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## Challenges of Integrating an Evidence-based Intervention in Health Departments to Prevent Excessive Gestational Weight Gain among Low-income Women

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### Abstract

**Objective**—To examine health departments' (HD) capacity to adapt and implement an intervention to prevent excessive gestational weight gain.

**Design and Sample**—Seventy-seven stakeholders (nurses, nutritionists, social workers, health educators, health directors, and multilingual service providers) in nine HDs participated. A descriptive mixed methods approach was used to collect data at workshops held on site to introduce the evidence-based intervention (EBI) and discuss its adaptation.

**Measurements**—A survey was administered to assess the intervention's fit with the HDs context. Generalized logit mixed models were used to analyze the survey data. The discussions of adaptation were audiotaped and thematically analyzed to identify factors influencing implementation.

**Results**—The majority of stakeholders desired to participate in the training portion of the EBI, but they were reluctant to adopt it, and noted a lack of adequate resources. From the audiotaped narratives, three themes emerged: 1) Patient needs and resources, 2) Perception about adaptability of the EBI, and 3) The complexity of the EBI for pregnant populations.

**Conclusion**—Although the EBI was effective for low-income non-pregnant populations in southeastern regions, pregnancy and complex antenatal services make this intervention unrealistic to be adapted as a part of prenatal care at HDs.

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## Keywords

Pregnancy; Translation research; Dissemination research; Obesity

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## Introduction

When a pregnancy is accompanied by excessive gestational weight gain, mothers and the child experience an increase in risk for adverse outcomes. These include maternal gestational diabetes, newborn macrosomia, and possible future obesity and type 2 diabetes for both (Catalano & deMouzon, 2015). Recently, a number of interventions have been tested that aim to limit the risk for excessive gestational weight gain (Althuisen, van der Wijden, van Mechelen, Seidell, & van Poppel, 2013; Barakat, Lucia, & Ruiz, 2009; Byrne, Groves, McIntyre, & Callaway, 2011; Dekker Nitert, Barrett, Denny, McIntyre, & Callaway, 2015; Dodd et al., 2014; Harden et al., 2014; Harrison, Lombard, Strauss, & Teede, 2013; Hawkins et al., 2015; Hui et al., 2014; Kong, Campbell, Foster, Peterson, & Lanningham-Foster, 2014; Nascimento, Surita, Parpinelli, Siani, & Pinto e Silva, 2011; Renault et al., 2014; Rhodes et al., 2010; Ruiz et al., 2013; Thornton, Smarkola, Kopacz, & Ishoof, 2009; Vinter, Jensen, Ovesen, Beck-Nielsen, & Jorgensen, 2011; Wolff, Legarth, Vangsgaard, Toubro, & Astrup, 2008). Although evidence remains inconclusive, a meta-analysis study suggests that these interventions reduce overall risk by 20% (Muktabhant, Lawrie, Lumbiganon, & Laopaiboon, 2015). In these studies, some interventions utilize behavior modification techniques to increase physical activity and healthy eating in pregnant women, through group and individual counseling sessions. These interventions generally start early in the second trimester and run through pregnancy (Asbee et al., 2009; Bogaerts et al., 2013; Quinlivan, Lam, & Fisher, 2011; Thornton et al., 2009). They require attendees to visit clinics or off-site study locations multiple times, some of which are synchronized within regular prenatal care visits.

Since these lifestyle interventions are complex, they can be problematic when it comes to implementation and thus they require strong organizational commitment. Indeed, many interventions found to be effective in clinical trials fail to translate into real world patient care programs. In dealing with the intervention adaptations, limited evidence exists to guide stakeholders in different organizations on what works where and why. In the State of North Carolina where our study was conducted, county health departments provide prenatal care services and other maternal-child social programs for low-income women and their children. Prenatal care programs are, however, not provided uniformly and clients' and providers' cultural and racial compositions vary across health departments. Some HDs provide an antenatal clinic and nutritional counseling onsite, whereas others provide partial antenatal care services and the rest is provided by private clinics via partnerships. Funding mechanisms to support antenatal care and other supporting programs, such as the Special Supplemental Nutrition Program for Women Infants and Children (WIC) or Pregnancy Care Management (PCM), provide another layer of complexity. These conditions, in addition to diversity in populations whom they serve, suggest that incorporation of lifestyle interventions into multiple existing programs demands deliberate and systematic formative processes.

Evidence is further limited as to how these interventions are adapted and disseminated in clinical settings where multiple service programs already exist and resources are scarce. Facing these challenges, a potential approach is to modify an already existing evidence-based weight loss intervention that had been tested with non-pregnant low-income women, and then implement it among pregnant women in willing local health departments. The Weight Wise Program (WWP), which was tested and found to be effective at producing modest weight loss among low-income women (Samuel-Hodge et al., 2009), was selected as the evidence-based intervention for this study. This behavioral weight loss intervention was informed by the Diabetes Prevention Program (DPP, 2002) and selected dietary principles from the Dietary Approaches to Stop Hypertension (DASH) eating plan tested in the PREMIER trial (Appel et al., 2003). WWP is a comprehensive program including dietary, physical activity, and behavioral components shown to be effective in promoting modest weight loss (e.g., caloric restriction, moderate physical activity, self-monitoring, goal-setting, etc.). Six health departments participated in WWP. At each site, a dietitian, a nurse, four health educators were trained to use behavioral strategies to facilitate nutrition and physical activity behavior changes and deliver the weight loss intervention with fidelity. Altogether, 189 women were enrolled (average 51 years, BMI 37.3 lb., 53% non-Hispanic Black, and 43% were uninsured); 40% of participants lost 5% or more of their initial body weight. Delivering this intervention in HDs by incorporating into existing services and programs likely holds greater promise for reaching underserved pregnant women in a more sustainable fashion, than would implementation as an additional layer of a separate program.

The Consolidated Framework for Advancing Implementation Research (CFIR), in which Damschroeder and her colleagues reviewed available reports and categorized factors associated with implementation of new interventions, guided the formative processes required for structuring this intervention (Damschroeder et al., 2009). The purpose of this formative study was to examine the barriers and capacity of HDs to adapt and implement WWP for pregnant women to prevent excessive gestational weight gain.

## METHODS

A descriptive mixed methods approach was used to collect data at workshops. Eighty-five local health directors, covering 100 counties in the State of North Carolina, received a letter of invitation to participate in this study in February 2014. Eleven HDs (11/85; 13%) expressed interest, and nine of them participated. The workshop was conducted from June 2014 through April 2015. Workshops were audiotaped, and a survey was administered at the end of each of the workshops. The protocols were approved by the Institutional Review Board at the University of North Carolina at Chapel Hill (#14-0984).

### Workshop

Each workshop was conducted on site and was two hours long. Two investigators (SY and CS) conducted all workshops together with a research assistant. Agenda included an introduction (SY and CS), a presentation about behavioral intervention for weight management (CS) and lifestyle intervention in pregnancy (SY), a discussion session among attendees for adaptation, and a survey for participants. During the discussion, several

materials were presented to guide participants' planning for adaptation. A matrix of the WWP's core components (e.g., individual counseling, weekly group sessions, self-monitoring, feedback) and existing services at HDs were presented in a grid form to map out which core components aligned with existing programs and services and which components did not. Then, three potential formats for implementation were presented. The first option was to incorporate the WWP into existing prenatal care visits (Traditional format). The second option was to design a new group prenatal care format (Group format). The last option was to partner with another organization to ensure implementation of all WWP components (Community partnership format). Individual HDs were free to create their own format or combine any of the three, and were prompted to consider which format best suited existing HD structure.

## Survey

At the end of the workshop, a survey was administered. The survey asked participants to assess the fit between the intervention and their HD's capacity for adaptation, resources, training, and support for implementation. The 21-item survey used a 5-point Likert scale (strongly disagree, disagree, undecided, agree, and strongly agree) in four domains: **acceptance** (e.g., relevance, comfortable, or past experiences), **resources** (e.g., staffing, spaces, budget, or time), **training** (e.g., technical advice, protocol, or follow-up), and **support** (e.g., peers, administrator, or internet-base) (Bartholomew, Joe, Rowan-Szal, & Simpson, 2007). Cronbach's alpha values in the Bartholomew et al. study ranged from 0.72 to 0.89. In our study, Cronbach's alpha was equal to 0.87, indicating a high degree of internal consistency.

## Statistical Analysis

Generalized logit models were used to examine the association between study covariates and level of agreement for each survey question. Response choices in agreement were collapsed into three levels from the original five levels: agree (agree/strongly agree), undecided, and disagree (disagree/strongly disagree). Covariates included gender, birth year, race and ethnicity, type of occupation (e.g., nurse, dietician, health educator), administrative role (yes or no), and HD. To assess domain and covariate effects on level of agreement across survey questions, a generalized logit mixed model was fit to account for the correlation among responses within each subject. The level of significance was set to 0.05 in all analyses, which were implemented in SAS (Version 9.4).

## Thematic Analysis

The discussions of implementation during the interactive discussions were audiotaped and thematically analyzed to identify factors that influenced implementation (Hsieh & Shannon, 2005). The Consolidated Framework for Implementation Research (CFIR) provided conceptual guidance during analysis (Damschroder et al., 2009). The CFIR constructs were grouped into five levels of factors that influence implementation --- the intervention characteristics, the outer setting, the inner setting, the characteristics of individuals, and the process. Two of the co-authors (SY, AF) independently coded nine transcripts using Atlas.ti software (version 7). Coding discrepancies were discussed until coders reached a consensus.

## RESULTS

### Participants and Settings

From nine HDs, seventy-seven stakeholders (mean (SD) age: 45 (10.8) years) whose jobs were associated with maternal and child health services (nurses, nutritionists, social workers, health educators, health directors, and multilingual service providers) participated. There were two males (2.7%), two Latinos (2.7%), 18 Black non-Hispanics (24%), 7 American Indian/Alaskan (9.3%), and 49 White non-Hispanics (65%). Table 1 shows summary statistics for stakeholders' age, gender, race/ethnicity and occupation. The majority of participants were female (97.3%) and White non-Hispanic (65.3%), while African-Americans and American Indians/Alaskans represented 24% and 9.3% of stakeholders, respectively.

### Survey Results

**Domain and Covariate Effects**—The survey results showed that the ways individual items were rated differed significantly by domain. The majority of stakeholders desired to participate in the training. Compared with statements in the acceptance domain, stakeholders were more likely to agree with statements in the training domain than to disagree [log odds ratio (LOR) 2.21,  $p < 0.0001$ ]. However, stakeholders were also reluctant to adopt WWP for pregnancy. Specifically, compared with statements in the support domain, stakeholders were more likely to disagree with statements in the acceptance domain than to agree [LOR 2.10,  $p < 0.0001$ ] or remain undecided [LOR 1.98,  $p < 0.0001$ ]. Finally, the majority of stakeholders noted a lack of adequate resources. Compared with statements in the support domain, stakeholders were more likely to disagree with statements in the resources domain than to agree [LOR 3.73,  $p < 0.0001$ ] or remain undecided [LOR 1.26,  $p = 0.001$ ]. Table 2 provides estimates of LORs, i.e., differences in log odds, for each pair of domains that significantly differ from zero, along with their p-values and 95% confidence intervals (CIs).

**Items and Covariate Effects**—In assessing how the answers to each individual question (item) differed by covariate values, we found items in three domains (Acceptance, Resource, and Support Domains) that significantly varied by age. In the Acceptance Domain, older stakeholders were significantly less likely to agree with the item, “You expect the things you learned in this workshop will be used in your work, if your HD decides to move forward with an EBI.”, than remain undecided. The estimated log odds of agreeing with this statement relative to remaining undecided decrease by 0.1 for each year of stakeholder age [ $p = 0.01$ ; 95% CI = (-0.18, -0.03)]. In the Resource Domain, older stakeholders were significantly less likely to disagree with the item, “You have the time to do the set-up work required to adapt and implement an EBI.”, than agree or remain undecided. For each year of stakeholder age, the estimated log odds of disagreeing decrease by 0.07 [ $p = 0.03$ ; 95% CI = (-0.13, -0.01)] relative to remaining undecided and by 0.09 [ $p = 0.03$ ; 95% CI = (-0.16, -0.02)] relative to agreeing. Also, in the Support Domain, older stakeholders were more likely to agree with the item, “Staff members at your work are interested and supportive of implementing an EBI”, than disagree or remain undecided. For each year of stakeholder age, the estimated log odds of agreeing increased by 0.08 [ $p = 0.01$ ; 95% CI = (0.02, 0.15)]

relative to remaining undecided and increased by 0.12 relative to disagreeing [ $p=0.15$ ; 95% CI = (-0.04, 0.28)].

**Effects of Race/Ethnicity and Job Type**—Black/African-American stakeholders were more likely to disagree than agree any statement compared with American Indian/Alaskan stakeholders [LOR = 1.77,  $p=0.02$ ; 95% CI = (0.34, 3.20)]. In addition, Black/African-American subjects were more likely to disagree than remain undecided compared with White subjects [LOR= 0.86,  $p=0.05$ ; 95% CI = (1.72, 0.01)]. As opposed to remaining undecided, health educators were more likely to agree with any statement than nurses [LOR= 1.30,  $p=0.01$ ; 95% CI = (0.35, 2.24)], nutritionists [LOR = 1.39,  $p=0.03$ ; 95% CI = (0.13, 2.65)], and social workers [LOR= 1.32,  $p=0.02$ ; 95% CI = (0.23, 2.42)].

### Thematic Analysis of Discussion Session Transcripts

The transcripts of the discussion sessions were analyzed according to the CFIR model (Damschroder et al., 2009). We identified three areas: patient needs and resources (33 quotations); stakeholders' perception about adaptability of the WWP (31 quotations), and complexity of the intervention (10 quotations). Participants identified lack of transportation, substance abuse and mental health complexities among pregnant women, and inconvenience of services for the patient as important considerations in the area of Patient Needs and Resources. In second area of the Stakeholders' Perception about Adaptability of WWP, participants pointed to inconvenience to patient and logistical difficulties as potential problems. Stakeholders found that liabilities related to the exercise classes, staffing limitations and budget cuts were contributing factors in the third area of the framework, the Complexity of the Intervention. Given the complexities and problems the stakeholders found in WWP adaptation to their health departments, it is unlikely to be a realistic intervention to implement.

**Patient Needs and Resources**—The patient needs and resources to be considered included transportation issues due to rural environments, the characteristics of the population—a large portion of pregnant women with mental health issues including substance abuse—and the stakeholders' perceptions and observations about patients' convenience of appointments. A combination of being in a rural area and the lack of access to transportation made the situation a prohibiting barrier. Comments from the stakeholders included: “pregnant women are far away from town centers- transportation is an issue”; “Part of our problem is, we are a very spread out county”; “we have a lot of transportation issues”; and “We don't have a public transportation system, and we don't have taxi services.”

Another grave combination in the area of patient needs was that a large portion of the population that the stakeholders serve, experienced substance abuse and mental health illnesses. These acute care needs superseded the need for preventive lifestyle intervention as evidenced by the following statements: “There are many clients with drug dependence issues and mental health issues, that, during pregnancy priorities might be misaligned. “We are dealing with a lot of ladies who are bipolar, have substance issues.” The fact that patients were inconvenienced was also repeated: “it has to be outside of their appointment time. You

are lucky if you can keep them there an hour. I've got them stomping and screaming at 45 min.” and “there are high percentage of no shows.”

**Stakeholder's Perception about Adaptability of the WWP**—Stakeholders first identified a group care format such as centering or an add-on to WIC as viable options: “WIC would be the most obvious way to tag on educational information about weight”; “...the last 30 minutes of the Centering session could be used to introduce weight wise material.” However, the stakeholders quickly addressed logistical difficulties with these options: “clients were already waiting up to 3 hours to see WIC”; and it “takes about 30 minutes for nurse, 15 minutes for lab, 30 minutes for doc, overall it takes 3 hours.” These quotations alluded to problems with efficiency in existing programs. Stakeholders also implied that there would be problems with the adaptability of the existing programs: “but Centering has strict rules and guidelines”; “have had problems with scheduling and no shows for centering.”; and “...with WIC appointments, it's, you know, 15 minutes and most of that's not even really discussing nutrition.” In addition, the timing of WIC programs and the WWP could be incompatible: “they come in for routine prenatal care around 12 weeks, they are interviewed by the nurse then see one of the providers, then they go through WIC”; and “by the time they get on WIC they are in their second or third trimester”; “Not enough appointments in prenatal care- women are often not started on WIC till late in pregnancy, and its hard to do any more counseling than what is already being done.”

**Stakeholders' Perceived Complexity of the WWP Implementation**—Two phenomena emerged in this group of statements. The first was a liability related to recommended physical activity for pregnant women, and the second was the disruptiveness to add any program when financial and organizational resources were stretched out. Statements included: “the exercise piece is almost, to me, more hands-off--. Like, people do not want to touch a pregnant woman. They don't want to have any liability for that.” There was also discussion about staffing and staff retention: “Staffing would play a role in the ability to create monthly classes and finding providers (mainly RNs) to teach these classes”; and “there have been budget cuts, lack of personnel to deliver counseling.”

## DISCUSSION

Although health departments have found WWP was effective at promoting weight loss among low-income non-pregnant women in the South, the results of this pilot study suggest that WWP may not be acceptable or feasible for use with pregnant women. Stakeholders uniformly recognized the need for weight management interventions for low-income pregnant clients. However, they reported that they lacked the resources necessary to implement the intervention. The issue of lack of resources emerged consistently in the survey and the discussion sessions. Stakeholders had to navigate layers of requirements imposed by existing programs. They reported that their hands were “tied to” county, state and federal policies, regulations, and budgets, which may not necessarily reflect evidence-based public health needs.

The layers of requirements also affected prenatal care services for low-income women, which were often lengthy and fragmented. Because pregnant women often were asked to

stay for a long time (up to 3 hours) and to visit repeatedly for various protocols and programs, stakeholders were unwilling to add additional components to women's visits. Stakeholders also expressed a desire to not add visits for women who often had to travel long distances to get care. This lack of resources juxtaposed with patient inconveniences resulted in the final consensus by many that the proposed intervention was neither feasible nor acceptable.

The Department of Human Health Services in North Carolina provides maternal and child health services through five divisions: Division of Medical Assistance, Division of Mental Health/Developmental Disabilities/Substance Abuse Services, Division of Public Health, Division of Social Service, and Division of State Operated Facilities. Coordinating services within the requirements of these five divisions and other programs creates barrier adopting innovative programs and improving care.

Lifestyle interventions can reduce the risk for excessive gestational weight gain in overweight and obese pregnancy by 20% (Muktabhant et al., 2015). In several recent randomized trials with overweight or obese pregnant women, significant reductions in gestational weight gain in the intervention groups were reported (Asbee et al., 2009; Bogaerts et al., 2013; Harrison et al., 2013; Quinlivan et al., 2011; Thornton et al., 2009; Vinter et al., 2011; Wolff et al., 2008). However, these studies were implemented in high resource antenatal care clinics. Few studies have tested community-based lifestyle interventions for pregnant women who were overweight or obese (Hui et al., 2014; Kong et al., 2014), and those studies have not been effective in limiting gestational weight gain with overweight or obese women.

Most of studies that reported significant reduction on gestational weight gain were executed as a part of prenatal care, and direct care providers (doctors and midwives) took the key roles as interventionists. For example, Quinlivan et al. conducted a randomized trial (n = 124) in a hospital clinic in a socially disadvantaged area in Australia (Quinlivan et al., 2011). The study applied a simple intervention embedded in routine clinic work. Prior to a routine visit by a physician/a nurse-midwife, each participant spent 5-minutes on a food survey for the day before. Subsequently, the doctor or nurse-midwife used the data to provide a short behavior intervention during the visit. All of these studies were short in terms of each interaction, convenient in that the intervention encounters were woven into routine prenatal care, and repeated at each prenatal care visit. From these viewpoints, group prenatal care may need to be more carefully examined vis-à-vis evidence-based intervention for low-income women populations. Group prenatal care was often mentioned as an "ideal" venue, but it was also noted to difficult to schedule in a shorter period.

In summary, geographic spread and lack of transportation in rural areas will remain a significant barrier to access to prenatal services. Similarly coordination of multiple services needs innovative solutions in order to expand the capacity of Health Departments to provide efficient and effective services. Women centered care calls for short, simple, convenient, and empowering experiences at local Health Departments. Partnering with community organizations and local hospitals are also needed to address logistics. Before adding one more program, existing services need to be streamlined to make each visit shorter and



simpler so that both pregnant women and their clinicians can use their limited time effectively. Existing programs impose an inconvenience to the target populations and logistical issues in implementing the intervention. At the same time, a critical need exists for adaptable weight management interventions that can be integrated into routine prenatal care for low-income pregnant women.

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**TABLE 1**

## Baseline Data of Stakeholder Participants and Health Departments

<b>Variable</b>	<b>Median (IQR<sup>1</sup>) or N (%)</b>
Median age in years (IQR)	47 (18)
N (%)	
<b>Gender</b>	
Female	75 (97.30)
Male	2 (2.70)
<b>Race/Ethnicity</b>	
American Indian/Alaskan	7 (9.33)
Black/African-American	19 (24.00)
White	50 (65.33)
Other	1 (1.33)
<b>Health Department<sup>2</sup></b>	
Davidson	6 (7.79)
Gaston	10 (12.99)
Granville-Vance	13 (16.88)
Guilford	11 (14.29)
Hoke	6 (7.79)
MTW	6 (7.79)
Nash	4 (5.19)
Onslow	5 (6.49)
Robeson	16 (20.78)

<sup>1</sup>IQR = interquartile range

<sup>2</sup>Health Department = Davidson, Gaston, Guilford, Hoke, Nash, Onslow and Robeson are County Health Departments, and Granville-Vance and MTW are District Health Departments.

**Table 2**

Estimates of significant log odds differences, p-values, and 95% CIs for four domains

<b>Domains</b>	<b>LOR estimate, p 95% CI (disagree vs. agree)</b>	<b>LOR estimate, p 95% CI (disagree vs. undecided)</b>	<b>LOR estimate, p 95% CI (agree vs. undecided)</b>
Resources vs. Support	3.73, p < .0001 (3.01, 4.46)	1.26, p = .001 (0.51, 2.00)	-2.57, p < .0001 (-3.03, -2.1)
Resources vs. Training	3.84, p < .0001 (3.15, 4.54)	1.05, p = .005 (0.32, 1.77)	-2.91, p < .0001 (-3.37, -2.44)
Acceptance vs. Support	2.10, p < .0001 (1.42, 2.79)	1.98, p < .0001 (1.21, 2.74)	

  

<b>Domains</b>	<b>LOR estimate, p 95% CI (agree vs. disagree)</b>	<b>LOR estimate, p 95% CI (agree vs. undecided)</b>	<b>LOR estimate, p 95% CI (disagree vs. undecided)</b>
Training vs. Acceptance	2.21, p < .0001 (1.57, 2.86)	0.51, p = .02 (0.08, 0.94)	-1.76, p < .0001 (-2.50, -1.02)
Acceptance vs. Resource	1.63, p < .0001 (1.18, 2.08)	2.40, p < .0001 (1.95, 2.85)	0.72, p = .003 (0.25, 1.19)