Coordination of Care between WIC Nutritionists and Pediatric Physicians at Geisinger Health System

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1 ABBREVIATIONS USED IN THE PROTOCOL

Abbreviation	Term
AAP	American Academy of Pediatrics
AE	Adverse event
BMI	Body Mass Index
EHL	Early Healthy Living/Lifestyles
EHR	Electronic Health Record
GIRB	Geisinger IRB
GMC	Geisinger Medical Center
GWV	Geisinger Wyoming Valley
HALF	Healthy Active Living for Families
ID	Identity
IRB	Institutional Review Board
MRN	Medical Record Number
PCP	Primary Care Provider
PHI	Protected Health Information
PSL	Pediatric Service Line
SAE	Serious adverse event
SES	Socio-economic status
WIC	Women, Infants, and Children Program

2 ABSTRACT

This project aims provide better care and improve population health through coordination of community and clinical services for a high-risk, vulnerable population of infants and mothers. Specifically, this project will coordinate care for Geisinger patients who are also participating in the Women, Infants, and Children (WIC) Program. More than half of the United States population participates in the federally-funded WIC program, originally established in 1971. Mothers of WIC participating infants receive nutrition education at least 5 times during the infant's first year of life and during which time they also receive nutrition education from the infant's physician at least 6 times during well child visits. Mothers report receiving inconsistent and conflicting nutrition messages, particularly about growth, and this is a point of their frustration with community and clinical care. Poor messaging impedes knowledge, behavior, and attitudes toward healthy eating and growth, and may be associated with higher rates of rapid weight gain in infancy and subsequent childhood obesity. This project aims to improve consistency of nutrition, feeding, and growth messaging through training and coordination across WIC community and Geisinger clinical settings.

This prospective study will have two sequential phases 1) observational study; 2) interventional randomized controlled trial. Mother/guardian-infant pairs of infants that have a Geisinger primary care provider in the Geisinger Pediatric Service Line and who participate or are eligible and plan to participate in WIC will be enrolled in a single phase of the study. The purpose of the observational phase is to obtain a baseline of participant measures with usual, uncoordinated care in the Pediatric Service Line and WIC. The purpose of the randomized controlled trial is to evaluate the differences between groups that experience coordinated versus uncoordinated care. Two phases are necessary because the Geisinger Pediatric Service Line (PSL) implements a standard of care, known as Early Healthy Living/Lifestyles (EHL) screening, that is not implemented nationally and potentially limits the generalizability of study findings. In prior studies (IRB# 2012-0363), the EHL screening tool has been evaluated. The EHL screening is undergoing modifications to improve health literacy, numeracy, and alignment with evidence-based recommendations. Thus, the PSL will temporarily turn off the EHL screening for these revisions and staff training, thus allowing for an observational phase of usual, uncoordinated care. The updated EHL screening tool (Attachment 1) will be made available as standard of care in the PSL when phase 2 begins [Note that this is a clinical screening tool and not a study questionnaire]. Mother/guardian-infant dyads in both groups of phase 2 will be exposed to the EHL screening but only one group will have coordinated care with WIC. Knowledge, behavior, and attitudes are expected to be more desirable among mother/guardian-infant pairs with coordinated care when compared to those receiving status quo. Additionally, infants with coordinated care are expected to have slower (as opposed to rapid and risky) weight gains in comparison to infants with uncoordinated care. Mothers/guardians are expected to indicate greater satisfaction with coordinated versus uncoordinated care.

3 BACKGROUND AND SIGNIFICANCE

Rationale: WIC nutritionists and PCPs are viewed as credible and trustworthy sources of parenting and feeding information during the first few years of life.[1] Two issues call for the need to coordinate care and messages: 1) WIC mothers, a high risk population, are regularly exposed to care in two settings (health care and community) but the care, i.e., preventative education, is not coordinated resulting in conflict in messaging and confusion among WIC mothers; and 2) care in both settings is oriented toward primary prevention with similar institutional expectations and situational challenges that could be overcome by coordination between settings. A series of reports from the Institute of Medicine, the American Academy of Pediatrics, and the White House Task Force on Childhood Obesity call for a coordination of efforts locally, between primary care and community programs like WIC, on issues such as consistent messages to enhance childhood obesity prevention.[2, 3, 4]

Existing knowledge: WIC mothers and children experience expert-level preventive care, i.e., nutrition messages and parenting education, in two distinct settings- community and health care, but care is not coordinated and ultimately is perceived as inconsistent among WIC mothers.[5, 6, 7] Inconsistent messages contribute to parent confusion about effective preventive practices. Adding further complexity to mother's learning is the need to synthesize inconsistent information with well-intentioned but often conflicting, inaccurate advice available on the web that is often not evidence based.[8, 9] This cluttered context for learning in the midst of an immediate need for credible and consistent information calls for coordinated care through WIC nutritionists and PCPs to exponentially enhance prevention opportunities.[10]

Gaps: Recent national guidelines that address prevention and management of childhood obesity and its comorbidities[11, 12] recommend assessing/monitoring to occur in primary care settings, recognizing that health care-centered efforts alone cannot affect change, but they can complement and potentially enhance public health efforts such as WIC.[13] Because obesity is a complex, multifactorial condition, efforts to leverage and more importantly, coordinate care and touch-points across settings are likely to offer the best opportunities for prevention. WIC nutritionists and PCPs share an appreciation for obesity prevention despite shared barriers to prevention care: limited time, training/skill, resources, and lack of parent interest.[14] In the context of advanced health information technology, Geisinger has reliable approaches and tools that are available and tested to reduce these barriers with automation, data synthesis, and risk algorithms to improve quality of care. Further, these tools have been used to align preventive care delivery with community partners, consistent with the principles of the Chronic Care Model,[15] to reliably and effectively improve patient outcomes and reduce downstream costs associated with uncoordinated and fragmented care.[16-18]

Our solution-oriented approach recognizes the opportunity to coordinate care across settings, using technology and workflow redesign solutions to coordinate care between community and health care settings to improve health outcomes for a high-risk population. Our coordinated care

model aims to support mothers and families to reduce early childhood obesity risk with preventative educational care plans and consistent messages as central components. Developing a system for coordinated care and communications for WIC and PCPs could be an effective and efficient way to decrease conflict in messaging, increase dose, and reinforce preventative education to optimize the effectiveness of early-life intervention on parenting behavior and child health outcomes.

Disease/Diagnosis: Data from the National Health and Nutrition Examination Survey demonstrate the need for early intervention to prevent obesity: 1 in 10 infants and toddlers are obese[19] with those from lower socio-economic (SES) households at greater risk than their higher-SES counterparts.[20-26] Pennsylvania is 1 of 3 states to demonstrate significant increase in obesity rates among low-income preschoolers (aged 2-4 years) from 2008-2011.[27] Further, Black/African American children showed divergence from white/Caucasian children in BMI growth trajectories by age 5 years even when controlling for known economic status, calling for greater attention to reduce health disparities.[28] Excessive rapid weight gain during infancy also predicts obesity later in life,[29-32] increasing the risk for health disparities.[31, 33-35] Thus, infancy is a sensitive period when parents can and should intervene to establish healthy patterns that may last a lifetime to combat the obesity epidemic.[36] These issues provide strong justification for focusing efforts on obesity prevention in low-income and racial/ethnic minority group mother/guardian-infant dyads, starting in early life in Pennsylvania.

Population to be Studied: Mother/guardians of newborn Geisinger patients who are also WIC eligible or participants.

Endpoints: Process outcomes include consistent messaging, patient engagement and satisfaction, maternal knowledge, attitude, self-efficacy, and maternal and child behavior; the primary impact outcome is rate of infant weight gain.

Significance: This study will generate data demonstrating that a coordinated care model between community and health care settings is an effective strategy to positively impact maternal and child health outcomes, specifically obesity prevention which is arguably the most significant health issue facing millions of children with lifelong health, social, and economic effects. In addition, we will demonstrate that an adapted responsive parenting intervention that is tailored to the needs of each mother-infant dyad and includes coordinated care between health care providers and long-standing public health nutrition program will significantly improve diet quality and obesity prevention outcomes in children. Together, this evidence will support public health/policy efforts that focus on coordinated care models for exponential health benefits and strategies to reduce early pediatric obesity.

4 HYPOTHESIS AND SPECIFIC AIMS

4.1 Hypothesis

The project tests the hypothesis that an individually-tailored, responsive parenting obesity prevention intervention that coordinates care provided by WIC nutritionists and primary care providers will be more effective than usual care at 1) delivering consistent messages and 2) changing maternal and infant behavior to 3) reduce/prevent obesity in infants.

4.2 Specific Aim 1

Establish the efficacy of an individually-tailored behavioral intervention designed to prevent overweight at age 1 by providing coordinated, personalized care on responsive parenting across multiple settings.

4.3 Specific Aim 2

Conduct mediation analyses to improve understanding of how the intervention components, parent factors, and child behaviors influence rapid weight gain and to explain differential responses to our responsive parenting intervention that coordinates care across settings (WIC clinics, PCP).

5 PRELIMINARY DATA

The proposed research was guided by the social cognitive theory[37, 38] and uses the responsive parenting framework[39-41] to increase parenting self-efficacy and prevent excessive weight gain in infancy. It is well evidenced that parents play an integral role in shaping children's lifestyle behaviors.[42] Responsive parenting, which involves prompt, contingent and appropriate interaction with the child, has been associated with desirable outcomes ranging from cognitive and psychosocial development to protection from disease and mortality.[41, 43] For example, maternal responsiveness in early childhood has been associated with social competence, fewer behavioral problems,[44] increased intelligence and cognitive growth.[45] In a randomized controlled trial that taught first time mothers how to parent responsively, infants in the intervention had lower weight status at 1year when compared to control participants.[46] These infants also slept longer, had higher levels of emotional self-regulation, and had mothers who were more responsive and reported higher parenting competence.[46-48] In addition, preliminary data reveal that the responsive parenting intervention successfully prevented excessive rapid weight gain during the first 6 months of life for both predominately breastfeeding and formula feeding mothers. However, these studies were conducted in a predominately white, affluent, low-risk sample. In the proposed study, we will supplement the HALF curriculum developed by the AAP, with our responsive parenting curriculum, following cultural sensitivity refinements, and test the efficacy of this intervention in a coordinated care model, targeting low-income families and families from racial/ethnic minority groups.

6 STUDY DESIGN

6.1 Description

This prospective study will have two sequential phases 1) observational study; 2) interventional randomized controlled trial. In phase 2, qualifying participants will be randomized 1:1 to receive either Treatment A or Treatment B.

6.2 Study Population

6.2.1 Approximate Number of Subjects

Approximately 715 Geisinger subjects will participate in this study, 15 mother/guardian-infant pairs will participate in the observational phase and a total of 350 mother/guardian-infant pairs will participate in the RCT phase. The study team has accounted for participant drop-out by planning to enroll 350 Geisinger subjects, recognizing that a to meet power calculations a total of 15 observational control dyads and 350 intervention/control dyads are needed. Mother/guardian-infant pairs of infants that have a Geisinger primary care provider in the Geisinger Pediatric Service Line and who participate or are eligible and plan to participate in WIC will be enrolled in a single phase of the study. Pregnant women who are eligible for or participate in WIC who also intend to have their newborn receive care from a Geisinger primary care provider in the Geisinger Pediatric Service Line will be enrolled in a single phase of the study.

6.2.2 Inclusion Criteria

Mother/guardian-infant pairs of infants that have a Geisinger primary care provider in the Geisinger Pediatric Service Line and who participate or are eligible and plan to participate in WIC will be enrolled in a single phase of the study. Inclusion criteria:

- Parent of child between the ages of birth up to 6 months of age, preferably the mother. If mother is not available, then father/guardian can be enrolled.
- Child must be patient of Geisinger Health System primary care provider in the Pediatric Service Line. (Phase 2 only: child must be a patient Partners in Pediatrics, Geisinger Health System primary care provider in the Pediatric Service Line)
- Mother is English speaking.
- Child must be eligible for WIC Program in Pennsylvania. (Phase 2 only: child must be eligible for WIC Program in Luzerne County, Pennsylvania).
- Infant birth weight ≥2500 grams.
- Infant gestational age ≥37 weeks.
- Infant is a singleton birth.

Pregnant women (≥27 weeks gestation) who are eligible for or participate in WIC who also intend to have their newborn receive care from a Geisinger primary care provider in the Geisinger Pediatric Service Line will be enrolled in a single phase of the study. Inclusion criteria:

- Mother is English speaking.
- Mother must be eligible for WIC Program in Luzerne County, Pennsylvania.
- Post-delivery, the infant birth weight ≥2500 grams.
- Post-delivery, the infant gestational age ≥37 weeks.
- Post-delivery, the infant is a singleton birth.

6.2.3 Exclusion Criteria

Exclusion criteria include:

- Mother/guardian is planning to leave the county where she was enrolled within 6-9 months.
- Mother/guardian is less than 18 years of age.
- Mother is older than 55 years of age.
- Infant death.
- Infant is greater than 6 months of age.
- Mother/guardian does not have a working telephone or way to communicate with study staff.
- Cognitively impaired adults (determined subjectively by recruiting research staff, if parent is unable to answer verbal questions from research staff).
- Mother has condition that would affect postpartum care or her ability to care for her newborn [e.g., narcotic drug use: heroin, cocaine, meth, pain pills, etc.], or major depressive disorder.
- Mother did not receive prenatal care from, nor did she deliver at, Geisinger, but she does screen positive for major depressive disorder via the following process:
    - Study staff administers PHQ2 questionnaire and mother scores as high risk (≥4), subsequently study staff administers full PHQ9 questionnaire.
    - In the event that the mother scores ≥10, the study staff will contact Geisinger Psychologist (O'Dell) who will call the mother within 24 hours and, if suicide risk is indicated, will keep the mother on the line while 911 services are contacted.
    - In the event that the mother scores <10 on the PHQ9, the study staff will proceed with enrolling the mother into the study and mail to the mother a list of behavioral health services.

- Infant will be adopted.
- Infant has a congenital anomaly or neonatal condition that significantly affects feeding and/or growth (e.g., cleft palate, complex congenital heart disease, etc.)

6.3 Recruitment

Phase One: Observational Study

Trained research staff will visit Geisinger Medical Center (GMC) and Geisinger Wyoming Valley (GMC) hospitals each weekday, Monday-Friday, to identify mothers who have delivered infants in those facilities within the previous 24 hours. A Partial Waiver of Authorization for Recruitment is requested to review the mother and newborn electronic medical record for initial eligibility screening. Pre-screening items are listed in Attachment 2 along with the recruitment script that research staff will use when they visit potentially eligible mothers of newborns, discuss the study, and ask the mother some brief screening questions about if she and her infant are participating in WIC, or if they are eligible to receive WIC benefits, and to learn of the mothers intended clinic for pediatric care for the newborn child. For those potential subjects who delivered on Friday or Saturday and may have been missed at the hospital, study staff will also generate patient lists each week for eligible children who will be receiving well child care at PSL clinics, to identify potential participants who are scheduled for a well child visit, and contact will be made by a research staff member at that clinic prior to the infants well child visit. Only study staff will have access to the patient list; only approved information that is necessary to determine if the mother/infant dyad is eligible for the study will be extracted from electronic medical records.

Phase Two: Randomized Controlled Trial

The recruitment process for Phase Two is the same as Phase One with the exception of adding inclusion criteria, as indicated in section 6.2.2. Additionally, a flyer approved by Geisinger Corporate Communications will be distributed via social media and in WIC clinics to allow potential participants to opt-in to recruitment by providing their contact information to the study team. Study staff will contact potential participants for eligibility screening.

6.4 Study Duration

6.4.1 Approximate Duration of Subject Participation

Subjects will participate in the study for approximately 30 minutes per survey packet and there are 4 sets of survey packets for approximately 2 hours of participant time.

6.4.2 Approximate Duration of Study

Phase One: Observational Study

Phase One, Observational Study will be completed in approximately 11 months due to rolling recruitment. The end of the study is marked by the last survey packet at 7 months.

Phase Two: Randomized Controlled Trial

Phase Two, Randomized Controlled Trial will be completed in approximately 18 months due to rolling recruitment. The end of the study is marked by the last survey packet at 7 months. Study participants who are enrolled at 28 weeks gestation may be in the study for an additional 2 months.

6.5 Procedures

Phase One: Observational Study

Potential participants will be approached by a trained IRB-approved research assistant during their stay at GMC or GWV labor and delivery to inquire if the patient and their infant would be interested in enrolling in the research project. The research assistant will explain the study in-depth to the patient to ensure they understand the scope of the project. In addition, the patient will given a packet containing an information sheet which explains the contents of the study packet, two copies of the consent form of which one will be signed and kept by the study team and the other the patient will sign and take home, a flyer outlining the WIC program and how to enroll, and information regarding signing up for MyGeisinger to assist in monitoring their child's care. Should the patient opt to sign-up for MyGeisinger during their stay in Labor and Delivery, each research assistant will be equipped with a Geisinger iPad on which the RA can enroll the patient in the MyGeisinger system.

Enrolled participants will be asked their preference for receiving survey packets, either by United States Postal Service or an emailed link to an electronic survey system, REDCap. Participant preference for hard versus electronic survey packets, respectively, will be obtained after consent and during the enrollment process. Participants completing survey packets electronically will be directed to the Pennsylvania State University's REDCap. Hard copy survey packets will be mailed to Dr. Savage Williams, Penn State University. Participants will complete an enrollment packet (Attachment 3) during the initial screening and recruitment into the research study followed by survey packets at 2 months (Attachment 4), 5 months (Attachment 5), and 7 months (Attachment 6), as well as a survey regarding patient perception of coordination of care and personalized care, corresponding with duration of study participation. Each mailed survey packet will be accompanied by a cover letter instructing the parent to return the survey using the pre-paid stamped envelope. If the mother/guardian is unable to complete the survey in the hospital, the survey packet will be distributed, per participant preference, and returned within one week. Parents that complete the 2, 5 and 7 month survey packets will receive a $50 gift card for their

time. Parents will be sent a thank you letter accompanying the gift card to recognize their time spent completing the study surveys. If the parent completes all survey packets at each time points indicated above, they will receive an additional $50 gift card to thank them for completing all study surveys.

Mother/guardian-infant dyads will attend pediatric well child visits, per standard of care, and WIC visits in a normal, naturalistic fashion. Pediatric participant data will be extracted from their electronic health records and WIC records to document visit frequency, physical exam, and feeding or nutrition-related metrics. To lessen the burden upon mother of the pediatric patient, the study will extract parent enrollment measures that are currently collected in the electronic medical record at Geisinger. These measures will not include any PHI elements. The data extracted as part of the research study will include anthropometric measures such as height and weight. These measures were originally included in the enrollment packet as questionnaires, however, due to sensitive time for the mother and to reduce burden this information will be extracted from the EHR. There will not be coordination of these data between WIC and Geisinger PCPs during the observational study. Participants will know that they are enrolled in the observational study but PCPs and WIC will be blind to their participation in the study.

Per requests by Geisinger Women's Health, study flyers will be hung in Women's Health as a means to make potential participants aware that they may be asked to enroll in the study during their time in Labor and Delivery.

Phase Two: Randomized Controlled Trial

Procedures for Phase Two, Randomized Controlled Trial are the same as those for Phase One, Observational Study except that: 1) participants will be randomized to the treatment or control groups following participant consent/authorization/agreement. An electronic program will be used to randomly assign patients to a group; 2) Pediatric participant data will be extracted from their electronic health records and WIC records to document visit frequency, physical exam, and feeding or nutrition-related metrics 3) Pediatric participants will be given educational materials based on upon their recruitment in the intervention/control arm. These data will be electronically shared between WIC and Geisinger PCPs for the purpose of coordinating care for a 6 month intervention period and then disabled. Geisinger and WIC will share agreed upon data elements using a secure, File Transport Portal (FTP) site daily. Verification of shared participants between GHS and WIC will be authenticated with mother's name, mother's telephone number, date of birth, date of delivery, infant name, and birth date. To increase the likelihood of intervention arm participants enrolling in WIC, the mother's telephone number will be transferred. The telephone number will be used by WIC to contact the participant and schedule an initial visit with a WIC nutritionist in Luzerne County. Following authentication, random participant IDs will be assigned to protect confidentiality; and 3) Participants will be blind to group assignment, however PCPs and WIC will know group assignment because shared data for participants in the treatment group will be electronically displayed in the EHR at Geisinger and the QuikWIC

system at WIC for the purpose of coordinating care. A trained research assistant or project coordinator will access the participating patient's medical record for the purposes of creating a documentation encounter in which the data collected from the QuikWIC system will entered. This data will be stored in EPIC flowsheet rows. The data will then be displayed for the provider in the progress note to assist in the coordination of care. All participants will complete an informed consent form which will include PHI elements being shared. Throughout enrollment in the study, intervention participants will receive a phone call from a trained Geisinger nurse to assist with providing educational guidance for their child (feeding, sleep, tummy time, etc.) We anticipate this call will last around 10 minutes. To best serve the pediatric patient population enrolled in this RCT, the study team will be providing both intervention and control participants with educational materials that were developed in part by the AAP, but also vetted studies which were conducted at The Pennsylvania State University. Educational materials will be distributed to WIC for use during nutrition visits, as well as, provided during enrollment into the study and sent via mail. The purpose of the educational materials is to provide added value to parents enrolled in the study and assist them in providing care for their infant. To ensure participants are able to attend their scheduled WIC nutritionist appointments, the study team will provide a small business-size colored card at enrollment with the WIC contact information to reschedule their appointments if the need arises. The reschedule information is as follows: 1-570-826-1777 or Toll free- 1-800-367-6347 Extension 244. In addition, during the 7 month enrollment period, the EHL survey (standard of care) will not fire for control participants, this will be sent via mail included in the 2,5,7 month survey packets. Post-enrollment, the study team will also mail a postcard to participants thanking them for participating in the study and a short high level overview of their participation. The post-card will also serve as a reminder that the participant will be receiving surveys at 3 time points throughout their enrollment. For intervention patients that do not complete the EHL screener at their regularly scheduled WCV, the study team will send a mailed copy of the EHL survey to the home for the parent to complete. To ensure that intervention participants are presented the opportunity to complete the EHL screener, the study team will include a paper copy of the screener in the participant's enrollment packet. The survey will only be included should the participant choose not to sign-up for MyGeisinger and prefer to complete the survey on paper Enrollment in MyGeisinger is not an inclusion/exclusion criteria. For participants that are given the EHL screener at enrollment, once the screener is completed at home, the participant will be asked if they could please bring the survey with them to their initial WIC visit. The screener will be used to better inform the WIC nutritionist visit and does not contain PHI. The screener will then be collected by the WIC nutritionist and transferred electronically back to Geisinger study staff. This data is essential in comparing intervention and control participants. To ensure that our participants are able to receive their survey packets in a timely manner, whether by mail or email as indicated by the participant, a study staff member will contact the participant via phone call. This phone call will consist of confirmation of receipt of survey, and to allow the participant to ask any questions that have arisen through the process of reading the questionnaire and answering the questions to the best of their ability. If the study team is unable to reach the participant via phone, a voicemail will be left asking the participant to call the study team back if they did not receive their survey. Participants will also receive an

email or mailed reminder which includes the survey to complete should it not be returned within a timely manner. The mailed reminder will be sent to the participant with a self-addressed stamped envelope in which to return the survey. The participant is not required to return the re-mailed survey if they have completed the initial copy which was sent. Once the survey is received from the participant, a $50 will be sent thanking them for their time and participation. Information collected in the study surveys is time sensitive and directly related to the child's age at the 2,5,7 month time periods, thus it is important to receive the data in a timely manner. No data will be shared between WIC or PSU (as indicated in the above observational study) until an informed consent form is completed and the participant understands their role in the study and what will be shared.

The study team also plans pursue recruitment of eligible pediatric patients at newborn visits in participating Partners in Pediatrics clinics. Due to the nature of recruitment in a labor and delivery environment, it is not always possible to capture all eligible participants, which introduces bias, and more than a third of the potential participants pre-screened are ineligible due to a non-participating pediatrician, and nearly a third of potential participants that receive direct recruitment are also not eligible due to a non-participating pediatrician. By instituting recruitment prior to delivery and at the newborn visit with participating pediatricians, the study team hopes to equitably capture the largest eligible population. To achieve this goal, the study team will provide WIC and Partners in Pediatrics sites with a study flyer, WIC income eligibility flyer, and a short information sheet to provide to eligible participants. The approved prenatal recruitment flyer will also be distributed via social media. A data analyst in the Obesity Institute will pull a recruitment list that screens all Geisinger patient-participants for eligibility and provide this to the study team daily. A research assistant on the project will then screen the patient's medical record via chart review to ensure all inclusion criteria are met and there are no additional exclusions (adoption, drug use, etc.). For patients screened as eligible, the study team would contact the regional director for pediatrics who would notify clinic staff to distribute materials at the 3-5-day newborn visit. For prenatal recruitment of non-Geisinger patients, interested participants will contact the study team. Afterwards, the study team will follow-up via phone (mobile or home) or email or mail to arrange to or discuss the study with the potential participant. If interested, the study team will then send two copies of the consent form, the enrollment survey, a pre-paid stamped envelope, and instructions on how to complete and return the consent form and survey. During the course of the phone call, should the participant elect to complete the enrollment survey via over the phone, the study staff member will record the survey responses utilizing the RedCap system which stores all participant survey results. In addition, the participant may also elect to receive the consent form and survey electronically via RedCap, during their conversation with the research assistant. If the participant chooses to receive the e-consent, an electronic version of the WEE consent form and enrollment survey will be send to the participant's email that they provide on the phone. The consent will be emailed and stored securely in the RedCap system, which is only accessible to approved GHS study team members. If the participant does not complete the e-consent in a timely fashion, the RedCap system will send automated reminders. Once the participant returns the consent form or e-consent form and

completed survey, they will be enrolled into the study and care will resume as noted above based upon whether the participant is randomized to the intervention or control arm.

To ensure providers are effectively utilizing the coordination of care display module that was built within EPIC, the study team plans to conduct physician shadowing at participating clinics in Luzerne County. This will include shadowing providers, ensuring the IT module is working as intended, and to provide any oversight/problem solving that is necessary. The study team will also use this opportunity to discuss physician satisfaction with the end product and improvements/modifications that should be made to improve efficiency and assist with current workloads.

6.5.1 Study Time and Events Table

Phase One: Observational Study

Study Procedures	**Day 1-8**	**Month 2**	**Month 5**	**Month 7**
Study Interval	Screening/Enrollment	Active phase		
Informed consent	X			
Demographics	X			
Medical history	X			
Weight	X	X	X	X
Physical examination	X	X	X	X
Vital signs	X	X	X	X
Standard of care EHL questionnaire	X	X	X	X
Study questionnaires	X	X	X	X
WIC information		X	X	X

Phase Two: Randomized Controlled Trial

Study time table and events for Phase Two, Randomized Controlled Trial are the same as Phase One, Observational Study except: Day 1-8 Geisinger and WIC will verify that the participant is a Geisinger patient who provided informed consent to participate in the study and the infant is enrolled as a WIC participant. After the participant is authenticated as receiving care at both Geisinger and WIC, data sharing will be enabled between Geisinger and WIC. Bi-directional data sharing between Geisinger and WIC will continue for the 6 month intervention (last data collection point at 7 months).

6.5.2 Study Flow Diagram

Figure 6.5.2-1: **Phase One Observational Study** Flow Diagram

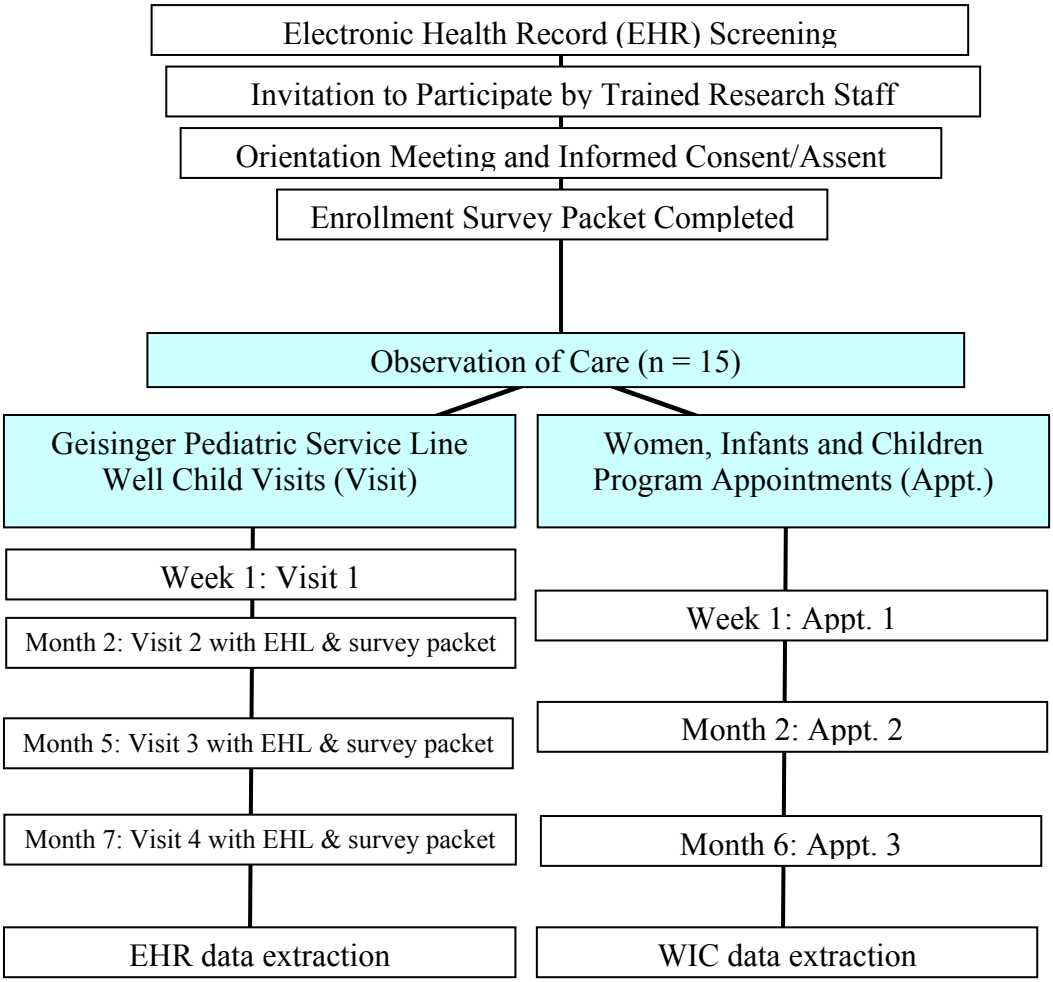
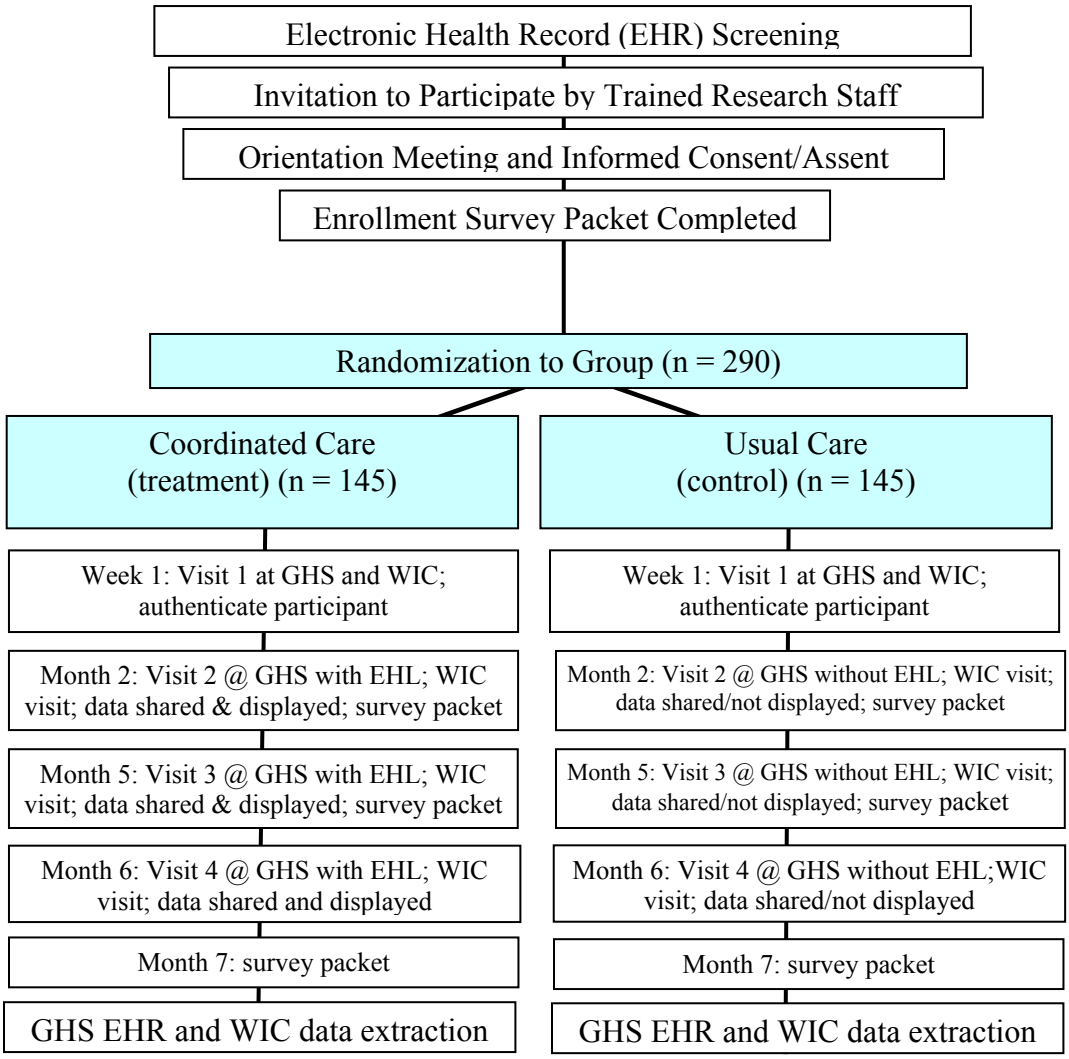


Figure 6.5.2-2: **Phase Two Randomized Controlled Trial** Flow Diagram

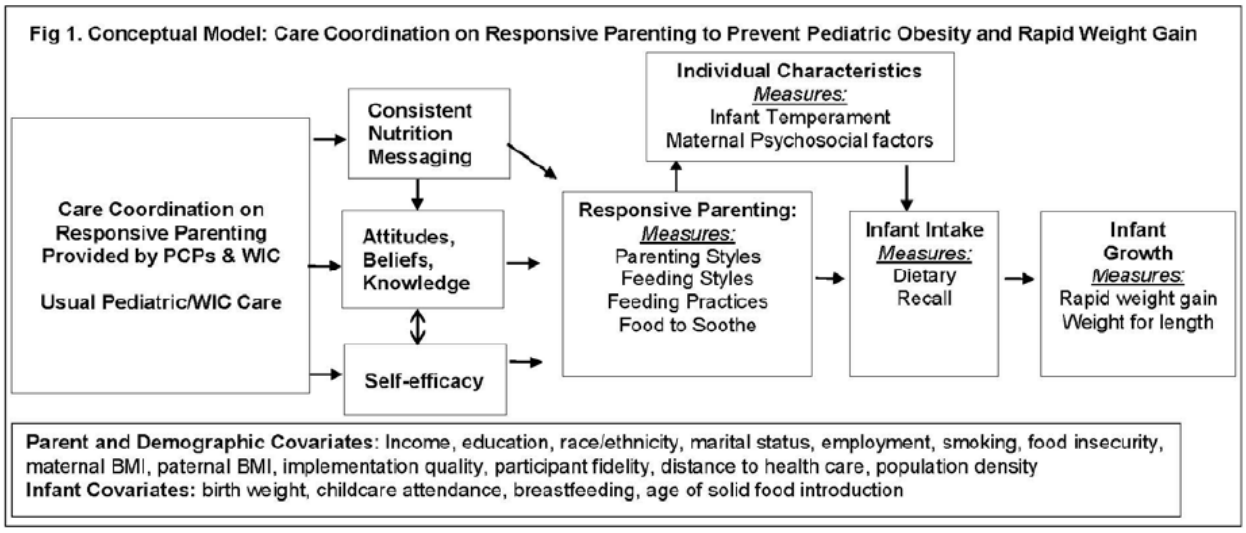


Primary Endpoints

The primary endpoint will be excessive rapid weight gain, or weight-for-age z-scores, at post-intervention. The phase one observational study provides the naïve condition of weight-for-age z-scores that will be compared to treatment group in the randomized controlled trial. A 0.67 difference in weight-for-age z-scores represents the distance between major centile lines displayed on infant growth charts. This difference is clinically meaningful, and upward percentile crossing of this magnitude has been the operational definition for rapid weight gain.

Secondary Endpoints

Secondary endpoints include consistent messaging; attitudes, beliefs, and knowledge; self-efficacy; and measures identified as "individual characteristics," "responsive parenting," and "infant intake" in Figure 1 boxes.



Footnote: Infant growth measures include rapid weight gain measured by change in weight-for-age z-score.

6.6 Statistics

The statistical analyses will be performed at the Pennsylvania State University by Dr. Savage Williams and Mrs. Michele Marini.

6.6.1 Statistical Analysis Plan

Subscales for survey instruments will be treated as parametric data, and repeated analysis of variance will be used to assess the effects of the future intervention on changes of these composite outcomes and changes in child growth. All models considered will include relevant time-varying and stable-covariates. Covariates to be considered in refining the analyses can be grouped into categories that include maternal biologic variables, socioeconomic and demographic variables, infant behavioral variables, and parental behavioral variables. A linear mixed-effects model, a generalization of regression, will be used to examine the relationship between weight-for-age z-score and study group. The moderating effect of maternal mental health and child temperament on intervention efficacy will be tested. Continuous secondary parental and infant behavior outcomes assessed at multiple time points, including sleep duration, feed duration, fussing and crying duration, feeding practices and attitudes and parenting sense of competence, will be analyzed using appropriate time series methods. These methods will allow us to create summary variables to identify patterns of change. These patterns will be predicted by

the effects of the model, namely study group, initial feeding mode intent, and their interaction. These secondary outcomes will be included as moderators in analyses of primary growth outcomes. The moderator hypothesis represents the interaction between these variables and the main effects of the model while including each of these variables as additional main effects. We will also test whether these secondary variables function as mediators; that is are these variables predicted by the effects of the model and, in turn, predict the primary outcomes. Using path modeling to test these models, we will be able to determine the direction of influence among the variables in the model.

6.6.2 Statistical Power and Sample Size Considerations

We have powered the study to detect a 0.67 difference in weight-for-age z-scores between the observational and future intervention groups. To detect this difference with 90% power and a 5% Type I error rate, 276 participants are required. This includes an anticipated 30% loss to dropout. This study is also powered on food to soothe a distressed child and uses nominal power = 0.8 and alpha = 0.05. If we assume that we can change 15% of mothers in the future treatment group to reduce their use of food to sooth as compared to mothers in the observational study, assume a constant variance of 1 and a retention rate of 67% during the study period, we will need to recruit 300 pediatric participants. We have experienced a 31-33% drop-out rate in previous studies of mother/guardian-infant dyads for longer than 3 months duration, and so assume a similar drop-out for this study.

6.7 Data Management

6.7.1 Data Collection and Storage

Primary data will be collected by trained study staff from patient electronic health records, WIC records, and survey questionnaires. Survey data will be maintained at the Pennsylvania State University. However, due to the sensitive nature of the PHQ-2 and PHQ-9, these data will only be collected and stored securely at Geisinger. No responses to the PHQ-2/PHQ-9 will be sent outside of Geisinger. WIC data will be collected electronically from the Pennsylvania WIC Program and transferred using an encrypted, data transfer portal. Patient data extracted from the electronic health record will be maintained in a data base created by a Geisinger data analyst; trained study staff will enter data into the database; and these data will be stored on a password-secured electronic server. Protected health information (PHI) will be collected; these data will be stored by study identification (ID) and not be related to patient name or medical record number (MRN). The study ID will be assigned at study entry. Participant name will be connect to the study ID through a numbered list that will kept separate and apart from medical record information. This list will be stored in a locked, secure filing cabinet in a locked office at Geisinger Health System. Participant names will not appear on any research records or used in research publications. The principal investigator will have the key to the locked office and locked cabinet.

6.7.2 Records Retention

Data will be kept for an indefinite period of time for IRB-approved use in future studies.

7 PROTECTION OF HUMAN SUBJECTS

7.1 Informed Consent

Phase One: Observational Study

The investigator will provide for the protection of the subjects by following all applicable regulations. The informed consent form, (found in Attachment 2), is submitted to the IRB for review and approval.

The following conditions apply to obtaining informed consent:

- A waiver of authorization is requested for pre-screening of potential participants

Before any procedures specified in this protocol are performed, a subject must:

- Be informed of all pertinent aspects of the study and all elements of informed consent.
- Be given time to ask questions and time to consider the decision to participate.
- Voluntarily agree to participate in the study.
- Sign and date an IRB-approved informed consent form.

Phase Two: Randomized Controlled Trial

The procedures for informed consent for Phase Two, Randomized Controlled Trial, are the same as those described for Phase One, Observational Study except that data sharing and care coordination are emphasized (found in Attachment 12).

7.2 Protection of Human Subjects Against Risks

During the pre-screening process, the mother's electronic medical record will be reviewed for eligibility prior to initial contact. If the mother has documented major morbidities and/or pre-existing conditions that would affect postpartum care or her ability to care for her newborn (e.g., narcotic drug use; heroin, cocaine, meth, pain pills, etc., chemotherapy, uncontrolled multiple sclerosis, or uncontrolled depression), then the mother will not be eligible for the study. These data will be used for pre-screening only and no identifiable information will be retained. The

study staff will take the following precautions to minimize risks related to loss of confidentiality: all data will be stored on a secure server only accessible to approved study staff via password-protected portable computers during recruitment and consent. Pediatric patients in the study will be assigned a study number independent of their MRN; this number will also be used to uniquely identify the mother/guardian. PHI obtained for recruitment will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

No identifiers will be retained in the data that is analyzed for intervention effects. All MRNs and any personal information will be removed prior to analysis. A sequential study ID will be used for each enrolled participant by a study staff member and there will be a master list of study ID numbers and participant names and addresses (that will not be stored with any collected data), in order to pay participants for the time involved with this research project. For research purposes, there is no need to know the participant name or any person-identified health information.

Primary data will be collected by trained study staff from patient electronic health records, WIC records, and survey questionnaires. Survey data will be maintained at the Pennsylvania State University. WIC data will be collected electronically from the Pennsylvania WIC Program and transferred using an encrypted, data transfer portal. Patient data extracted from the electronic health record will be maintained in a data base created by a Geisinger data analyst; trained study staff will enter data into the database; and these data will be stored on a password-secured electronic server. Protected health information (PHI) will be collected; these data will be stored by study identification (ID) and not be related to patient name or medical record number (MRN). The study ID will be assigned at study entry. Participant name will be connect to the study ID through a numbered list that will kept separate and apart from medical record information. This list will be stored in a locked, secure filing cabinet in a locked office at Geisinger Health System for a period of 5 years, after which time the identification list will be destroyed. Participant names will not appear on any research records or used in research publications. The principal investigator will have the key to the locked office and locked cabinet.

7.3 Data Monitoring Plan

This study presents no more than minimal risk for participants as the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered during daily life or the performance of routine well child visits.

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9 ATTACHMENTS

9.1 Attachment 1: EHL Screening Tool

9.2 Attachment 2: Pre-Screening and Recruitment Packet

9.3 Attachment 3: Enrollment Survey Packet

9.4 Attachment 4: 2 Month Survey Packet

9.5 Attachment 5: 5 Month Survey Packet

9.6 Attachment 6: 7 Month Survey Packet

9.7 Attachment 7: Coordination of Care Measures

9.8 Attachment 8: WIC Brochure

9.9 Attachment 9: MyGeisinger Enrollment Instructions

9.10 Attachment 10: WEE Information Sheet

9.11 Attachment 11: Patient Involvement in Care Questionnaire

9.12 Attachment 12: RCT Informed Consent