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Background, Rationale and Context

According to youth.gov, by age 22, only 50% of young moms have received a high school diploma and only 30% have received their GED. Births to young moms carry risks along with perpetuating the generational trend of teen births. Children born to moms less than 20 years old are more likely to drop out of school, become teen parents themselves, and have increased risk of experiencing abuse or neglect.[i],[ii]. Risks are enhanced when a young mother has additional children[iii]. While there have been declines in overall births to young moms in Forsyth County from 2008-2019, the absolute numbers of young moms with not only a first but multiple children still are alarming.

Imprints Cares is a local early education nonprofit that has been providing services in Forsyth County for the past 50 years. Two services provided by Imprints Cares are important to this project. One, Pediatric Parenting Connections (PPC), forms a partnership with medical providers by embedding a certified parent educator into local health clinics, Westgate Pediatrics, Downtown Health Plaza, and Winston East Pediatrics. This program serves as short term in-office parenting education for breastfeeding, behavior, and developmental concerns. It also serves as a referral point for the more intensive, Parents as Teachers (PAT) home visitation model. Both models are two-generation models devoted to addressing health disparities, promoting maternal health, and mitigating chronic toxic stress. Providing supports that recognize these challenges help young moms obtain positive outcomes[iv]. Intervening early with a two-generation approach can have positive effects for both young moms and children. There also are societal benefits in that the lifetime benefits of supporting young moms and promoting healthy birth spacing exceed those of the costs[v], [vi], [vii], [viii]. The benefits of providing parenting support to young moms can include mother's education, use of contraception, healthy birth spacing, child immunization compliance, reduction of child behavior problems (possibly), improvements in the home environment, and parents' realistic expectations for children[ix],[x], [xi]. The application of these services to young mothers comprises our Young Moms Program (YMP). As a community we are just beginning to realize the unintended outcome of COVID, one of which appears to be an increase in teen births.

As we continue to recover from the impact of the global pandemic, we must look closely at the significance home visiting programs have on creating authentic relationships with families, which in turn create opportunities for working with young moms to solve problems, achieve personal goals, and access essential resources. According to a Washington State Institute for Public Policy study (2004) Parents as Teachers had the largest benefit per dollar of cost ($1.23) of all pre-kindergarten early education programs. Imprints Cares traditional PAT program costs $3,436 per family annually,

which is a return on investment of $4.70 – 5.60 in future educational remediation, juvenile delinquency, teen pregnancy, substance abuse, and mental illness [xv]. Providing support to young moms in Forsyth County is something we cannot afford *not* to do.

Our project will address this emerging health crisis at a time when value-based care models as part of Medicaid transformation are rolling out throughout North Carolina and all programs have had to adapt to changing the delivery mechanisms to more remote offerings. During the pandemic, Imprints Care developed a hybrid model for provision of services through Parents as Teachers. Imprints Cares evidence-based Parents as Teachers hybrid model may have far reaching implications in establishing a pediatric value-based model that can be replicated throughout our community, state, and country. Since January 2021, Wake Forest Baptist Medical Center (WFBMC) has documented 82 births to young moms ages 14 through 21. Since July 2020 Imprints Cares family educators have received approximately 400 referrals from pediatricians with more than 320 families being served, 80%.

Further, as we are considering the intersection of equity with health and social policy, the YMP is an opportunity to directly address disparities in behaviors such as breastfeeding, completion of developmental screenings, and enrollment in early intervention that may be correlated with different demographic groupings. We know that while COVID-19 was traumatic for everyone, young children growing up in poverty were disproportionately impacted. The true impact of the pandemic and public health precautions (i.e., isolation) is just beginning to emerge. We continue to see increased trends in pregnancy in young moms, toxic stress and child maltreatment, food insecurity, and developmental/ behavioral regression in young children. As we enhance opportunities for young moms based on positive outcomes during the pandemic, we can rapidly embed responses to traumatic events into our approach. To the extent that some young moms are perpetuating a multi-generational pattern of early births, the proposed hybrid program is an opportunity to break a cycle linked to poor outcomes for young moms and their children.

Objectives

The objectives of this study are to assess cost-effectiveness of a Young Moms Program that incorporates a traditional Parents as Teachers home visiting parenting program to that of a hybrid virtual/home based Parents as Teachers program, against short-term outcomes, which in turn will serve as leading indicators of longer-term results. Specific outcomes are outlined in the measures section.

Methods and Measures

This is a community-engaged research collaboration between the non-profit Imprints Cares, the WFBMC Birth Center, and WFSOM. Because YMP is a tiered program model, services meet parents where they are through a “warm hand-off” approach that uses on one-on-one consultation and assessment-based interventions. The YMP is designed to address systemic barriers to the health and stability of young moms and their children such as the lack of coordination of service delivery or logistical barriers within the health system. The YMP also streamlines the referral pipeline, connecting

moms to evidence-based resources, and ensuring children complete all recommended assessments prior to kindergarten.

This research project is a pilot randomized controlled trial. We expect a total of 30 participants,15 in each arm of the study. For inclusion into this study participants must be an immediately post-partum mother, between 14-21 years of age who will reside with her newborn. The mother must be referred from either the Birth Center at Wake Forest Baptist Health or from one of the Wake Forest Baptist Health PPC partner practices. Exclusion criteria include that newborn of participating mothers must be >= 35 weeks of gestation and not have an extended NICU stay. These populations are excluded because medically complex newborns and a prolonged separation during the intervention period will directly affect our outcome measures. Participants must speak English or Spanish given our parent educators and other group participants are limited to those languages. Males are excluded as participants, the intervention and many of the outcome measures are only applicable to female participants.

Participants will be randomly assigned to one of the two variants of the Parents as Teacher home visitation model, traditional or hybrid. The study's research coordinator, who is not directly involved with the delivery of services, will manage the randomization and assignment process; all consented participants will be given a system-generated unique identifier, which cannot be linked to patient identity by anyone except the research coordinator. This information will be securely maintained by the research coordinator. The team will complement the treatment groups' data with population data extracted from WFBMC's Epic system. Analysts will use rigorous techniques (e.g, Propensity Score Matching) to create a matched control group.

Both formats and all interventions included in the study are the current models of care for our existing PAT/YMP services. The hybrid model was developed in 2020 in response to the need to move services virtually as home visitation was not allowed during COVID-19 lockdown.

Through the traditional PAT model, participants will be referred through a warm hand-off from the Birth Center or one of WFBH community pediatric centers to Imprints Cares. A PAT certified family educator will meet with the family focusing on a one-on-one consultation and assessment-based interventions. Participants in the traditional PAT model will receive two home visits a month and participate in monthly peer (group) connections throughout the study period.

In the hybrid PAT model, participants will be referred through a warm hand-off to Imprints Cares from the Birth Center or one of WFBH community pediatric centers. A PAT certified family educator will meet with the family focusing on a one-on-one consultation and assessment-based interventions. Study participants will begin receiving services by participating in the virtual "What You Do Matters" program, an evidence-based PAT curriculum. After completion of the virtual program, young moms will begin receiving once a month home visits and participate in monthly peer (group) connections.

By including two variants in this pilot project, the study team will assess the cost-effectiveness of the two approaches, against short-term outcomes, which in turn will serve as leading indicators of longer-term results. At the end of the official study period, participants will be eligible to continue in the program until the child's school entry into kindergarten.

Both models will be staffed by qualified family educators that have been trained in the Parents as Teachers Foundational Curriculum, the Circle of Security model, and breastfeeding educator certification program. Imprints Cares also has a mental/behavioral health family educator on staff to address emergent mental/behavioral concerns as they arise. These approaches have been documented to nurture parental attachment and secure relationships[xii].

Outcome Measures

The team will use several published assessments:

Protective Factors Survey. The Protective Factors Survey (PFS) is a validated parent survey designed that assesses protective factors in five areas: family functioning/resiliency, social support, concrete support, nurturing and attachment, and knowledge of parenting/child development. The PFS will be implemented at week one, week six, and end of study, as it requires parent-child interactions for completion.

Ages and Stages Questionnaire 3rd edition. The Ages and Stages Questionnaire (ASQ 3) is a validated developmental screening designed for use by and with parents. The ASQ 3 screens for developmental milestones in communication, gross motor, fine motor, problem solving, and personal-social skills. The ASQ 3 will be implemented at the recommended intervals designed by its publisher (2, 4, and 6 months).

Ages and Stages Questionnaire: Social-Emotional 2nd edition. Similar to the ASQ 3, the Ages and Stages Questionnaire: Social-Emotional (ASQ:SE 2) is a validated screening of social and emotional behaviors. The ASQ:SE 2 will be implemented at the recommended intervals designed by its publisher (2, 4, and 6 months).

Patient Health Questionnaire. The Patient Health Questionnaire (PHQ 9) is a self-administered questionnaire that is validated for use in assessing the severity of depression. The PHQ 9 will be administered as a baseline assessment as well as an end-of-study assessment.

StimQ2-I. The StimQ2-I is a validated, interview-based assessment of home environments for use with infants ages five to 12 months. The StimQ2-I focuses on cognitive stimulation by the primary caregiver and contains several scales: Availability of Learning Materials, Reading-Verbal, Parental Involvement in Developmental Advance, and Parental Verbal Responsivity. The StimQ2-I will be implemented at the end of study, as it requires parent-child interactions for completion.

In addition to these assessments, the team will use an intake questionnaire to capture parent demographic and health information as well as baseline knowledge about child development and parenting and a monthly questionnaire used to assess mother's status on continuance of secondary education, breastfeeding, and use of contraception. A monthly questionnaire, which will be developed for use in this study, also will assess infant developmental milestones.

Further, the team will access health information captured in WFBMC's Epic system, including completion of Well-Child Visits and recommended immunizations. A WFBMC study team member will extract data on participants as well as a matched control group. The study team will conclude the study with participant focus groups, to collect additional qualitative feedback and insights. Finally, the team will develop and implement Fidelity of Implementation (FOI) quality

assurance guidelines and checklists to capture the degree to which project services are delivered as expected. FOI scores will be used as a predictive variable with the goal of establishing a minimum service threshold for short-term outcomes.

Proposed Statistical Analyses

Descriptive Analyses. All data will be subject to descriptive analyses, including measures of central tendencies and frequency distributions, as appropriate for the type of data collected. Descriptive analyses will support our understanding of participant characteristics and equivalency of samples in the traditional and hybrid models.

Inferential Analyses. Inferential analyses, such as t-tests, multiple regression, and Analysis of Variance, will be conducted to test for change between baseline and end-of-study data collections with the PHQ 9, and the PFS. The PFS will be administered at service week one, service week six, and at the end-of-study to assess differences between the models at promoting protective and nurturing behaviors. Tests also will be used to assess differences between the models on maternal outcomes such as continuance of secondary education, breastfeeding, and use of contraception and child-focused outcomes such as STIMQ2-I, completion of Well Child Visits and immunizations. The study team will work with CTSI Biostatistical Support services to advise and guide the analytic approach.

Proposed Cost Effectiveness Study Design. One of the primary challenges of completing cost studies is fully accounting for all costs and benefits. Therefore, the study team will use this project period to identify the spectrum of costs associated with serving one young mother and her child. These data will be compiled to generate an average cost of service and establish outliers that exist when there are particularly risky or traumatic cases. In addition, the team will establish short-term benefits (achievable after six-months of services) along with the program implementation conditions necessary to achieve them. We will utilize the services of BERD and Q-Pro to assist in advising in areas of study design, data analysis, and data management.

Study Timeline

Study Milestone	**M1**	**M2**	**M3**	**M4**	**M5**	**M6**	**M7**	**M8**	**M9**	**M10**	**M11**	**M12**
Achieve IRB approval	●											
Enrollment of teen moms		●	●	●								
Baseline data collected		●	●	●								
Services delivered		●	●	●	●	●	●	●	●	●	●	
Week one data collected		●	●	●								
Week six data collected			●	●	●							
ASQ/ASQ-SE data collected (2,4, and 6m)				●	●	●	●	●	●	●	●	●
Monthly questionnaires and FOI checklists completed			●	●	●	●	●	●	●	●	●	
End of study data collected											●	●
Analysis and reporting completed												●

The project will track numerous milestones, including:

- Submission of IRB application and receipt of IRB approval. This milestone is critical as the project will not move forward without IRB approval.
- Enrollment of young moms by the project's four month. All participants will need to be enrolled by month four to ensure moms in both models can receive at least six months of home visitation services. In the traditional model, home visitation starts immediately upon

enrollment. In the hybrid model, home visitation starts at the completion of the six-week What You Do Matters virtual class.

- Collection of all baseline data. Baseline data will be collected at the time of enrollment and will consist of the enrollment form and the PHQ 9.
- Collection of week one and week six data. Data will be collected during the participant's first and sixth week (at the close of the What You Do Matters course) of services in both models (PFS).
- Collection of monthly questionnaires. Monthly questionnaires will be implemented with each participant, on a schedule developed by the family educator.
- Collection of ASQ and ASQ:SE data as recommended by the publisher (2, 4, 6m).
- Collection of end-of-study data (6 months after enrollment). In the final month of services, the team will collect the ASQ, ASQ:SE, PHQ 9, the PFS and the StimQ2-I.
- Collection of FOI checklist data. Project staff and supervisors will complete FOI checklists on a monthly basis. Each model will have its own checklist.
- WFBMC data extraction and compilation of analysis files. One of the WFBMC team members will work to securely extract health data for treatment and matched control group participants from the Epic system.

Human Subjects Protection

Subject Recruitment Methods

No additional PHI will be accessed or printed/transcribed above and beyond what is part of standard patient care and pre-defined job descriptions.

OB Home Visiting Staff

1) Our OB Home Visiting Nursing Staff as part of their standard workflow identify and visit all post-partum mothers that reside in Forsyth County, NC.
2) Of those, they will identify mothers that meet inclusion criteria for the study (14-21 years old, Spanish or English Speaking, will reside with their newborn upon discharge, and will follow up with a Wake Forest Baptist Health Pediatrician).
3) During their standard meeting, while the mother is still inpatient from her delivery, OB home visiting staff per their standard workflow will ask if the mother would like referral to Imprints Cares. If they identify a likely eligible participant, they will introduce study at that time, without promising the patient they are eligible. If the patient is interested in referral for either the study or services not provided as part of the study, the team will make a referral to Imprints Cares. The referral will indicate if the patient appears to be eligible for the study or not.

Imprints Cares

1) After referral from the PPC primary care physician or the OB Home Visiting Nursing Staff to the Imprints Cares program, intake staff will assess if new mothers meet criteria for participation in the study (14-21 years old, Spanish or English Speaking, will reside with their newborn upon discharge, and will follow up with a Wake Forest Baptist Health Pediatrician).
2) Imprints Cares intake staff will ask if the mother would like to participate in the study, explain the risks and benefits, and obtain consent/assent from all required parties This may be done in person if at the time of a clinic or intake home/community visit OR remotely via secure Docusign.
3) Imprints Cares staff will not directly benefit if a patient does or does not consent to the study, and patients are eligible for services if they do not consent, therefore it is not an undue influence to enroll patients.

Informed Consent

Signed informed consent/assent and parental permission to participate will be obtained from each subject as defined by participant age. Informed consent/assent and parently permission to participate will either be obtained in person if at the time of a clinic visit or intake home/community visit OR remotely via secure Docusign at by Imprints Cares Intake Staff approved as study staff by the IRB.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed at the time the newborn is 6 years old, consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

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Appendix (see relevant sections of IRB application)

1. Data collection form
2. Copies of each questionnaires or surveys that will be used
3. Consent form if one will be used