

INTRODUCTION TO APPLICATION

Research Plan Overview

Childhood asthma is the most common pediatric medical condition in the United States, and disproportionately affects children living in low-income, urban settings. Many low-income, urban families rely on emergency department (ED) services as their source for sick care for their child. This is often due to not having a primary care provider or sufficient access to their primary care provider for asthma management. Further, recognizing the intersection of racism and health, **minority children from low-income, urban families are disproportionately affected by asthma and related morbidities to an even greater extent.** To avoid an unintended consequence of worsening these asthma health disparities for low-income minority families, it is imperative that any parent-focused intervention designed to improve asthma outcomes is effective across varying demographics and languages.

The **Text2Breathe** study seeks to reduce disparities in pediatric asthma morbidity and ED reliance. Using a text-message enhanced health communication program, parents are equipped with tools to more effectively communicate with their primary care provider about their child's asthma and care needs. Text2Breathe targets Medicaid-insured children—a diverse population with a high proportion of children at high risk for poor asthma outcomes. The parent R01 project will examine the effect of the Text2Breathe intervention among Medicaid-insured children randomized to intervention and control groups. The heterogeneity of these groups may mask important differences in intervention effects for subpopulations in the intervention group (e.g., minority race/ethnicity). **Currently, there are no data on how or whether Text2Breathe, or similar pediatric m-Health interventions, will differentially impact families based on race/ethnicity or English language proficiency.**

Using data collected in the Text2Breathe Study, this supplement will focus on examining *intervention effectiveness* across subpopulations within the intervention group. I will examine reduced ED visits and morbidity by race and Limited English proficiency (LEP) (e.g., parents whose first language is not English). Additionally, I will examine if parental self-efficacy and asthma related outcome expectations, differentially effect primary care follow-up rates and knowledge of asthma management by parent race or LEP. **This supplement will enhance our ability to examine the effectiveness of the intervention across subgroup populations, by examining whether and how the intervention differentially impacts asthma-related health outcomes by parent race/ethnicity or LEP.**

Candidate Career Development Plan Overview

My research experiences have focused on healthcare services for children and youth with special healthcare needs (CYSHCN), and their families. I earned my PhD in rehabilitation sciences in 2016; I am currently a second-year postdoctoral research fellow at the Center on Outcomes Research in Rehabilitation within the Department of Rehabilitation Medicine at the University of Washington. My long-term career goal is to become an independent researcher, conducting research that aims to improve access to healthcare and related services for CYSHCN, with a focus on the needs of diverse and marginalized families.

Through this supplement, **I seek to cultivate additional content knowledge concerning best practice to optimize parent-provider communication and partnership for CYSHCN, with a specific interest in varying cultural and language considerations.** This supplement will cover a 2-year period and will include a structured career development plan that includes a mentorship plan and coursework in health services and bioethics research to allow me to complete my MPH degree.

At the end of the 2-year supplement, I will have submitted an NIH K-series career development award application. Knowledge gained from this diversity supplement, combined with my current content knowledge in child health needs assessment and outcome measurement, will support the creation of my NIH K-series proposal. Using culturally-relevant ways of gathering data, combined with modern psychometric methods (e.g., item response theory), I will develop an innovate, parent-centered m-Health tool for CYSHCN that facilitates parent-provider communication and assesses health-related needs and outcomes.

2. Specific Aims

Asthma is the most common chronic pediatric medical condition in the United States, with a prevalence over 9.6% in children under 18 years of age.^{1,2} Low-income, urban children incur a disproportionate share of asthma prevalence and morbidity,^{2,4} 13% of children living below the poverty threshold are diagnosed with asthma compared to 8% of non-poor (>200% poverty),³ and poverty is associated with higher rates of asthma attacks.¹ Living in an urban area confers additional risk for asthma and increased ED utilization.^{4,5} Implementation of the National Asthma Education and Prevention Program's (NAEPP) Guidelines has contributed to reductions in asthma morbidity and mortality rates, and these guidelines emphasize establishing a partnership between healthcare providers and patients/families to promote effective asthma management.⁶

The NAEPP expert panel states, "building a partnership requires that *clinicians promote* open communication and ensure that patients have a basic and accurate foundation of knowledge about asthma..." (p.124),⁶ yet care partnerships also require that the patient/parent effectively communicate issues such as emerging symptoms or response to medications. Thus, our team conducted a randomized controlled trial (RCT) of a health communication (HC) intervention (*Patient Empowerment Program in Asthma Care - PEPAC*) consisting of face-to-face education on effective communication followed by a single "booster" call to reinforce intervention content. PEPAC was delivered in the context of a successful Emergency Department (ED)-based asthma education, medical care, and care coordination program for inner-city children (*Improving Pediatric Asthma Care in the District of Columbia - IMPACT-DC*), and resulted in more partnerships with primary care providers (PCPs) for asthma care and lower ED visits than the ED-based intervention alone.⁷ However, the unique environment of the IMPACT-DC clinic and need for significant resources to implement the face-to-face intervention limits generalizability. **Therefore, grounded in Social Cognitive Theory, we propose to expand the scope of our HC intervention for parents of urban, low-income children with asthma by delivering important educational and behavior change content using text messages.** Recent reviews have showcased the efficacy of text-messaging for health behavior changes in preventive behaviors (e.g., increasing immunization rates) and for improving adherence to treatment recommendations (e.g., improving diabetes self-management).^{8,9} Delivering content via mobile technology, part of a growing field called "mobile health" or "mHealth", may be particularly useful among lower-income, urban families for whom the use of mobile and text messaging is widespread as an available and efficient means of communication.¹⁰

With the goal of reducing disparities in pediatric asthma morbidity and urgent care reliance, we will test the efficacy of a mHealth HC intervention ("Text2Breathe" – T2B) designed to equip urban, low-income parents with tools for more effectively communicating with their children's PCPs and managing their child's asthma. A total of 276 parents of children seen in the Seattle Children's ED for an asthma exacerbation (or related diagnosis according to ICD9 codes) will be randomized to standard ED asthma care with or without T2B. The T2B group will receive interactive and individualized instruction about asthma care communication and asthma self-management via text message interactions during the intervention period. Outcome data will be obtained from text message surveys and telephone interviews at baseline, 3, 6, 12, 18, and 24 months post-enrollment. This RCT will address the following aims:

Aim 1: To improve urban, low-income children's asthma-related health outcomes (primary outcome: reduced ED visits for asthma care, secondary outcome: lower morbidity) over 12 months.

Hypothesis 1a: Children of parents who receive T2B will make fewer ED visits for asthma care than those receiving standard ED asthma care alone.

Hypothesis 1b: Parents who receive T2B will report lower morbidity (i.e., days of impairment) than those receiving standard care.

Aim 2: To improve adherence to asthma care guidelines (primary care utilization for asthma care and improved parent asthma care self-management) over 12 months.

Hypothesis 2a: Parents who receive T2B will report increased primary care utilization (i.e., more frequent follow-up with their child's PCP for routine asthma care) than those receiving standard care.

Hypothesis 2b: Parents who receive T2B will demonstrate greater knowledge of asthma self-management than those receiving standard care.

Hypothesis 2c: Primary care utilization and improved self-management will mediate the effect of T2B on children's asthma-related health outcomes.

Aim 3: To improve parent cognitions (parental self-efficacy and outcome expectations) regarding partnering with their child's PCP for asthma care over 12 months.

Hypothesis 3a: Parents who receive T2B will report greater self-efficacy in communicating with their child's PCP about their child's asthma care and greater outcome expectations for effective treatment and control of their child's asthma symptoms than those receiving standard care.

Hypothesis 3b: Parental self-efficacy and outcome expectations will mediate the effect of T2B on adherence to asthma care guidelines.

This trial can reduce pediatric health disparities by verifying the efficacy of a mHealth HC intervention that can extend to other chronic conditions and have health and policy implications.

Appropriateness of a Pediatric-Focused Mobile Health (m-Health) Intervention Across Racial and Language Demographics

Research Plan

A. Background and Significance

1. Asthma Prevalence and Disparities

Asthma is the most common chronic pediatric medical condition in the United States,¹ affecting an estimated 6.2 million children annually.² Poorly controlled pediatric asthma contributes to over 700,000 visits a year to emergency departments (ED).¹ Children living in impoverished, urban settings are disproportionately affected by asthma,³ and the disparate impact of asthma is even worse among black and Latino children, and children whose parents have limited English proficiency (LEP) in these urban low-income areas.⁴⁻⁶ A 2017 longitudinal study revealed that black race and Latino ethnicity are significantly associated with worse asthma outcomes including 1) asthma knowledge, 2) asthma-related quality of life, 3) asthma severity, and 4) asthma control. Access to appropriate asthma-related healthcare services is essential to reduce asthma disparities among minority children.⁷

2. Current Trends in Access to Care

The intersection of racism and health needs leads to compounded disparities for minority children with special healthcare needs, often meaning many families do not access appropriate healthcare services.⁸ The socio-ecologic framework posits that various aspects of a child's environment directly and indirectly impact the child's health and development.⁹ Drawing on this framework, Beck and colleagues¹⁰ examined several biologic, social and ecologic variables to provide a greater understanding of factors influencing asthma-related hospital readmissions for black children compared to their white counterparts. The study revealed that black children were over two times as likely to be readmitted for an asthma-related illness compared to white children; this resulted from significant differences in almost every socio-ecologic variable measured, including disease management practices and access to primary care. Trivedi and colleagues note that black children with asthma have fewer visits with their primary care providers and are less likely to have a written asthma treatment plan than white children.¹¹ Further, Spanish-speaking parents of children with asthma have reported poorer experiences with asthma care guidance, including being taught what to do during an attack and being advised to change their child's home and school environment.¹² To address issues with access to appropriate care for minority children with asthma, innovative methods to cultivate effective partnerships between parents and providers are needed.

3. Emerging Trends in Supports to Families

The National Asthma Education and Prevention Program Guidelines emphasize development of a patient-provider care partnership is essential for improving asthma control and reducing exacerbations (e.g., ED visits).¹³ To cultivate these partnerships, appropriate tools are needed. Mobile Health or m-Health, according to the National Institutes of Health Consensus Group, is defined as the use of mobile and wireless devices to improve health outcomes, healthcare services, and health research.¹⁴ The efficacy of m-Health technologies (e.g., text-messaging, mobile applications) is in part due to their convenience as a method of health information exchange.¹⁵ Similarly, m-Health technologies are effective for modifying health behavior because behavioral cues (e.g., reminders) can be sent/received asynchronously, when and where they are most relevant or appropriate.¹⁶ Due to its popularity among urban, low-resourced populations, relatively low cost, and demonstrated efficacy in improving health behaviors, m-Health technology is uniquely well-suited for addressing pediatric health disparities. The **Text2Breathe** study seeks to reduce disparities in pediatric asthma morbidity and ED reliance using an m-Health model. Through an enhanced text-message health communication program, parents are equipped with tools to more effectively communicate with their primary care provider about their child's asthma and care needs, supporting improvements in parent-provider communication and partnership.

B. Innovation

1. Importance of Empowering Parents of Minority Race/Ethnicity to Manage Their Child's Asthma

A study examining racial/ethnic differences in parent's perceptions of asthma revealed that black and Latino parents expressed significantly more worry about their child's asthma compared to white parents, and Latino parents were significantly more concerned about asthma medication practices than both black and white parents.¹⁷ This worry stems from uncertainty concerning asthma management practices. Parental uncertainty in asthma management practices is often a result of asthma management education that does not meet the

needs of many minority parents. Recognition of this disconnect is imperative to improving asthma management practices and related outcomes among children of minority race/ethnicity.

A 2017 study exploring the beliefs and practices of asthma management among black caregivers revealed important considerations when advising caregivers with limited resources how to manage their child's asthma.¹⁸ Many caregivers were implementing their own self-management techniques, such as restricting the child's physical activity or using steamy showers in lieu of the prescribed medication management plan, when there were either personal or financial barriers to obtaining the prescribed preventive and rescue medications. These parents then turned to the ED when these unsanctioned self-management techniques failed during asthma exacerbations. In contrast, parents whose children received care from healthcare practices that emphasize cultural humility are less likely to underuse preventive asthma medications and report better management of care.¹⁹ Thus, empowering parents to effectively manage their child's asthma, regardless of the family socio-economic context, must be a focal point of interventions designed to minimize disparities among children of minority race/ethnicity with asthma.

At the individual level, empowerment strategies focus on improving one's self-efficacy; according to Social Cognitive Theory,²⁰ self-efficacy is a critical mechanism for changing health behaviors (e.g., medication adherence, following up with PCP). Greater self-efficacy among black parents is positively associated with more question-asking and information-giving regarding medical content.²¹ The Text2Breathe intervention aims to act on and improve parental self-efficacy concerning asthma management, and to modify parental outcome expectations concerning their child's asthma. To reduce racial/ethnic disparities in asthma care management and related outcomes, it will be critical to understand whether the intervention mechanisms to improve parental self-efficacy and modify outcome expectations are effective among parents of minority race/ethnicity.

3. Evaluating Intervention Effectiveness Across Demographic Subgroups

Implementation science is the study of methods to promote the systematic uptake of research findings into routine healthcare practices to improve quality and effectiveness of services.²² As we consider the effectiveness of Text2Breathe, we must also examine how that potential effectiveness varies across race/ethnicity and language. This is a key element of implementation science that should be considered across all stages of intervention evaluation, and in particular, in early stages of evaluation so that the intervention can be adapted and improved to meet the cultural needs and expectations across various communities.^{23,24} Without this additional information on Text2Breathe, we will not be able to speculate on how the future implementation of the intervention will impact asthma disparities.

Currently, there are no data on how or whether Text2Breathe, or similar pediatric m-Health interventions will differentially impact families based on race/ethnicity or English language proficiency.²⁵ **This supplement will enhance our ability to examine whether the intervention differentially impacts asthma-related health outcomes by child race/ethnicity or parental LEP.** Further, this work will provide important insights into ways m-Health can be used to support families of minority CYSHCN.

C. Research Design and Methods

1. Text2Breathe Study Design

This study employs a parallel-groups RCT design. The Text2Breathe intervention consists of a personalized, interactive text-messaging program with asthma and health communication education, as well as follow-up reminders for scheduling asthma care appointments with primary care providers, annual flu vaccines, and medication refills. The intervention targets parents/guardians of Medicaid-insured patients seen in the Seattle Children's and Mary Bridge ED for treatment of asthma. These are patients at high risk for having poorly-controlled asthma, and thus are likely to experience greater asthma morbidity.

The m-Health intervention includes two to three asthma education-focused messages sent each week for the first three months, with one message focused on asthma education and a second message on health communication. Parents also receive text message reminders to follow-up with their child's primary care provider (PCP) for asthma care at appropriate intervals, based on the asthma care guidelines and relative to the date of the ED visit/enrollment into the program. Some messages prompt participants to respond (e.g., key content questions, follow-up reminders for PCP visits, achievement of asthma management goals). Once a participant replies to a text message, the system sends a subsequent text message with appropriate feedback. The program also allows participants to send a variety of keywords at any time to receive additional messaging.

2. Text2Breathe Data Collection

Once consent to participate in the study is provided, parents complete a baseline interview questionnaire focusing on healthcare utilization, asthma self-management and morbidity, and parental self-efficacy and

outcome expectations. Participants are then randomized to usual care or the intervention group. Data on child and parent outcomes are collected in-person at enrollment and by telephone interviews at 3, 6, and 12 months post-enrollment. Following completion of participation in the intervention, a review of electronic medical records is conducted by a trained research assistant.

3. Text2Breathe Study Measures

ED visits for asthma care

Parents report whether and how many times their child was taken to the ED because of asthma during the past 12 months using two questions that have previously been used in multiple national surveys. Since our two partnering EDs for this study are the primary EDs utilized by children in the Seattle-Tacoma area, we will be able to validate much of the parent-reported ED utilization data with review of the electronic medical record at each site.

Asthma Morbidity

Asthma morbidity will be assessed by the questions used in the Inner-City Asthma Consortium (ICAC).^{26,27} Morbidity will be measured as the number of days (or nights) of impairment in the prior two weeks.

Primary care visits

Similarly, to ED visits, a review of electronic medical records will be conducted to confirm visits to primary care providers.

Parental Self-Efficacy

Parents will complete the *Medical Competence Communication Scale (MCCS)* to assess their perception of their own communication during their child's most recent medical visit.²⁸ The 16 self-competence items from the MCCS will be administered. Wording of questions is modified to state, "my child's medical problem" rather than "my medical problem."

Parents will also complete the *Parent Asthma Management Self-Efficacy Scale (PAMSES)*, a valid and reliable instrument designed to measure parent self-efficacy in preventing and managing children's asthma exacerbations.²⁹

Parental Outcome Expectations

To assess parents' beliefs about the level of asthma-related quality of life that is possible and can be expected for their child, we will administer a widely-used eight-item measure of parental expectations for asthma treatment.³⁰ This scale has been used in multiple pediatric asthma intervention studies. Parents respond to statements about their expectations (e.g., "I believe that my child can be symptom free most of the time.").

4. Text2Breathe Diversity Supplement Data Analysis

I will assess whether the intervention has a differential overall effect on rate of ED visits at 12 months, and whether indirect effects of the intervention through mediators vary by child minority race/ethnicity status (i.e., minority versus non-minority). These mediators include 1) adherence to guidelines (primary care use, knowledge of self-management, and 2) parent cognitions (self-efficacy, outcome expectations),

Aim 1 of the parent R01 study is to examine the intervention effect on 1) the number of ED visits for asthma care during the 12-month interval following randomization, and 2) the number of days of impairment during the two weeks prior to the 12-month interview. I will examine whether this intervention effect varies by child race/ethnicity and language.

I will utilize negative binomial regression to estimate incidence rate ratios (IRRs) and 95% confidence intervals (CIs) for count data. The independent variable in each model will be study group. The exponentiated form of the regression coefficient will reflect the relative difference between groups in the annual rate of ED visits or frequency of impaired days. I will focus on whether there is a differential impact of the intervention for children of minority race/ethnicity, with more exploratory analyses of smaller subgroups of LEP.

Statistical Power

Intermediate results suggest that approximately 73% of the total study sample of 260 will be of minority race or ethnicity (non-white or Hispanic/Latino). Assuming a 2-tailed type 1 error rate of 5% and using the 12-month assessment as the primary outcomes, we will have 80% power to detect a clinically-relevant reduction of 34% for our Aim 1 primary outcome (number of ED visits for asthma care during a 12-month interval) among minority intervention group children compared with non-minority intervention group children. This power analysis is based on an estimated average rate of 1.28 ED visits per year in the usual care group (estimate based on 2012 ED records). We will also assess whether the intervention effect varies across more specific subgroups of race, ethnicity, and LEP on a more exploratory basis, due to anticipated smaller sample sizes for these groups. In the case that the differential intervention impact does not reach the level estimated above (i.e.

a reduction of 34% for the primary outcome), we can conduct analyses with minority children compared with the overall sample to increase our power to detect smaller differences.

Aim 3 of the parent R01 study is to improve parent cognitions (parental self-efficacy and outcome expectations) regarding partnering with their child's PCP for asthma care over 12 months. I will examine whether parent cognitions differentially impact this partnership across race/ethnicity and LEP.

I will use linear regression models to evaluate whether the intervention effect on measures of self-efficacy and outcome expectations varies by racial and language demographics groups. A path analysis will then be conducted to assess whether parental self-efficacy and outcome expectations (defined using the three validated instruments) partially mediate intervention effects on primary care follow-up rates and knowledge of self-management and specifically whether this occurs differentially by race/ethnicity and LEP.

E. Anticipated Findings

This study will yield important findings to help us evaluate whether the Text2Breathe intervention has a differential impact by child race/ethnicity, and perhaps parental LEP. These findings will be critical, because if the differential intervention effect favors non-minority children, the intervention could have unintended consequences of widening disparities (by providing greater benefit to non-minority children). In this case, the intervention would need to be adapted to ensure effectiveness among minority children before further implementation, testing, and dissemination, or use for other chronic diseases. If the intervention impact differentially favors minority children, the intervention can be implemented, disseminated, and adapted to other chronic diseases, with an expectation of a narrowing of disparities (by providing greater benefit to minority children).

Hypotheses

I hypothesize that the effect of the intervention on our primary outcomes, both in terms of direct and indirect effects, will vary by race/ethnicity, with the greater impact for minority children. Further, I hypothesize that our exploratory analysis by race, ethnicity, and LEP will demonstrate a similar trend.

In addition to participating in the manuscripts of the parent R01 as a co-author and study team member, I will also complete three additional first-authored manuscripts as part of this diversity supplement study. These are:

1. Can an m-Health intervention narrow racial/ethnic disparities in asthma-related outcomes?
2. Effectiveness of an m-health pediatric asthma management intervention among minority and limited English Proficiency children
3. Effectiveness of an m-health intervention to improve parental confidence in asthma management across race/ethnicity and language demographics

F. Human Subjects

This supplement will not require any additional submissions or amendments to the IRB but will rely on the parent R01 study IRB approval.

In addition to the protections and considerations of the parent study, I have aligned myself with the Treuman Katz Center for Pediatric Bioethics to receive mentorship and feedback on considerations when working with data representative of vulnerable populations during this project (e.g. minorities and low-income families).

Career Plan

The Candidate

During my education and training, I have focused on health and healthcare services for children and youth with special healthcare needs (CYSHCN) in low-resource communities. Through my work, I have learned how critical communication and support between parents and clinicians is for this population, particularly for CYSHCN of minority race/ethnicity. Unfortunately, these vulnerable CYSHCN and their families often have the poorest access to services, and often receive less than adequate primary care services. This interaction between racism and health status, often leads to compounded disparities for **racial/ethnic minority CYSHCN** and their families. To address this issue, **my long-term career goal is to become a nationally-recognized expert and independent researcher focused on improving parent-provider communication and increasing access to high-quality supportive resources for racial/ethnic minority CYSHCN and their families.**

1. Candidate's Background

I earned my PhD in rehabilitation sciences in 2016; I am currently a second-year postdoctoral research fellow at the Center on Outcomes Research in Rehabilitation within the Department of Rehabilitation Medicine at the University of Washington. My research during my doctoral and post-doctoral training has primarily focused on measuring access to and outcomes of health and health services for CYSHCN, with a focus on the needs of families in low-resource settings. I have spent the last two years completing training in advanced health outcome measurement development and clinical application under an Advanced Rehabilitation Research Training grant through the National Institute of Disability, Independent Living and Rehabilitation Research (NIDILRR).

During my doctoral and postdoctoral training, I co-authored fifteen manuscripts; I was the first or second author for six of these. I also second-authored a book chapter, co-authored a training module on cultural awareness and humility for the Leadership and Education in Neurodevelopmental Disabilities (LEND) National Fellowship Program, and co-authored 20 conference presentations and posters. I developed a self-report measure of experience and skill development for youth with cognitive disabilities in recreational activity settings that resulted in one first-authored published manuscript and two others currently under review. I have also been substantially involved in the development of the *Caregiver Benefit and Stress Scales* for caregivers of children with and without special healthcare needs. I am second author of the development and validation manuscript for these scales and served as the presenting author of this project at the American Epilepsy Society Annual Meeting this past December.

These experiences in working to improve services for CYSHCN have informed my research goal of focusing on **enhanced parent-provider communication and support**. Recognizing that many families of CYSHCN in low-resource communities lack appropriate access to primary and specialized care services, **I plan to develop interventions using innovative technologies (e.g., m-Health) to support healthcare access and partnership between healthcare providers and vulnerable families.** This diversity supplement will provide the experience and mentorship that I need to make a successful transition from fellow to new faculty and afford me the opportunity to expand my areas of expertise to include innovative interventions designed to address health disparities.

2. Career Goals and Objectives

This diversity supplement will allow me to develop in-depth content knowledge of interventions designed to address health disparities resulting from socio-ecologic influences. Asthma is the most common pediatric medical condition, disproportionality affecting CYSHCN of minority race/ethnicity. Examining intervention outcomes in regard to race and English language proficiency serves as an ideal context to acquire content knowledge specific to m-Health intervention considerations. Further, I will obtain an in-depth understanding of randomized clinical trial design and implementation.

This supplement will cover a two-year period and consists of a structured career development plan that includes a mentorship plan and coursework in health services research and bioethics to allow me to complete my MPH degree. Knowledge gained from this supplement, combined with my current content knowledge in health-related measurement for CYSHCN and their families, will support the creation of my NIH K-series proposal to **develop a new m-Health tool that facilitates parent-provider communication, supports family disease management, and assesses health-related needs and outcomes.** This tool will assess both child and socio-ecologic factors most important to families, supporting my long-term research goal of improving parent-provider communication and resource support among racial/ethnic minority CYSHCN and their families.

3. Career Development and Training

A. Mentorship Team

My mentorship team includes my primary research mentor (Tumaini R. Coker, MD, MBA), a health communication advisor (Helene Starks, PhD, MPH), and a bioethics research advisor (Ben Wilfond, MD).

Tumaini Coker, MD, MBA (Primary Mentor), UW Associate Professor, Department of Pediatrics; Director of Research, Seattle Children's Center for Diversity and Health Equity; Principal Investigator, Seattle Children's Center for Child Health, Behavior, and Development, Co-Director, Integrating Special Populations, UW Institute of Translational Health Sciences.

As Primary Investigator of the Text2Breathe R01, Dr. Coker will provide hands-on mentorship for each element of this supplemental study. For the past year, Dr. Coker and I have met on a weekly basis for research and career mentorship. During this time, she and I have worked on a project using the National Survey of Children's Health. This project focuses on identifying socio-ecologic factors that influence access to healthcare for minority race/ethnicity CYSHCN. Additionally, she is supporting me as first-author of a manuscript describing facilitators and barriers to recruitment of diverse research participants using findings from a multi-site survey at the University of Washington, Seattle Children's, and Fred Hutch Cancer Research Center.

In preparation for this supplement proposal, we met on a weekly basis; we will continue weekly meetings throughout the project period. In addition to her guidance with the day-to-day needs of this proposed study, she will also provide guidance in grant writing, career planning, and manuscript development. I will also join Dr. Coker's weekly team meetings to provide more experiential learning on clinical intervention conduction and will help me to build relationships with the sites involved in the study and learn from her academic collaborators.

Dr. Coker is currently the principal investigator of two NIH R01 projects, both focused on improving primary care services for children in low-income communities using innovative structures and processes for care. Her research focuses on community-engaged design and evaluation of innovative interventions to reduce socioeconomic disparities of care among children. Dr. Coker's work has been published widely, in journals such as JAMA, Pediatrics, and the American Journal of Public Health, and has been covered by media outlets, including the Wall Street Journal, CNN, USA Today, and NBC. She has received multiple prestigious national awards, including AcademyHealth's Nemours Child Health Services Research Award, the Association of American Medical Colleges (AAMC) Herbert W. Nickens Faculty Fellowship, and the National Medical Association's Council on Concerns of Women Physicians (CCWP) Research Award. She has been a mentor for multiple trainees and junior faculty during her career (see attached list of mentees).

Helene Starks, PhD, MPH (Health Communication Advisor), UW Associate Professor, Department of Bioethics and Humanities; Adjunct Associate Professor, Departments of Health Services, Family Medicine, and Pediatrics; Director of the Metrics, Quality and Evaluation Core, Cambia Palliative Care Center of Excellence.

Dr. Starks' research expertise focuses on clinician-patient communication, qualitative and mixed methods research designs and analyses, research ethics with vulnerable populations, and quality improvement and systems change. Dr. Starks has also contributed to this proposal and will advise me on the data analysis and reporting of findings throughout the tenure of the supplement. I will meet with Dr. Starks monthly, and more frequently as needed one-on-one. She will join my quarterly mentorship team (Drs. Coker, Starks, and Wilfond meetings (described below).

Benjamin Wilfond, MD (Ethics Advisor), Professor and Chief, Division of Bioethics; Professor, Pulmonary and Sleep Medicine, Department of Pediatrics; Adjunct Professor, Department of Bioethics and Humanities, University of Washington School of Medicine; Director, Treuman Katz Center for Pediatric Bioethics

Dr. Wilfond will help me operationalize a working framework for addressing inequities experienced by CYSHCN that is rooted in health equity principles. Dr. Wilfond will support me in development of this framework by providing guidance in ethical considerations when analyzing the interaction dynamics between clinicians and parents, interpretation of results, and implications of findings for future work. Additionally, Dr. Wilfond will support me in the development of strategies to support the inclusion of low-income and minority families specific to my K-series proposal. Dr. Wilfond will meet with me monthly one-on-one and will also join my quarterly mentorship team meetings.

B. Mentorship Team Meeting and Evaluation Plan

I will continue my current one-hour weekly meetings with Dr. Coker in her research office, which is near mine. Dr. Coker will continue to be available between these weekly meetings for in-person and phone

discussions as well. Additionally, I will meet with Drs. Starks and Wilfond monthly and more frequently when needed. Drs. Coker, Starks and Wilfond, and myself will join together as a group for quarterly meetings.

My research and career progression will be evaluated every six months. I will provide my advisory team with my annual career and research goals. My career goals include a variety of areas, including coursework, journal submissions, grant applications, and national conferences. My mentoring team will collectively and individually provide a detailed evaluation of my progress based on my pre-determined research and career goals, as well as others that they identify. These formal evaluations will be completed by Dr. Coker every 6 months and collectively by my mentorship team at the end of year one and year two.

I will also present my work regularly at three different on-campus research seminars. I will give formal presentations of my work each year at Seattle Children's Center for Diversity & Health Equity research seminars, the Seattle Children's Research Institute (SCRI) Center for Child Health, Behavior, and Development's Works in Progress Seminars, and the Development Medicine Teaching Rounds. I will complete three manuscripts from this supplement (planned submission during Spring, Summer and Fall of year 2) and submit a K-series application for cycle 1 in 2019 (February, 2019).

C. Training in Advanced Statistical Methods

Throughout my doctoral and postdoctoral work, I have received training in both qualitative and quantitative analyses. While I consider myself a mixed methods researcher, as this is the nature of measurement development, item response theory based, and traditional psychometric analyses are only one component of quantitative analyses techniques. Because I intend to replicate the proposed analyses of the parent grant in the context of varying racial and language demographics, I will seek additional training in advanced statistical analyses through the Biostatistics, Epidemiology, Econometrics and Programming (BEEP) Core at Seattle Children's Hospital. The BEEP core is already providing statistical consultation on the Text2Breathe intervention study. I will take advantage of this connection, to receive additional training and consultation specific to the analyses proposed in this supplement.

D. Training in Pediatric Bioethics

The Treuman Katz Center for Pediatric Bioethics at Seattle Children's supports a fellowship for MDs. While as a PhD, I am not eligible to participate due to the clinical responsibilities of the fellowship, I have worked with Dr. Wilfond and Dr. Doug Diekema, director of education at the Treuman Katz Center, to undertake many of the same training activities as the clinical fellows.

1. Scholarly Activities

The primary emphasis of the Bioethics Fellowship is to develop skills and experience in research related to pediatric bioethics. With Dr. Wilfond serving as a bioethics mentor to me on the proposed supplement project, I will receive specialized training in ethical considerations both in research and clinical practice as they relate to CYSHCN.

2. Educational Activities

Fellows are expected to participate in regular educational activities of the Center for Pediatric Bioethics. I will participate in activities including weekly fellow seminars, the annual pediatric bioethics conference and visiting professor lectures and seminars.

3. Teaching Activities

Bioethics faculty will provide mentorship and guidance in developing teaching skills. With this support, I will be expected to actively participate in leading educational programs sponsored by the Center for Pediatric Bioethics. I will give lecture presentations and lead case-based group discussions.

E. Planned Course Work

This supplement will allow me to complete coursework specific to content considerations and research methodologies for both the proposed supplemental research and for my K-series proposal. Building on my coursework and training in person-centered health measurement, I will complete coursework that will expand my knowledge in the areas of clinician-patient communication and ethical issues of access to clinic and community services for vulnerable families in resource-limited settings. Planned courses over two years are listed below.

Design of Medical Studies

Design of medical studies, with emphasis on randomized controlled clinical trials. Bias elimination, controls, treatment assignment and randomization, precision, replication, power and sample size calculations, stratification, and ethics.

<p>Fundamentals of Implementation Science Provides an introduction to the emerging field of implementation research by outlining various methods that are applied to improving implementation (including applied engineering, management tools, health systems, and policy research), and using experiential case studies. Addresses barriers to effective replication and scale-up in local settings.</p>
<p>Research Ethics and Regulation Explores the ethical foundations, principles, concepts, and U.S. laws related to the conduct of research with human subjects.</p>
<p>Ethics and the Social Determinates of Health Engages student in ethical questions that confront healthcare workers who serve poor and minority patient populations. Students examine questions about clinicians' duties and patient responsibilities, controversial disease prevention programs and policies, and broader questions of social justice.</p>
<p>Ethical Issues in Pediatrics Provides a survey of contemporary ethical issues that arise in the clinical and research environment when children are involved, including the role of children and adolescents in decision-making, the limits of parental decision-making authority, and issues related to genetic testing, transplantation, research, and public health.</p>

F. Research and Career Plan Timeline

		Year 1				Year 2			
		Quarters				Quarters			
		1	2	3	4	1	2	3	4
	IRB approval								
	Clean & analyze data								
	Manuscript prep & submission								
Career Plan	Promotion to Acting Instructor								
	Coursework								
	Submit/ present abstracts to PAS*								
	Submit/ present abstracts to AH**								
	Presentations at UW venues								
	K-series writing and submission								

*Pediatric Academic Societies Annual Meeting

**Academy Health Annual Research Meeting

F. Future Work – NIH K Series Career Development Award

In February of 2019 (supplement Year 1), I will submit an NIH K-series career development application informed by my work on the Text2Breathe study. Submitting to cycle 1 will allow for additional time should a resubmit be needed. **My K proposal will focus on creating a new, flexible m-Health tool designed to facilitate parent-provider communication and assess health-related needs and outcomes.** This tool will serve as a central facilitator of patient-centered healthcare in primary care settings for black and Latino families of CYSHCN. It will afford opportunities for improved communication with clinicians across a range of important topics central to addressing child and family needs, as well as improving clinical care outcomes.

Patient-centered healthcare occurs when the environment supports patient engagement and activation in health care decisions, when knowledge is shared, when information flows freely, when the system supports flexibility in accommodating patient preferences and values, and when patients maintain ready access to their own medical information.³¹ As part of the growing recognition of the importance of patient-centered healthcare, diverse interventions are being drawn on to support these efforts. m-Health uses mobile and wireless devices to improve healthcare services and outcomes.¹⁴ Through technologies such as text-messaging and mobile applications, information between patient and providers is shared. Evidence supporting the value of m-Health in the management of pediatric chronic conditions is emerging.³²⁻³⁵ Similar to the Text2Breathe intervention, efforts to improve parent-clinician communication and disease management using m-Health have emerged for varying pediatric chronic conditions including diabetes³⁶ and cancer.³⁷

Improving communication between providers and families of CYSHCN is imperative to supporting family-centered care. However, assessment of outcomes relating to the exchanges of information and care received, are also pertinent to this this goal. In the field of pediatrics, a call has been made for a paradigm shift in how quality measures are developed and implemented. Specifically, recognition that until there is a way to measure quality of care in areas where consumers are the best source of knowledge, information will remain limited.³⁸

Many contemporary measures³⁸⁻⁴⁰ designed to assess quality of care in pediatric primary care settings ask about the coverage of topics by the provider. These measures often present an unnecessary response burden (over 40 items), have item stems of differing recall length, use varied response options, or do not consistently assess socio-ecologic factors pertinent to low-income children and families (e.g. neighborhood safety, transportation needs). Additionally, the format (e.g., paper-pencil) and scoring requirements of many outcome measures make them difficult to utilize in clinic settings. Further, there is a great deal of evidence that many important health and development topics assessed by these measures are not covered during visits due to time limitations,^{41,42} further highlighting the need for a paradigm shift in pediatric care quality assessment development and implementation.

Recognizing the need for improved outcome assessment in pediatric primary care, and the emerging evidence showing the value of m-Health in supporting parent-provider communication for families of CYSHCN, I will develop an m-Health based tool that allows for brief, flexible, and targeted *information exchange*. I will propose to redesign how we conduct outcome assessment in pediatric primary care so that information sharing occurs in response to information gathered from parent-report questions.

This tool seeks to move beyond assessing routine topic coverage. It will directly assess the needs of the child and family on an on-going basis *and* afford pediatric providers a way to be responsive to those needs in real time. I will utilize culturally appropriate ways of collecting health related information and modern psychometric methodology (e.g. IRT) to develop customizable item banks, covering a range of topics most relevant to the needs of the child, their family, and the clinician. Items will cover both general (e.g., achievement of developmental milestones) and condition specific health-related topics (e.g. medication management), as well as broader psychosocial support needs (e.g., food and housing security). Parent responses to items will trigger a follow-up response by an automated system with 1) curated information designed to address the parent's needs/concerns based on responses to items and 2) an option for direct follow-up by the primary care clinic, if indicated as desired by the parent.

Development of this tool will serve as an important step towards shifting the paradigm of quality assessment in pediatrics by putting the needs of the child and the family at the forefront of clinical decision making, and the response to those needs at the center of pediatric care quality assessment.

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