HH4M study excluded women who had preeclampsia but did not have a live birth. Because the intervention was web-based and available in English and Spanish, women were also required to be able to communicate in either English or Spanish at an 8^{th} grade level and have access to the internet. Likewise, women had to have access to either a smartphone or tablet as both the control and intervention groups were required to measure their weight and blood pressure at the onset of the study, after three months, and after 9 months at study completion. Participants were mailed iHealth devices including an automatic blood pressure cuff and scale which were linked to a mobile app that could be accessed only on a smartphone or tablet. In order to tailor the intervention to postpartum women with a recent history of preeclampsia, women who had either Type 1 or Type 2 diabetes, were pregnant at the time of recruitment, had a diagnosis of hypertension (blood pressure > 140/90 mmHg), or were on medications for the treatment of hypertension were excluded from the study.

Subjects who met initial criteria consented for the release of their medical records for the validation of preeclampsia under the study's definition. Preeclampsia was defined as having the following documented in the medical records: a normotensive record prior to the preeclamptic

event, either a systolic or diastolic blood pressure ≥ 140/90 mmHg before delivery and outside labor, a positive proteinuria measure within 2 weeks of a hypertensive measure of at least one of the following: 1) ≥300 mg/24h on a 24-hour urine collection, 2) urine protein to urine creatinine ratio ≥0.3, or 3) +1 or greater on a urinary dipstick ("Hypertension in Pregnancy - ACOG," n.d.). Because one of the outcome measures for the study is the reduction of blood pressure, and the study aimed to only enroll women with preeclampsia non-superimposed on hypertension, the study excluded women whose medical records and baseline measurements demonstrated chronic hypertension. In addition, women with the following conditions were excluded: 1) substance abuse disorder at the time of recruitment, 2) prescription medication use associated with weight gain (including atypical antipsychotics, respirdal, clozapine, olanzapine, quetiapine) at randomization, 3) self-reported an active eating disorder such as anorexia nervosa, bulimia, or binge eating, and 4) those under active treatment for cancer, who had a personal history of heart disease, stroke, kidney disease, gastric bypass or bowel surgery resulting in malabsorption, or who had an active medical problem that would interfere with following of the Dietary Approaches to Stop Hypertension (DASH) diet or changes in blood pressure and/or weight.

Recruitment Strategy

The primary recruitment goal for the HH4M study was to enroll a sample of 150 women within 12 months after the start of recruitment. In addition, the HH4M study also aimed to recruit a diverse population of women in terms of geographic distribution, as well as racial and ethnic identification that reflected the minority composition of birth in the United States. In order to reach this population goal during the time frame required by the funding organization, the HH4M study devised a patient-centered social media and web-based recruitment approach in

partnership with an advisory committee and with patient input gathered through focus groups. The major partner for the HH4M study was the Preeclampsia Foundation, the largest disease-specific lay organization for survivors of Preeclampsia that provides educational resources to its subscribers. The Principle Investigators of the HH4M study, Ellen Seely, MD, and Janet Rich-Edwards, ScD, MPH, both as advisors for the Preeclampsia Foundation Registry, which provides a unique partnership for the research efforts and the recruitment of a disease specific population. Other supporting organizations included the March of Dimes, a nonprofit that strives to improve the health of mothers and babies, and BabyCenter, a parenting website that provides information for parents and parents-to-be.

Through a variety of recruitment sources, subjects were directed to an online Recruitment Questionnaire (RecQ) to determine initial eligibility. Sources of recruitment included social media and website postings from the Preeclampsia Foundation, March of Dimes, Craigslist, and BabyCenter (**Social Media Posts – Appendix A**). The Preeclampsia Foundation utilized a series of blog posts on their website and sponsored sources, in addition to website postings of study advertisements on both their English and Spanish websites and Twitter/Facebook social media pages. The March of Dimes posted study advertisements on their website and social media pages in both English and Spanish. HH4M staff members posted study advertisements on a variety of Craigslist sites with specific focus on regions and communities with large amounts of diversity and minority populations. Representatives from BabyCenter posted study announcements on both their English and Spanish websites and social media pages (Facebook, Twitter, and Google +), as well as in the month-based Birth Clubs, which serve as community forums for mothers with similar expected delivery dates.

In addition, the National Association of County and City Health Officials (NACCHO) disseminated recruitment materials to providers in their 2800 community health clinics for patient referrals. NAACHO attempted a three-pronged strategy for recruitment: 1) outreach to individual and local health departments that provided services for prenatal and postpartum women; 2) outreach to maternal child adolescent health (MCAH) audiences via listerv email blasts, newsletters, website, and Facebook/Twitter announcements; 3) NAACHO wide outreach via internal communication channels and partnership engagement to distribute recruitment tools. Likewise, five selected physicians from across the U.S. who work in minority clinics to be posted in their offices, and flyers were also placed in three Women Infants & Children (WIC) Program offices.

Perceived Barriers and Strategies Utilized to Overcome Them

In order to maximize their efforts and meet their two goals, the HH4M advisory committee considered several potential barriers to recruitment and incorporated strategies in both the study design and recruitment tools to mitigate those barriers. First, one of the largest perceived barriers to participation was that women would not have enough time to come to a medical facility to complete surveys, interventions, and surveys. The target population contained women with young children, thus the prospect of physical visits at a certain location was perceived to be compounded by the possible need for childcare. In order to avoid these issues, HH4M was conceived as a completely remote study and could be completed from home. The only scheduled meetings, which were optional, were with a lifestyle coach who is a registered dietician, which were completed by phone and/ or email at the subject's convenience. An additional anticipated barrier was that women would be unlikely to participate due to time

constraints given the demands of early childcare for new mothers. In order to address this perceived barrier, the HH4M website and intervention was designed so that all study participants were able to have access and complete tasks at any time during the day. All modules and measurements were not required to be completed on a fixed time schedule, and participants were allowed to complete all exercises at their own pace.

Another anticipated concern was that many participants of diverse backgrounds might find a lack of identification with the study staff, recruitment materials, or website design. In order to address this concern, a series of steps were taken so that potential participants might better identify with the study. No images of any staff members were posted on any websites affiliated with the HH4M study, and no racial or ethnic identification of study staff members was ever communicated in the recruitment process or during the study. Likewise, no face to face interaction occurred between study staff and participants, and all communication during recruitment was via email or phone call. Furthermore, recruitment postings and website graphics included images of mothers from a diverse set of backgrounds. Finally, another anticipated barrier to recruiting a diverse population was language. As a means of allowing more women to understand recruitment materials and participate, all aspects of the study could be accessed in both English and Spanish, and recruitment efforts were posted in both English and Spanish in various outlets. Spanish was chosen as an additional language to English because it is the fastest growing minority language, and it is the most widely used language outside of English in the United States (Lopez, 2013).

Recruitment Questionnaire and Procedure

Once women came in contact with one of the recruitment announcements, a link or QR code provided in the posting lead the women to an online Recruitment Questionnaire that contained questions to help determine initial eligibility for the study. The Recruitment Questionnaire was designed and delivered through Research Electronic Data Capture (REDCap), a web-browser based electronic data capture software used primarily for designing and maintaining clinical and translational research databases. With respect to this senior honors thesis project, the questions of interest included self-reported source of recruitment, age, race, ethnicity, and zip code. Options for responses to the question "How did you hear about the study?" included the Preeclampsia Foundation (Website, Facebook, and Twitter), Facebook, Twitter, BabyCenter, Craigslist, Google, Flyer, Doctor Referral, Email, Family/Friend, and Other with the option to specify further. Survey respondents were instructed to select a racial identification, with the option for multiple selections, of the following choices: 1) Caucasian, 2) African American, 3) Asian, 4) Native American or Alaska Native, 5) Native Hawaiian or Other Pacific Islander, and 6) other with the option to specify further. Respondents were also asked whether they identified ethnically as Hispanic or Non-Hispanic. Finally, respondents were asked to report their current zip code. In response to these questions, the two groups that will be described in this project will be the survey respondents (total responses to the REDCap Recruitment Questionnaire), and the enrolled population (n=150).

Following completion of the Recruitment Questionnaire, all eligible participants were subsequently contacted by telephone to determine further interest in participation and to screen for specific criteria that were either not addressed or fully covered in the survey. Following the phone screen, participants consented for the release of their medical records for the validation of

preeclampsia based on the study's definition. Once the diagnosis had been validated through medical records, eligible participants were sent consent forms and iHealth devices in order to further validate that subjects met inclusion criteria for baseline weight and blood pressure measures. Once these measures were taken, participants reviewed consent materials over the phone and subjects were instructed to mail the signed consent form back to the study staff. Participants then completed the Baseline Questionnaire and were subsequently randomized into either the intervention or control arm of the study (**See Consort Diagram -Appendix B**).

Data Collection and Medical Record Abstraction

For the survey respondents, all subjects who filled out the Recruitment Questionnaire, survey response data was recorded via REDCap instrument entry (**Appendix C**). For the enrolled population, relevant clinical measures were abstracted from the medical records. Medical record abstraction methods were devised in a standard of practice that defined where to look in the medical records for each measure in an order of priority (**Appendix D, E**). Measures included: gestational age at delivery, birthweight of baby, z-score for birthweight by gestational age, singleton or multiple pregnancy, sex of baby, APGAR scores (1 minute and 5 minute), mode of delivery, gravidity, and parity at diagnosis of preeclampsia.

Gestational age recorded was the weeks and days of gestation at the time of delivery of the infant of the pregnancy complicated by preeclampsia. *Birthweight* of the baby was recorded in grams and converted if in other units. Z-score can be defined as the number of standard deviations above or below a reference population mean. The z-score was calculated by comparing the observed birthweights and gestational ages to a standard for birthweight by

gestational age (Olsen, Groveman, Lawson, Clark, & Zemel, 2010). The following equation was used to calculate this value: z-score = (observed value - mean value of the reference population) / standard deviation value of reference population. *Singleton or multiple pregnancy* pertained to the number of viable fetuses that were delivered in the pregnancy complicated by preeclampsia. Sex of the baby was defined as male or female. *APGAR scores* at both 1 minute and 5 minutes after delivery were recorded. APGAR scores are a measure of newborn health defined the sum of scores (1-2) for the following criteria: skin color, pulse rate, grimace (irritability reflex), activity, and respiratory effort. *Mode of delivery* was defined as either vaginal or caesarian section delivery. *Gravidity* was as the number of pregnancies that the subject experienced at the point that they were diagnosed with preeclampsia, including the current pregnancy at diagnosis. *Parity* was defined as the number of living children the subject had at the time of diagnosis of preeclampsia. In addition to the measures abstracted from the medical records, *baseline BMI* and *time since delivery* were determined.

Participants were mailed two iHealth devices, an automatic blood pressure cuff and a digital scale. Devices were linked to a mobile application on either a smartphone or tablet, and all weights and blood pressures were sent remotely to a server operated by the HH4M staff. For baseline measurements, women were instructed to use the scale to record two simultaneous weight, which in combination with their self-reported height, would deliver two BMI measures to the server, which were averaged. In order to determine the time since delivery for all subjects, the delivery date abstracted from the medical records was compared to the date the participation consent form was signed.

Data Analysis

All data was exported from REDCap instruments and measures were analyzed via STATA IC (version 14.2). For the Recruitment Questionnaire, a dataset for all survey respondents was exported with all identifiable information removed. Survey entries that contained duplicate email addresses and phone numbers, unlinked to survey responses, were removed.

As previously noted, the two groups analyzed are survey respondents (total responses to the REDCap Recruitment Questionnaire), and the enrolled population, defined as those who were ultimately consented and randomized into the HH4M study. All continuous data was initially analyzed via descriptive statistics, including means and standard deviations, and percentages were determined for all discrete data. Percentages determined were compared via contingency tables, a Fisher Exact test was employed to determine P-values, and statistical significance was defined as $P<0.05$.

All responses to determine recruitment source and race were sorted and those that selected "Other" were analyzed to determine if any reassignments were needed based on what the participants specified. Social Media and Web-based sources included all of the responses except the following: flyer, doctor referral, family/ friend, or other. For the demographic data abstracted from medical records of the enrolled population, a dataset for all measures was generated for the calculation of percentages, means, and standard deviations. Singleton pregnancies were separated from multiple pregnancies for the analysis of birthweight, gestational age, and z-score as a multiple pregnancy can have an impact on these measures. For the geographic distribution, zip codes reported in the Recruitments Survey for the enrolled population were mapped using Batch-Geo, a web-based program that placed pinpoints on a map

for the locations of each zip code. The number of states and distribution between U.S. regions, which were defined by the U.S. Census Bureau, were counted by hand (Geography, n.d.).

These methods have been approved by the Tufts University Institutional Review Board via Exempt Category 4: IRB Study #1702012 and the Brigham and Women's Hospital Institutional Review Board Protocol # 2014P002765/BWH (**Appendices F and G**)

IV. RESULTS

Socio-Demographic and Clinical Characteristics of Study Sample

Of the enrolled women, they were on average in their early 30s, overweight with an average BMI of 27.6 kg/m^2, and 1.4 years since delivery when consented to participate. Approximately 70% of the population were primparious in that their preeclamptic pregnancy resulted in their first child. Likewise, the plurality of the enrolled population identified as Caucasian (90%) and non-Hispanic (89%) (**Table 1**). The vast majority (94%) of all pregnancies in the enrolled population were singletons with 64% of deliveries occurring by C-section. The APGAR scores were on average 7 and 8.4 for 1 and 5 minutes respectively, and the average birthweight of the singleton babies was 2098 grams. As expected with women with preeclampsia, preterm delivery was common (69% of all deliveries), with an average gestational age at delivery of 34.3 weeks for singleton babies. The Z-score for the standard birthweights by gestational age was -0.83, which is roughly 1 standard deviation below the population mean. Thus, the women in the study were on delivering early, and when adjusted for gestational age, the babies were underweight (**Table 2**).

In terms of racial and ethnic demographics, both the enrolled population and all those who filled out the survey were mostly Caucasian and non-Hispanic. Ninety percent of the enrolled population identified on the Recruitment Questionnaire as Caucasian, which was a significantly higher proportion compared to 75.4% of the survey respondents ($P < 0.0001$). Likewise, 8% of the survey respondents identified as African American compared to only 3% of the enrolled women which was also a significant difference ($P = 0.0357$). Few women identified as Asian, Native American/ Alaska Native, or Native Hawaiian/ Other Pacific Islander from both groups. Many in both groups identified as “Other” or selected multiple races and thus were

considered as "Multi-Racial," and significantly more survey respondents identified as "Other" compared to the enrolled population (P = 0.0024). Of the enrolled group, 11% identified as Hispanic compared to 26% of the survey completion group, which was a significantly higher proportion (P<0.0001). In addition to a variety of clarifications, a large portion of the women who selected "Other" indicated that they were Hispanic or Latina racially identifying, which shows confusion over race vs. ethnicity (**Table 3**). The subjects enrolled in the study represented 41 out of 50 U.S. states with the largest percentage living in the South (35%), followed by the Midwest (29%), the West (19%), and the Northeast (17%) (**Figure 1, 2**).

Sources of Study Recruitment

Among the enrolled population (n=150), most (90%) reported that they heard about the HH4M study from a social media or web-based outlet. Among those who filled out the Recruitment Questionnaire (n=1509), nearly the same proportion (89%) reported seeing the study from social media or web-based outlet (**Figure 3**). Although a larger percentage of the enrolled population compared to survey respondents reported the Preeclampsia Foundation outlets (Website, Facebook, and Twitter) as their source of recruitment (P=0.00211), for both groups, the Preeclampsia Foundation was the largest source of recruitment. Of the enrolled, a significantly larger proportion (41%) reported Facebook, compared to survey respondents (22%) (P<0.0001). On the other hand, 22% of survey respondents reported hearing about the study from BabyCenter, compared to only 3% of enrolled participants could be attributed to this source (P<0.0001). In a similar vein, 8% of total respondents reported coming in contact with the study via Craigslist advertisements posted; however, no members of the enrolled population reported this source (P<0.0001). Some of the responses for those who selected "Other" included previous

focus group and Do Not Qualify (DNQ) individuals from other studies for which members of the research staff were recruiting. Additional responses to other included March of Dimes and NAACHO, which were not included as specific options for selection, Instagram, and other non-specified support groups (**Table 4**).

V. DISCUSSION

The first aim of this study was to identify recruitment strategies utilized by the HH4M study that participants reported as the primary means of learning about the study, completing the Recruitment Questionnaire and subsequently enrolled in the longitudinal study. *The second aim was to examine* the socio-demographic and clinical characteristics of the sample enrolled in the HH4M study.

Recruitment Source

Overall, the HH4M study was successful in enrolling the targeted sample size of 150 women with a recent history of preeclampsia within the 12-month time frame using a variety of recruitment strategies. Of those who were ultimately enrolled, 90% reported having heard about the study from social media and web-based sources. The largest sources of recruitment overall were the Preeclampsia Foundation (46%) followed by Facebook (41%), which both had significantly higher proportions in the enrolled population compared to the total survey respondents. Despite a number of survey responses from BabyCenter and Craigslist, significantly fewer individuals (3% and 0%) were actually enrolled from those sites.

Although current literature suggests that social media and web-based tools may be useful for clinical trial recruitment--both in terms of reducing costs and reaching a larger number of potential participants-- few studies have highlighted which tools are successful and how they compare to conventional recruitment methods. Moreover, few studies have explicitly examined the utility of these recruitment methods for postpartum women (Frandsen et al., 2014; Shere et al., 2014). One exception to this lack of research includes a recent study published in March of 2017 which assessed the feasibility and cost of online recruitment of postpartum women compared to a face-to-face recruitment strategy nationwide in Australia. Participants for an

anonymous online survey investigating postpartum general health and psychological well-being, the *Living with a Young Baby Survey* (LYBS), were recruited via both targeted Facebook and BabyCenter advertisements from January to February of 2015. For comparison, the investigators also drew upon the Household Income Labour Dynamics in Australia (HILDA), a longitudinal nationally representative household panel survey conducted annually since 2001. The HILDA survey requires both a face-to-face interview and paper questionnaire for completion, and the investigators specifically analyzed time-points 11 and 13, with a total of 579 respondents from both waves (wave 11 n= 288; wave 13 n= 291). In comparison to the HILDA survey, the investigators recruited 264 women from BabyCenter over 9 days and 819 from Facebook in 4 days of active advertisements. Investigators reported that online recruitment was significantly less costly and more efficient in recruiting the targeted population, compared to the face-to-face approach (Leach et al., 2017). The findings from the LYBS and the HH4M study suggest that both Facebook and BabyCenter may be cheap and effective tools for clinical trial advertisement for postpartum women. However, it is important to note that the LYBS only recruited postpartum women for a single survey and did not have an inclusion or exclusion criteria.

Sociodemographic and Clinical Characteristics

Despite significant efforts to reach racial/ethnic minority groups, 90% of the enrolled population identified as Caucasian and 11% identified as ethnically Hispanic. However, of the survey respondents, there was a significantly larger proportion of Hispanic, and African American identifying individuals.

According to the National In-Patient Sample from 2014, a set of longitudinal hospital inpatient databases included in the Healthcare Cost and Utilization Project that comprises the

largest publically available all-payer inpatient healthcare database in the United States (includes a weighted 7,543,178 total delivery hospitalizations), 47% of women with a diagnosis of preeclampsia were White/European, 20% were Black/African, and 18% were Hispanic/Latino as reported in the medical records. For both the survey respondents and the enrolled population, the racial composition was relatively homogeneous, with a predominantly Caucasian sample. Despite this, the reported percentage of enrolled participants in HH4M study who self-identified as Hispanic (11%) was close to the proportion in the NIS sample (19%). Those self-reporting as Hispanic among survey respondents (26%) was higher in the HH4M sample than in the NIS sample. This descriptive comparison suggests that while HH4M recruitment strategies recruited a predominantly Caucasian sample, efforts to recruit in Spanish-language social media and web-based outlets may have had an impact on recruiting and enrolling a relatively representative percentage of Hispanic identifying women. Because the NIS does not validate preeclampsia, yet determines their percentages by a series of codes from discharge medical records, it is important to note that the rate of validated preeclampsia among certain groups may be lower at medical record validation than in discharge diagnosis. For example, because African Americans have a higher prevalence of chronic hypertension, it is possible that more African Americans might be excluded at validation for preeclampsia compared to the diagnosis noted on a discharge medical record (Lackland, 2014). In terms of geographic diversity, women in the National In-Patient Sample were distributed by hospital with 15% in the Northeast, 21% in the Midwest, 43% in the South, and 21% in the West ("National Inpatient Sample--HCUP," 2014) (**Appendix H**). This was comparable to the regional distribution of the HH4M study with the South also comprising the largest percentage (35%), and a representation of 41 out of 50 states.

As for maternal and pregnancy characteristics, the majority of women were primiparous during their preeclamptic pregnancy, and the majority of deliveries were C-sections. Likewise, deliveries were on average preterm, and birthweights were on average 1 standard deviation below the population mean for birthweight by gestational age. When comparing baseline characteristics for studies that contain cohorts of women with a history of preeclampsia, it is apparent that a variety of definitions of preeclampsia are utilized, and clinical characteristics are not uniformly reported. In reviewing studies that enroll cohorts of postpartum women with a recent history of preeclampsia, it is important to note the inconsistencies in sociodemographic reporting, as well as study definitions and criteria. Four postpartum preeclampsia studies conducted in Uganda, Brazil, Canada, and Norway have reported a well distributed range of C-sections for their populations between 39% and 68%. Of these same studies, gravidity, parity, and APGAR scores were not reported, two studies reported mean gestational ages ranged from 35.6 to 36.8 weeks, and three studies reported mean birthweights ranging from 2300 to 3189 grams, which is slightly higher than the HH4M mean gestational age (34.3 weeks for singletons) and birthweight (2098 grams) (Amorim et al., 2015; Kahn et al., 2009; Nakimuli, Elliott, Kaleebu, Moffett, & Mirembe, 2013; Roten et al., 2015). These four studies, which were nation-based longitudinal postpartum preeclampsia trials, were selected for comparison as they maintained a similar design as the HH4M study. However, given the inconsistencies in exactly what is reported across preeclampsia cohort studies, it is important to recognize the limited ability to compare clinical measures.

Limitations

Before discussing study implications, it is important to note study limitations that may

affect findings. With the largest number of survey respondents and enrolled participants descending from the Preeclampsia Foundation, and because the study reached out to participants on a self-reported case basis, it may be that subscribers to the Preeclampsia Foundation, which provides countless educational resources about preeclampsia to its members, may be more aware of the criteria for a diagnosis of preeclampsia. One possible explanation for the difference in proportion of minorities in the survey respondents vs. the enrolled population could be the strict study criteria, and specific study definition. Because minorities often share a disproportionate number of comorbidities, it may be that these groups were excluded based on the HH4M specific criteria, such as the BMI cutoff and chronic hypertension (Opara et al., 2013). Future investigations should make an effort to determine how study criteria, as well as specific study definitions may have an effect on what individuals are enrolled and those that are excluded. Despite reaching the target population size and efforts to diversify the cohort, the population enrolled was largely Caucasian. The extent to which the recruitment tools and the entire recruitment process played a role in the population obtained is yet to be determined. Future efforts should investigate, through focus groups or structured interviews, the perceptions and attitudes towards the recruitment advertisements and interactions with the study staff through the recruitment process.

Recruitment efforts were targeted towards women who self-reported having preeclampsia. Once medical records were obtained for these women, the burden of reliability was shifted towards the research staff to validate diagnosis of preeclampsia. The HH4M research groups is currently pursuing an analysis of those who did not qualify for the study based on their medical records to determine who these people were demographically, what specific aspects about their medical records disqualified them, and if they would have been enrolled in the study

had the definition of preeclampsia followed different guidelines. Future investigations should also look at those who did not respond to a phone screen (n=99) despite initially qualifying for the study to determine any demographic or recruitment source differences. Likewise, future studies should consider targeting specific community centers that have longstanding and consistent engagement with minority communities to help overcome some of level of mistrust that functions as a barrier to recruitment.

It has been suggested through focus groups and other studies that, African American women specifically, may be likely to respond to some non-traditional outlets such as church groups and congregations, as well as periodicals and media (television and radio) that cater to their communities (Smith et al., 2007). Because these outlets are often expensive, social media may provide a cheaper alternative to these targeted media campaigns. By targeting and utilizing the social media outlets of specific African American and minority health advocacy organizations, such as the Black Women's Health Imperative, it may be possible to reach more minorities for participation. Once minorities are engaged, it may be possible to capitalize on "snowball sampling" which may be helpful especially with the recruitment of African Americans due to established and trusted relationships among the social networks of these participants (B. Watson, Robinson, Harker, & Arriola, 2016). Given that only 8% of survey respondents identified as African American, and ultimately only 3% of the enrolled population identified as African American, compared to the NIS proportion (20%), future efforts should look into what about the recruitment efforts for HH4M may have failed to reach and enroll this population.

In terms of data collection for recruitment source, the selection options on REDCap may have been misleading for some participants, which may likely be due to the viral nature of social media. Because all Preeclampsia Foundation advertisements on Facebook shared as general

posts on their page, it is difficult to say whether the people who reported "Facebook" as their source of recruitment may have come in contact with Preeclampsia Foundation materials. Likewise, some confusion may have arisen with regard to hearing about the study from "Family/Friend" especially if the recruitment tool was directly sent or shared publically using social media. However, the viral nature in this case as well as the "snowball sampling" effect may also be a benefit to generate a large number of responses in a short amount of time. Despite this benefit, the most salient limitation with regard to the recruitment strategy was the ability to generate a denominator for social-media and web-based content views or engagements. Because the recruitment tools were disseminated largely through tweets announcement posts on various partner Facebook pages, no data was collected on how who was able to view the content. Given the large success in recruiting through Facebook as a platform, future studies should consider utilizing Facebook advertisements that are able to provide more information about post reach and engagement for a very low cost, reported in several studies as roughly $20 per compliant participant and cost-per-click below one U.S. dollar (Fenner et al., 2012; Leach et al., 2017).

For medical record data abstraction, consideration should be paid towards the many difficulties that a study staff may face when attempting to locate clinically relevant measures in the records supplied. As noted in the baseline characteristic tables of the enrolled population, some measures were often unable to be located in any of the records requested with APGARs and birthweight often left out of the reports (**Table 1, 2**). Future studies that aim to collect medical records for validation and abstraction should consider electronic medical records for easier data collection and increased measure accountability.

Although the HH4M study utilized the same standards for Classification of Federal Data on Race and Ethnicity issued by the National Institutes of Health (NHS), the option to select

"Other" left some ambiguity in the exact racial makeup of both groups. In future studies, it would be beneficial to exclude the option for "Other" and include descriptions for those who do not identify with any of the listed race options. Some short descriptions for classification might be as follows: Black or African American (A person having origins in any black racial groups of Africa), White (A person having origins in any of the original peoples of Europe, the Middle East, or North Africa), Asian (A person with origins in any of the original peoples of the Far East, Southeast Asia, or the Indian Subcontinent) (Evans, 2015). Likewise, the question to select "Hispanic or Non-Hispanic" for ethnicity should be placed before any racial question as to clearly denote the difference between the two classifications.

Conclusions and Implications

Overall, social media and web-based recruitment efforts allowed for the recruitment of the target sample size despite strict inclusion and exclusion criteria and a very short window of time in which recruitment had to be completed. Partnering with a patient advocacy organization was key to successful recruitment within a short timeframe, however the sample was largely pulled from those engaged with the advocacy organization. Not only did the Preeclampsia Foundation play a pivotal role in reaching out to potential participants, the Director of the Preeclampsia Foundation was an extremely valuable collaborator on the study staff who was in attendance at every weekly study meeting. Likewise, the study was able to secure PCORI grant funding largely due to partnership with the lay organization, as PCORI requires that studies work directly with patients who are involved with the research process.

Despite significant efforts to recruit minorities, targeting Spanish-speaking groups was relatively successful in reaching and enrolling Hispanic women, but efforts to reach other

racial/ethnic groups were not as successful in achieving a diverse sample. Studies that aim to incorporate social media and online recruitment tools should utilize tools that allow for further analysis like Facebook advertisements such that a better determination of engagement can be assessed. Furthermore, the "snowball sampling" effect of social media should be utilized to improve participation of those in the social networks of targeted minority populations. Moreover, these studies should also consider a diverse means of media engagement that aims to further reach and ultimately enroll minority women. The next major step must include focus groups with minority women to determine which social media venues they are most likely to utilize and trust, and how better we can reach them for clinical trial recruitment.

The findings in this study add to the newly emerging body of research that examines the effectiveness of utilizing social media tools to meet recruitment goals. Given the success of the HH4M study in recruiting a nation-wide population within a short time frame, other studies should consider implementing similar tactics in order avoid delayed or failed recruitment. However, going forward, studies should be mindful of the constraints of time allotted for recruitment, and the effect that it may have on reaching a diverse sample.

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VII. TABLES AND FIGURES

Table 1. *Maternal Characteristics of Enrolled Population*

Table 1. Maternal Characteristics	**Mean (SD)**
Age (years)* (n=150)	30.9 (4.6)
BMI (kg/m^2) (n=150)	27.6 (5.1)
Gravidity (n = 149)	1.8 (1.2)
Parity (n = 149)	0.3 (0.6)
Time since delivery (yrs)	1.4 (1.2)
	n (%)
Primiparous (n=149)	105 (70)
Race (n=150): Caucasian African American Asian Other/Multi	135 (90) 5 (3) 1 (1) 9 (6)
Ethnicity (n=150): Hispanic Non-Hispanic	16 (11) 134 (89)
*Age at Recruitment Survey	

Table 2. *Pregnancy Characteristics of Enrolled Population Obtained via Medical Record Abstraction*

Table 2. Pregnancy Characteristics	**n (%)**
Singleton Pregnancy (n=149)	140 (94)
C-Section Delivery (n=147)	94 (64)
Preterm Delivery (n=150)	103 (69)
	Mean (SD)
APGAR score 1 min*(n=131)	7 (1.9)
APGAR Score 5 min*(n=130)	8.4 (1.1)
Birth Weight of Singleton Baby (g) (n=117)	2098 (905)
Gestational age of Singleton Baby at delivery (weeks) (n= 140)	34.3 (3.9)
Z-score of Singleton Baby (n= 117)	-0.83 (0.98)
*APGAR (score out of 10 based on appearance, pulse, grimace, activity and respiration)	

Table 3. *Reported Race and Ethnicity for Total Survey Respondents vs. Enrolled Participants.*

Table 4. Demographic Characteristics	Survey Respondents (n=1509)	Enrolled Population (n=149)
Race	**n (%)**	
Caucasian	1138 (75.4)	134 (90)*
African American	124 (8.2)	5 (3)*
Asian	10 (0.7)	1 (1)
Native American or Alaska Native	27 (1.8)	0 (0)
Native Hawaiian or Other Pacific Islander	2 (0.1)	0 (0)
Multi-Racial	30 (2)	3 (2)
Other	178 (11.8)	6 (4)*
	Survey Respondents (n=1504)	**Enrolled Population (n=149)**
Ethnicity	**n (%)**	
Hispanic	391 (26)	16 (11)*
Non-Hispanic	1113 (74)	134 (89)*

*Statistically significant comparison of proportions (P-values <0.05)

Figure 1. *Map of Enrolled Participants (n =150) by Zip Code. 41 out of 50 states represented.*

Figure 2. *Percentage of Enrolled Participants by U.S. Region.*

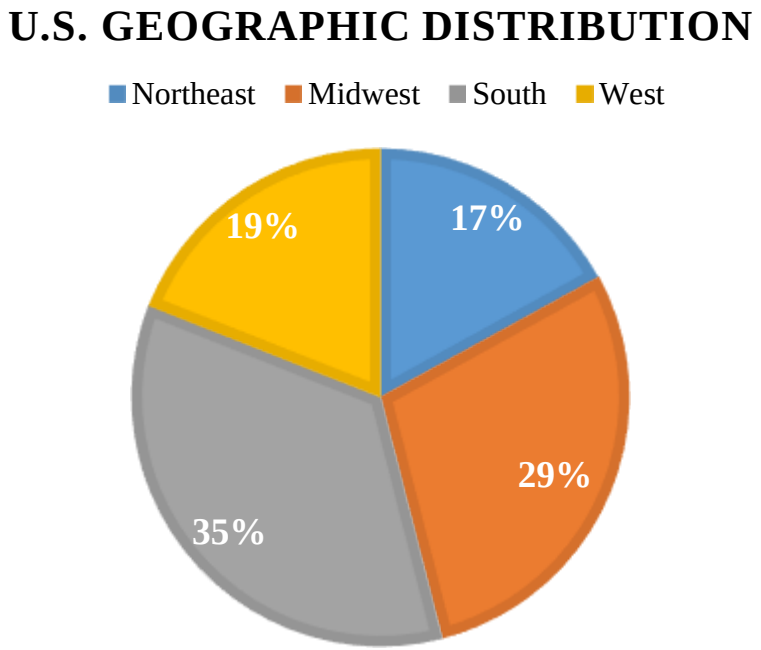
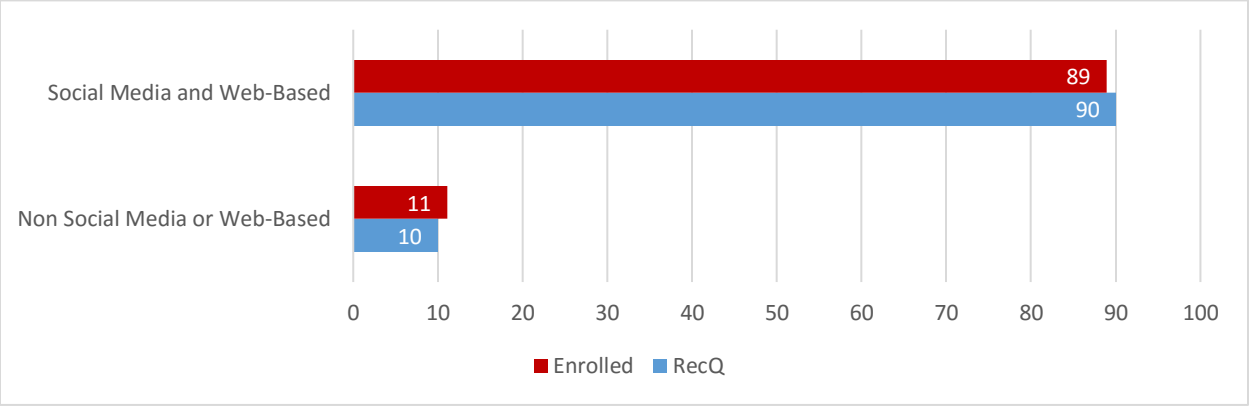


Table 4. *Reported Recruitment Source for Total Survey Respondents (n=1509) vs. Enrolled Participants (n=150).*

Table 4. Recruitment Source	Survey Respondents (n =1509)	Enrolled Population (n =150)
	n (%)	
Preeclampsia Foundation (Website, Facebook, and Twitter)	528 (35)	69 (46)*
Facebook	332 (22)	61 (41)*
Twitter	11 (0.7)	0 (0)
BabyCenter	332 (22)	4 (3)*
Craigslist	130 (8.6)	0 (0)*
Google	9 (0.6)	1 (0.7)
Flyer	33 (2.2)	3 (2)
Doctor Referral	24 (1.6)	1 (0.7)
Email	15 (1)	2 (1.3)
Family/ Friend	60 (4)	5 (3.3)
Other	35 (2.3)	4 (3)

*Statistically significant comparison of proportions (P-value <0.05)

Figure 3. *Reported Percentage of Recruitment Source: Social Media and Web-Based Sources vs. Non-Social Media and Web-based*



No statistically significant comparison (p-values >0.05)

VIII. APPENDICES

Appendix A. Social Media Posts

Facebook post:

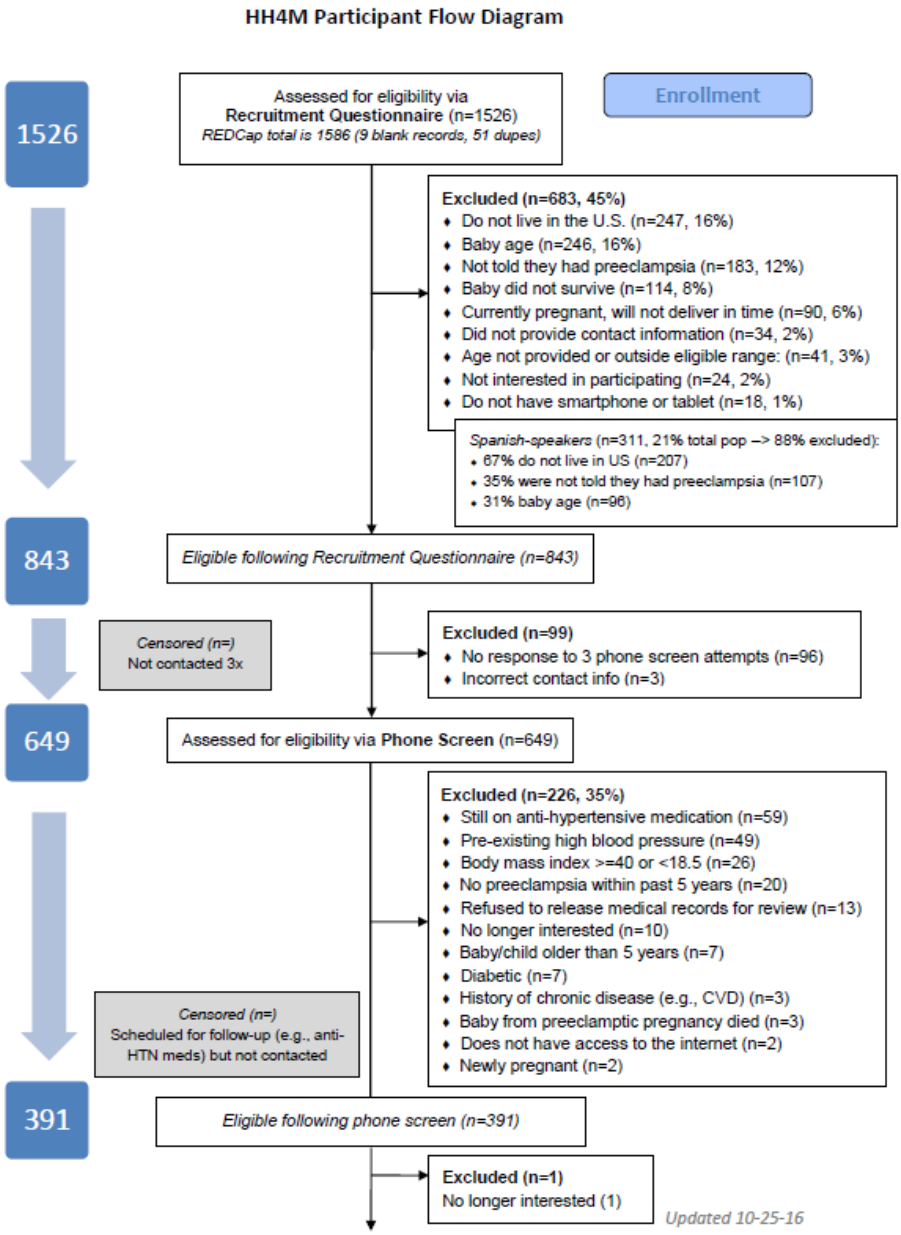
Facebook copy:
This online research study, Heart Health 4 Moms (HH4M), focuses on healthy behaviors in new mothers with recent preeclampsia to improve their long-term health. You must live in a U.S. state or territory and have access to an internet-enabled smartphone or tablet. Up to $250 stipend will be provided. This research is being conducted by Brigham & Women's Hospital in Boston and the Preeclampsia Foundation. Learn more at www.HH4M.org.

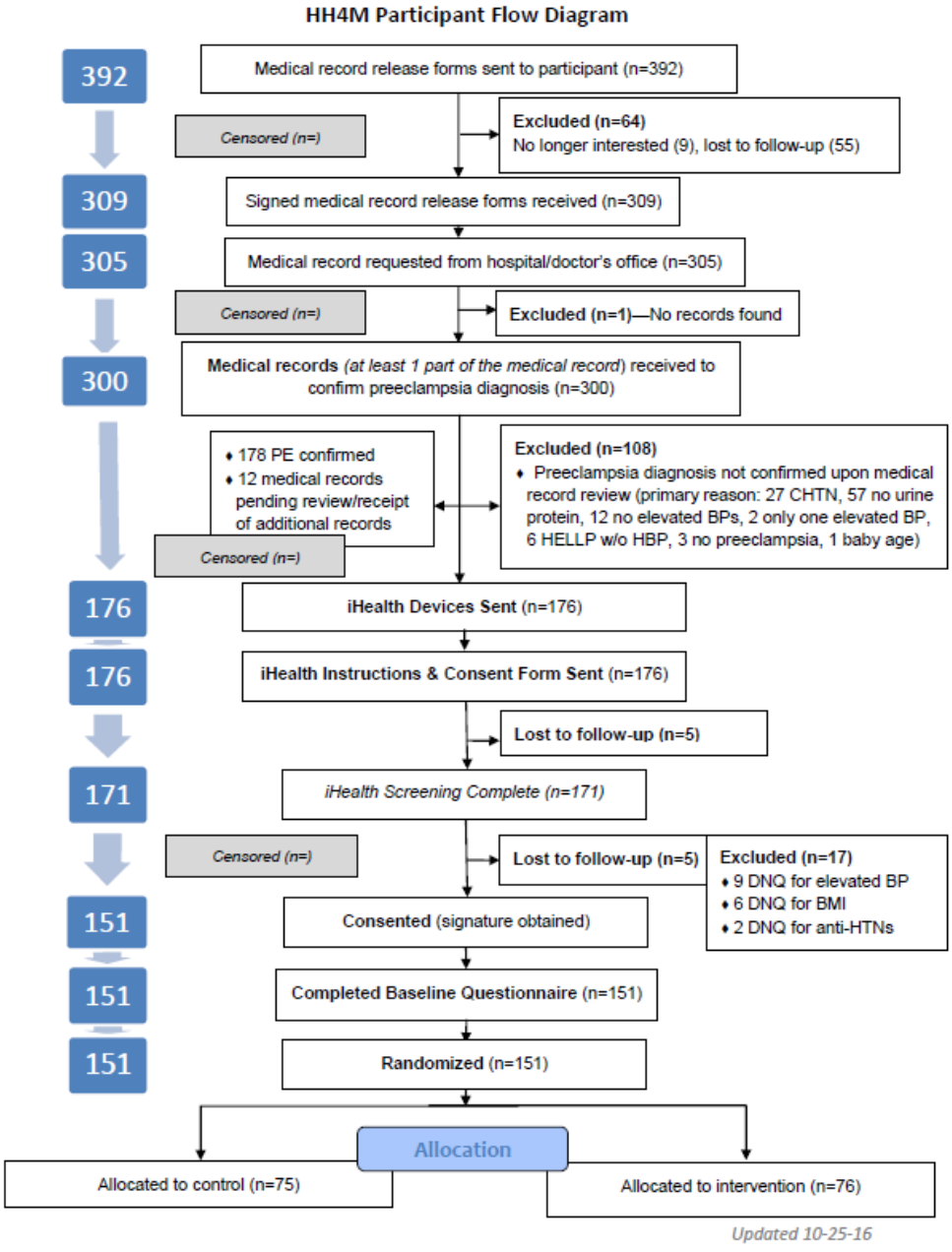
Alternative Facebook post:

Copy:
This online research study, Heart Health 4 Moms (HH4M), focuses on healthy behaviors in new mothers with recent preeclampsia to improve their long-term health. You must live in a U.S. state or territory and have access to an internet-enabled smartphone or tablet. Up to $250 stipend will be provided. This research is being conducted by Brigham & Women's Hospital in Boston and the Preeclampsia Foundation. Learn more at www.HH4M.org.

Twitter post:
Had a baby in the past 5 months? Was your pregnancy complicated by preeclampsia? You may qualify for a research study http://www.hh4m.org

Appendix B. Participant Recruitment Consort Diagram




HH4M Participant Flow Diagram
392
Medical record release forms sent to participant (n=392)
Censored (n=)
Excluded (n=64)
No longer interested (9), lost to follow-up (55)
309
Signed medical record release forms received (n=309)
305
Medical record requested from hospital/doctor's office (n=305)
Censored (n=)
Excluded (n=1)—No records found
300
Medical records (at least 1 part of the medical record) received to confirm preeclampsia diagnosis (n=300)
♦ 178 PE confirmed
♦ 12 medical records pending review/receipt of additional records
Censored (n=)
Excluded (n=108)
♦ Preeclampsia diagnosis not confirmed upon medical record review (primary reason: 27 CHTN, 57 no urine protein, 12 no elevated BPs, 2 only one elevated BP, 6 HELLP w/o HBP, 3 no preeclampsia, 1 baby age)
176
iHealth Devices Sent (n=176)
176
iHealth Instructions & Consent Form Sent (n=176)
Lost to follow-up (n=5)
171
iHealth Screening Complete (n=171)
Censored (n=)
Lost to follow-up (n=5)
Excluded (n=17)
♦ 9 DNQ for elevated BP
♦ 6 DNQ for BMI
♦ 2 DNQ for anti-HTNs
151
Consented (signature obtained)
151
Completed Baseline Questionnaire (n=151)
151
Randomized (n=151)
Allocation
Allocated to control (n=75)
Allocated to intervention (n=76)
Updated 10-25-16

Appendix C. Recruitment Questionnaire REDCap Data Entry Instrument:

31	race Show the field ONLY if: [preferredlang] = '1'	What race do you consider yourself? Please check all that apply.	checkbox 1 race___1 White 2 race___2 African American 3 race___3 Asian 4 race___4 Native American or Alaska Native 5 race___5 Native Hawaiian or Other Pacific Islander 6 race___6 Other
32	otherrace Show the field ONLY if: [race(6)] = '1'	Please specify which race(s) you consider yourself	text
33	sp_race Show the field ONLY if: [preferredlang] = '2'	¿Con qué raza(s) se identifican con? Por favor marque todas las que apliquen.	checkbox 1 sp_race___1 Blanca 2 sp_race___2 Afroamericana 3 sp_race___3 Asiática 4 sp_race___4 Indígena Nativa Americana o Nativa de Alaska 5 sp_race___5 Nativa de Hawai u otras Islas del Pacífico 6 sp_race___6 Otra
34	sp_raceother Show the field ONLY if: [sp_race(6)] = '1'	Por favor, cual raza se identifica con:	text
35	hisporlatina Show the field ONLY if: [preferredlang] = '1'	Do you consider yourself Hispanic or Latina?	radio 1 Yes 2 No
36	sp_hisporlatina Show the field ONLY if: [preferredlang] = '2'	¿Usted se considera ser hispana o latina?	radio 1 Sí 2 No

<table>
<tr><td>37</td><td>heardofstudy

Show the field ONLY if:
[preferredlang] = '1'</td><td>How did you hear about this study?</td><td>radio<table><tr><td>1</td><td>Craigslist</td></tr><tr><td>2</td><td>Preeclampsia Foundation (Website, Facebook or Twitter page)</td></tr><tr><td>3</td><td>BabyCenter</td></tr><tr><td>4</td><td>Facebook</td></tr><tr><td>5</td><td>Twitter</td></tr><tr><td>6</td><td>Doctor referral</td></tr><tr><td>7</td><td>Email</td></tr><tr><td>8</td><td>Google</td></tr><tr><td>9</td><td>Flyer</td></tr><tr><td>10</td><td>Family/Friend</td></tr><tr><td>11</td><td>Other</td></tr></table></td></tr>
<tr><td>38</td><td>other

Show the field ONLY if:
[preferredlang] = '1' and [heardofstudy] = '11'</td><td>Please list where you heard about the study:</td><td>notes</td></tr>
<tr><td>39</td><td>sp_findoutaboutstudy

Show the field ONLY if:
[preferredlang] = '2'</td><td>¿Como aprendió sobre esta investigación?</td><td>radio<table><tr><td>1</td><td>Craigslist</td></tr><tr><td>2</td><td>La Fundación de Preeclampsia (Sitio web, o página de Facebook o Twitter)</td></tr><tr><td>3</td><td>BabyCenter</td></tr><tr><td>4</td><td>Facebook</td></tr><tr><td>5</td><td>Twitter</td></tr><tr><td>6</td><td>Referencia de doctor</td></tr><tr><td>7</td><td>Correo electrónico</td></tr><tr><td>8</td><td>Google</td></tr><tr><td>9</td><td>Folleto publicitario</td></tr><tr><td>10</td><td>Familia/Amigo(a)</td></tr><tr><td>11</td><td>Otro</td></tr></table></td></tr>
<tr><td>40</td><td>sp_otherfindout

Show the field ONLY if:
[sp_findoutaboutstudy] = '11'</td><td>Por favor, escribe como aprendió sobre esta investigación.</td><td>text</td></tr>
</table>

Appendix D. Medical Record Abstraction Paper Instrument:

HH4M: PROTEINURIA PROJECT : ABSTRACTION SHEET

Subject Code: _____

Records Reviewed: ☐ **Initials & Date:** _____

Double Checked: ☐ **Initials & Date:** _____

Delivery Date:_____ **GA at Delivery (as mentioned in L&D note):**_____

Proteinuria defined by (put an asterix near the proteinuria within one week of the qualifying elevated BP):

A. >300mg/24h on a 24h urine collection

B. Urine Protein/ Urine Creatinine >0.3
(Enter Urine protein, urine creatinine followed by ratio)

C. 1+ or greater on a dipstick
(Report measure as reported in records: 1-4+ or semi-quantitative measure)

Date	GA	Type of exam (A, B or C)	Result

Singleton Pregnancy or Multiple Pregnancy (if multiple, specify twin, triplet, or more) (as mentioned in the L & D note)	Single or Multiple	Type of Multiple:
Sex of Baby (as mentioned in the L & D note) (circle)	M or F	
Apgar Score (as mentioned in the L & D note)	1 Minute:	5 Minutes:
Birth Weight of Baby (in grams) (as mentioned in the L & D note)	Grams:	Lbs/ Oz:
Mode of Delivery (as mentioned in the L & D note) (circle)	Vaginal or C-Section	
Gravidity and Parity (as mentioned in the L & D note)	Gravidity:	Parity:
Mention of Eclampsia (as mentioned in the discharge summary) (circle)	Y or N	
Mention of HELLP (as mentioned in the discharge summary) (circle)	Y or N	

Appendix E. Medical Record Abstraction SOP:

HH4M: PROTEINURIA PROJECT : ABSTRACTION SHEET

Subject Code: _____

Records Reviewed: ☐ **Initials & Date:** _____

Double Checked: ☐ **Initials & Date:** _____

Delivery Date:_____ **GA at Delivery (as mentioned in L&D note):** _____

If not in L&D, calculate from GA's throughout prenatal notes

Proteinuria defined by (put an asterix near the proteinuria within one week of the qualifying elevated BP):

A. ≥300mg/24h on a 24h urine collection

B. Urine Protein/ Urine Creatinine ≥0.3
(Enter Urine protein, urine creatinine followed by ratio)

C. 1+ or greater on a dipstick
(Report measure as reported in records: 1-4+ or semi-quantitative measure)

Date	GA	Type of exam (A, B or C)	Result

Note: operative notes could be the equivalent of L&D notes for C-section deliveries

Singleton Pregnancy or Multiple Pregnancy (if multiple, specify twin, triplet, or more) (as mentioned in the L & D note) If not in L&D, go to discharge summary, then postpartum notes	Single or Multiple	Type of Multiple:
Sex of Baby (as mentioned in the L & D note) (circle) If not in L&D, go to discharge summary, then postpartum notes	M or F	
Apgar Score (as mentioned in the L & D note) If not in L&D, go to discharge summary, then postpartum notes	1 Minute:	5 Minutes:
Birth Weight of Baby (in grams) (as mentioned in the L & D note) If not in L&D, go to discharge summary, then postpartum notes	Grams:	Lbs/ Oz:
Mode of Delivery (as mentioned in the L & D note) (circle) If not in L&D, go to discharge summary, then postpartum notes	Vaginal or C-Section	
Gravidity and Parity (from prenatal notes)	Gravidity:	Parity:
Mention of Eclampsia (as mentioned in the discharge summary) (circle) If no discharge, refer to L&D and prenatal notes for any mention	Y or N	
Mention of HELLP (as mentioned in the discharge summary) (circle) If no discharge, refer to L&D and prenatal notes for any mention	Y or N	

Appendix F. IRB Exemption Form

Tufts UNIVERSITY

OFFICE OF THE VICE PROVOST FOR RESEARCH

Social, Behavioral, and Educational Research
Institutional Review Board
FWA00002063

Title: Social Media and Web-Based Recruitment in an Preeclampsia Lifestyle Intervention Trial

February 17, 2017 | Notice of Action

IRB Study # 1702012 | Status: EXEMPT

PI: Nicholas Nasser
Faculty Advisor: Jennifer Allen
Review Date: 2/17/2017

The above referenced study has been granted the status of Exempt Category 4 as defined in 45 CFR 46.101 (b). For details please visit the Office for Human Research Protections (OHRP) website at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101(b)

- The Exempt Status does not relieve the investigator of any responsibilities relating to the research participants. Research should be conducted in accordance with the ethical principles, (i) Respect for Persons, (ii) Beneficence, and (iii) Justice, as outlined in the Belmont Report.
- Any changes to the protocol or study materials that might affect the Exempt Status must be referred to the Office of the IRB for guidance. Depending on the changes, you may be required to apply for either expedited or full review.

IRB Administrative Representative Initials: 

20 Professors Row | Medford, MA 02155 | TEL: 617.627.3417 | FAX: 617.627.3673 | EMAIL: SBER@tufts.edu

Appendix G. Partners Human Research Committee IRB Amendment

Partners Human Research Committee
116 Huntington Avenue, Suite 1002
Boston, MA 02116
Tel: (617) 424-4100
Fax: (617) 424-4199

Amendment: Notification of IRB Review
Protocol #: 2014P002765/BWH

Date: April 7, 2016

To: Ellen W Seely, MD
BWH
Medicine / Endocrine

From: Partners Human Research Committee
116 Huntington Avenue, Suite 1002
Boston, MA 02116

Title of Protocol:	Heart Health 4 Moms: Disease Prevention in Women with a Recent History of Pregnancy Complications
Version Date:	3/8/2016
Sponsor/Funding Support:	
	Proposal Title: Heart Hlth 4 Moms: Preeclampsi
	Name: Patient Centered Outcomes Research Institute
	Sponsor Number: CER-1306-02603
IRB Expiration Date:	3/11/2017
IRB Amendment #:	32
IRB Review Type:	Administrative
IRB Review Date:	4/7/2016
IRB Review Action:	Noted

This report has been reviewed and noted by BWH IRB .No further action is required.

Study Staff Added: Nicholas Nasser, Intern/Student

Questions related to this project may be directed to Nicole Elizabeth Marquez, nmarquez@partners.org, 617-424-4206.

CC: Geraldine Skurnik, MD, BWH - Medicine - Endocrine, Co-Investigator
Lindsey Weiss, BWH - Medicine - Endocrine, Research Assistant
Joeli Katz, BWH - Medicine - Women's Health, Research Assistant
Celestine Eliza Warren, BWH - Medicine - Women's Health, Research Assistant

Appendix H: National In-Patient Sample

Descriptive statistics for delivery hospitalizations with and without pre-eclampsia, National In-patient sample, 2013-2014 (N weighted, total delivery hospitalizations =7,543,178)

Sample Patient Characteristics		
	Pre-eclampsia, yes,	Pre-eclampsia, no, %
Race and/or Ethnicity		
White/European	47.2 (0.5)	50.2 (0.5)
Black/African	20.2 (0.4)	13.2 (0.2)
Hispanic/Latino	18.8 (0.4)	19.5 (0.4)
Other	8.0 (0.2)	10.5 (0.2)
*Missing	5.8 (0.4)	6.6 (0.3)
Age (years)		
12-18	4.2 (0.09)	3.5 (0.04)
19-25	29.7 (0.2)	30.6 (0.2)
26-35	50.0 (0.2)	54.1 (0.2)
36-45	15.5 (0.2)	11.8
46-55	0.3 (0.02)	0.09
Payer status		
Public insurance	46.3 (0.5)	43.8 (0.4)
Private insurance	48.7 (0.5)	50.4 (0.4)
Self-pay	4.8 (0.1)	5.7 (0.1)
*Missing	0.2 (0.05)	0.2 (0.003)
Hospital region		
Northeast	15.1 (0.5)	16.1 (0.5)
Midwest	20.6 (0.5)	21.3 (0.5)
South	42.9 (0.5)	38.2 (0.5)
West	21.4 (0.5)	24.4 (0.5)
Hospital teaching status		
Rural	9.1 (0.2)	10.4 (0.3)
Urban Non-teaching	27.2 (0.5)	32.3 (0.5)
Urban teaching	63.7 (0.5)	57.3 (0.6)
Multiple births		
Yes	5.6 (0.1)	1.7 (0.01)

Delivery hospitalizations with pre-eclampsia are identified using ICD-9-CM:

642.4x = Mild/unspecified PE w/o preexisting hypertension

642.5x = Severe PE w/o preexisting hypertension AND HELLP syndrome in addition to PE

642.6x = Preeclampsia + Seizures = Eclampsia w/o preexisting hypertension

642.9x = Hypertension during pregnancy with no specification of the hypertension being transient/ gestational or preexisting