Text2Breathe: Enhance Parent Communication to Reduce Pediatric Asthma Disparities

Study Protocol

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Version 6

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Objective/Aims: 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. 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. 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. 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.

Rationale: Chronic diseases, such as asthma, disproportionately affect urban, low-income children. A key recommendation of the National Asthma Education and Prevention Program (NAEPP) Guidelines for the Diagnosis and Management of Asthma is partnership between healthcare providers and patients (and their parents, for children). Facilitating parents' open communication with providers regarding healthcare status and concerns can equip them to more effectively partner with their child's primary care provider (PCP). Thus, improving the health communication skills of low-income parents could improve parent's adherence to treatment recommendations including utilization of the primary care for asthma care, and ultimately improve their child's asthma health outcomes. 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]

Study Design: A parallel-groups randomized control trial with low-income parents of children with physician-diagnosed asthma, ages 2-12 years inclusive, who are seen in the Seattle Children's ED or Mary Bridge Children's [for asthma care]. Each hypothesis will be tested by contrasting parents receiving T2B with parents receiving only standard ED-based care for their child's asthma, over 12 months.

Patient Selection: 276 parents of Medicaid-insured children ages 2-12 years inclusive, seeking asthma care at Seattle Children's or Mary Bridge Children's emergency department who are the primary owners of a mobile phone with text messaging service.

Outcomes: Outcome data on parental self-efficacy and outcome expectations, adherence to asthma care treatment recommendations (e.g. primary care utilization), and child

asthma outcomes (e.g., ED visits, asthma morbidity) will be collected via structured telephone interviews at 3, 6, 12, 18, and 24 months post- enrollment.

Study Aims & Hypotheses

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.

Background and Study Rationale

Pediatric Asthma Epidemiology

Asthma is the most common chronic pediatric medical condition in the United States,[1] affecting 6.5 million children under 18 years of age in 2005,[11] who annually make in excess of

700,000 visits to EDs.[12] Its prevalence in children has increased dramatically from 3-4% in 1980 to over 9.6% in 2009.[2] Despite effective guideline-based care, ED utilization and hospitalization has not decreased.[12] A study by Fletcher et al found that, by early adulthood, asthma led to reductions in health status, increases in obesity, and increases in work absenteeism,[13] suggesting a substantial economic impact both in health care costs and loss of workforce. Disparities in Asthma Care and Outcomes Disadvantaged, urban children incur a disproportionate share of asthma prevalence and morbidity.[1] Thirteen percent of impoverished children less than 18 years-old are diagnosed with asthma compared to 8% of those living above 200% of the poverty threshold.[3] Moreover, Medicaid-insured children are more likely to visit EDs, which are high cost, than their privately-insured counterparts.[14]

Guideline-based Asthma Care Improves Health Outcome - Validation of IMPACT DC

First published in 1991 and now in its third iteration, the NAEPP Guidelines for the Diagnosis and Management of Asthma provide a comprehensive approach to asthma management.[6] Dr. Stephen Teach (Consultant) and colleagues launched the IMPACT DC Asthma Clinic in 1992 to provide comprehensive asthma education, medical consultation and care coordination that is consistent with NAEEP guidelines. The clinic typically sees children within two weeks of an ED visit or hospitalization for an acute exacerbation, taking advantage of the "teachable moment" that naturally occurs after the crisis of an asthma attack. In a 90-minute visit, they meet with an asthma educator and a physician or nurse practitioner. The IMPACT DC intervention was validated in a prospective RCT involving 488 children with physician-diagnosed asthma aged 12 months to 17 years presenting to the ED for acute care of asthma.[15] The cohort was predominantly AA (86%) and economically disadvantaged (57% had annual household incomes <$30,000; 68% had public insurance). Prior to enrollment, reliance on the ED was high, with more than half reporting ≥4 ED visits in the previous 12 months. Despite the high morbidity of this cohort, 24% reported no scheduled visits to a PCP to discuss asthma in the prior 12 months.

Over the six-month follow-up period, patients in the intervention group had significantly fewer unscheduled visits (to urgent care or emergency departments) than patients in the control group [1.4 visits vs. 2.3 visits respectively, adjusted RR=0.6 (95% CI:0.5-0.8)]. Equally important, the intervention group reported more symptom-free periods and decreased asthma severity at one-month follow-up with improvements in several measures of quality of life that largely persisted over the six-month follow-up period. The intervention also increased more proximal behaviors such as adherence to long-term asthma control medications and reduced exposure to environmental triggers (e.g., smoking in the home).

Despite these efforts, the IMPACT DC intervention did not increase primary care utilization over the six months of follow-up [adjusted mean of 2.05 visits in the intervention

group vs. 2.04 visits in the control group, adjusted RR=1.0 (95% CI:0.85-1.18)]. In addition, the proportion of caregivers reporting their PCP to be their child's primary source of asthma care did not differ at one-month follow-up (48.7% in the intervention group vs. 49.1% of controls, p=NS). To better understand the implications of this shortcoming, our research team assessed the impact of parent-provider relationship on asthma outcomes for the 94% (n=460) of participating children whose parents identified a PCP.[16] At baseline, parent-provider relationship was significantly associated with improved markers of longitudinal asthma management such as fewer prior ED visits. Over the subsequent six months, it was associated with decreased hospitalizations. These findings suggest that failure to improve utilization of PCPs for usual asthma care limited the IMPACT DC intervention's effectiveness in improving child asthma outcomes. It is this deficiency in primary care utilization, which our subsequent health communication intervention was designed to address.

Rationale for Intervening to Improve Parent Communication: Enhancing Effects of IMPACT DC

Relevance of Effective Patient-Provider Communication to Guideline-based Asthma Care

Effective communication is necessary in the development of a patient-provider care partnership, which the NAEPP Guidelines emphasize is essential for improving asthma control and reducing exacerbations (e.g., urgent care visits).[6] Studies of patient-provider communication in adult populations have found that more patient-centered and partnership-building provider communication styles are associated with patient satisfaction with care, adherence to treatment plans and quality of healthcare.[17-21] Unfortunately, such communication is less frequently observed with low-income patients.[22]For children with chronic diseases, parents (i.e., primary caregivers) play a critical role in disease management and are necessary mediators of the patient-provider partnership. Though less abundant than in the adult literature, studies of parent-provider communication (PPC) have also found a relationship between communication and parent satisfaction with care, adherence to treatment recommendations, and discussion of psychosocial issues.[23-28] As it has implications for disease self- (or in this case parent) management, poor parent-provider communication could play a role in the increased morbidity associated with asthma among low-income, urban children.[29]

Shifting from Provider Communication Training to Parent/Patient Training

Previous interventions to improve patient-provider partnerships have primarily focused on improving provider communication skills and teaching providers to be more collaborative with patients and families.[30-35] While such training of providers remains an important priority, partnership with PCPs also requires that the patient/parent effectively communicate issues such as emerging symptoms or response to medications. Such active parent participation in communication with their child's provider is more likely to be parent-initiated than physician-prompted.[36] Some recent research suggests parents' communication with providers has implications for asthma outcomes; an asthma communication education intervention delivered to low-income parents in their homes showed a trend-level effect on higher controller to total medication ratio at the 12-month follow- up.[37] Thus, strengthening the communication skills of low-income parents may improve adherence to asthma care recommendations (e.g., controller medication use, routine visits with PCPs) thereby improving their children's asthma outcomes.

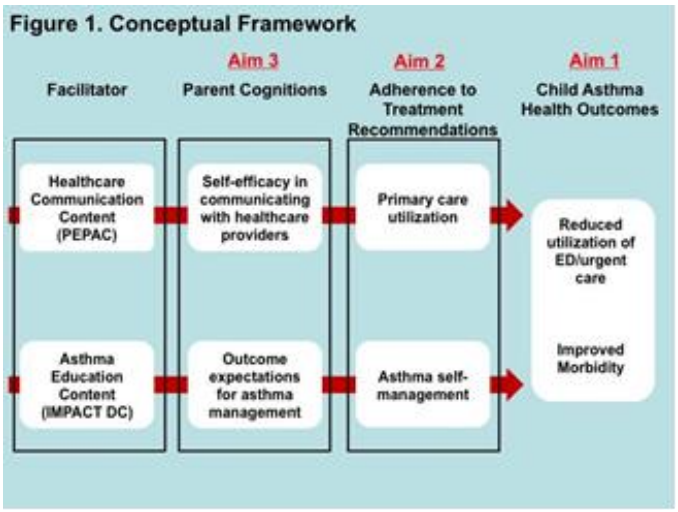
The Role of Parental Self-Efficacy in Improving Parent-Provider Communication (PPC)

A review of the empowerment literature by the Health Evidence Network of the World Health Organization concluded that empowerment strategies are one of the most effective vehicles for improving health and reducing health disparities among disadvantaged populations.[38] At the individual level, empowerment strategies focus on improving one's self-efficacy, and according to Social Cognitive Theory,[39] self-efficacy is a critical mechanism for changing health behaviors (e.g., medication adherence, following up with PCP). In her observational research on parent-provider communication, Dr. Horn (PI) examined whether parent-reported self-efficacy influences audio-recorded PPC among urban, African American (AA) parents. Results indicated that parental self-efficacy in communicating with their child's provider was an independent predictor of parent's disclosure of concerns to their child's PCP.[40] Moreover, the effect of high self-efficacy was specific to lower income AA parents. The study also found self-efficacy to be positively associated with more question-asking and information-giving regarding medical content by AA parents. Question-asking and information-giving by patients/parents are an important aspect of effective patient/parent-provider communication. Adult studies have found that patients who were more assertive and asked more questions during health care visits had better medication adherence, indicating more engaged patients experience better outcomes.[21] These results suggest that a health communication intervention for low-income parents aimed at improving self-efficacy and communication with providers may be effective at improving health behaviors.

Conceptual Framework for a Parent-Focused HC Intervention in Asthma Care

Building on Dr. Horn's observational work, our team developed a HC intervention to educate and empower parents to communicate more effectively with their child's PCP. Having the goal of increasing parent's self- efficacy in communicating with their child's PCP and improving primary care utilization for asthma care, this intervention was guided by Social Cognitive Theory (SCT), which recognizes the impact of one's environment on behavior, but focuses on an individual's ability, through behavior change, to alter that environment to suit their needs.[41] SCT helps explain how psychosocial factors can impact sustainable behavior change.[39] Psychosocial factors include cognitions such as perceived self-efficacy, which is the belief that one can successfully perform a required task in order to achieve a desired outcome. Environmental factors that contribute to behavior change (e.g., interventions) are facilitators - the provision of tools or resources that make a behavior easier to perform.[42]

As depicted in the top row of our conceptual model (Figure 1), our HC intervention as a whole serves as a facilitator for changing parents' health communication and primary care utilization behavior. Flores et al. found that parent mentors were effective in improving asthma outcomes for minority children by serving as counselors who taught parents about managing their child's asthma and facilitated the parents' navigation of the health care system.[43] In a similar manner, our HC intervention employs educators to equip parents with skills to achieve clear information exchange with their child's PCP. The modifiable psychosocial/ cognitive factor that we sought to impact with the intervention was self-efficacy, which we aimed to improve by educating parents and giving them tools/skills for effectively communicating with their child's PCP about asthma. Specifically, our Parent Empowerment Program in Asthma Care (PEPAC) provided face-to-face HC education in the context of an IMPACT DC clinic visit, with emphasis on the information-exchange components of an asthma care visit with their PCP. In sum, through facilitating effective communication and improving self- efficacy, our HC intervention aimed to increase parents' primary care utilization and thereby improve children's asthma outcomes.



Parent Empowerment Program in Asthma Care (PEPAC)

The PEPAC intervention as noted above, is a face-to-face HC intervention implemented in the context of the IMPACT DC clinic setting. The intervention is presented in a format easy for parents to remember, a communication toolkit consisting of 3 S's: Sharing information and concerns, Seeking information about diagnosis and asthma care plan, and Saying It Back for mutual verification.

- Sharing: The importance of planning for the history-taking component of the PCP visit is emphasized, having parents think through what health information they can provide, their questions and concerns regarding their child's asthma needs, and their overall goals for the visit.

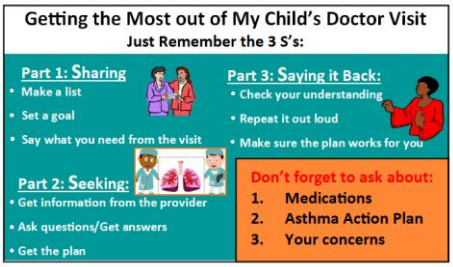
- Seeking: The physical exam and assessment aspect of the healthcare visit is described as information-seeking, primarily by the provider, so that they can develop a differential diagnosis or assessment and a plan for care management. The parent is also encouraged to seek information from the provider about the diagnosis and asthma care plan.

- Saying It Back: Information verification or saying it back is when parents clarify for themselves and the provider what the plan of care is for their child. It is an opportunity to address any difference between parent and provider goals for the care plan.

These 3 S's are conveyed to parents by a research assistant (RA) using a poster board as a visual aid.

Parents are then given a wallet-sized card (Figure 2) with their child's PCP name and contact information as well as a reminder of the 3 S's. The RA discusses the importance of

follow-up with the PCP for asthma care after the IMPACT DC visit. Parents then receive a "booster call" within two weeks of their visit to review the information learned during the intervention.



HC Intervention Improves Children's Asthma Health Outcomes – Validation of PEPAC

Our team recently completed a RCT evaluating whether our HC intervention (PEPAC) improved upon IMPACT DC's effectiveness at increasing primary care utilization for asthma care.[7] A total of 150 participants (77 intervention group) were enrolled, and data were collected at baseline, 2-months (n=138; 92% retention) and 6-months follow-up (n=130; 87% retention). Sample demographics are comparable to those reported above for the IMPACT DC trial. At enrollment, according to NHLBI classifications, 54.1% of children had mild persistent asthma, and 31.8% had moderate persistent. 50.7% of parents said their child had a written asthma action plan, and 83.0% identified their child's PCP as the primary source of asthma care. The intervention group was more likely to be on public insurance, to have household income <$30,000, and to have environmental tobacco/smoke exposure in home, thus these variables were controlled in multivariate analyses.

At two months post-enrollment, parents in the intervention group had significantly higher odds of identifying a PCP as their child's main source of asthma care (adjusted OR=12.6, 95% CI: 1.1-142.1) and reported a significantly lower rate of ED visits for asthma care between baseline and the 2-month assessment (adjusted IRR=0.3, 95% CI: 0.1-0.8). These significant differences in utilization of primary care and acute healthcare were not sustained 6-months post-enrollment. However, overall, these results indicate that a brief, in-person health communication intervention for parents of high-risk children with asthma can improve

adherence to recommendations of relying on PCPs as the usual source of asthma care and limiting utilization of EDs for asthma care, at least in the short term.

Lessons Learned from a Face-to-Face HC Intervention

In critiques of the PEPAC study, we identified two key limitations of our face-to-face HC intervention design. First, the brief nature of the PEPAC intervention likely constrained the effects on behavior change. In our proposed study, we will extend exposure to intervention content via mobile phone based text-messaging. The rationale for using text-messaging, specifically among this target population, is outlined in the Innovation Section (B.1.b.) below. Second, we did not take into consideration parents' beliefs about their child's asthma. Specifically, as noted in the Social Cognitive Theory, [39] in addition to self-efficacy, the parental cognition of outcome expectations, one's beliefs about the costs/benefits of a behavioral choice, may serve as a potentially modifiable factor impacting asthma outcomes. Along with issues of competing priorities, this may play a role in worse asthma outcomes for minority children. Therefore, in the currently proposed intervention, outcome expectations will be targeted by identifying parent's personal goals for their child's asthma outcomes, by sending messages containing relevant asthma information and that reinforce how health communication will help achieve these personal goals. These two key enhancements to the PEPAC intervention will contribute to sustainability of expected health behavior changes.

Innovation

Advantages of mHealth Innovations

mHealth, 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.[44] The efficacy of mHealth technologies (e.g., text-messaging, mobile applications) is in part due to their convenience as a method of health information exchange,[45] and, similarly, they are effective for modifying health behavior because behavioral cues (e.g., reminders) can be sent/received asynchronously, when and where they are most relevant/appropriate.[8] Moreover, mHealth technologies are gaining in popularity because they are available at relatively lower cost to payers, providers and patients.[46]

Albeit few, empirical evaluations have demonstrated that mHealth technology can be used in pediatric settings to improve children's chronic disease self-management (e.g., medication adherence, self- monitoring) [47,48] and parental adherence to preventive treatment recommendations.[49] In the context of pediatric asthma, recent text-messaging interventions have shown promising effects on controller-medication adherence,[50] asthma symptoms and quality of life.[51] The only known mHealth intervention aimed at parents targeted immunization

compliance, and documented significant effects on adherence to preventive treatment recommendations. Kharbanda, Stockwell and colleagues have documented consistent positive effects of their Text4Health program on increasing influenza and human papilloma virus vaccination rates among low-income minority youth.[46,49,52,53] Their intervention delivers text message reminders (date, time, location of clinics) to parents along with educational content about the benefits of and dispelling any misconceptions concerning the particular vaccination. Two of the noted advantages of this mHealth intervention are that text messages are short and thus may overcome literacy barriers in low-income populations, and by linking to electronic health records it has been delivered to large patient populations without incremental cost.[52]

Opportunity for mHealth Interventions to Address Health Disparities

Approximately 85% of American adults currently (as of Spring 2013) use the Internet, 56% own a smartphone, and 63% go online wirelessly with a laptop or cell phone.[54-56] Furthermore, 72% of Internet users reported looking online for health information with 31% of cell phone owners and 52% of smartphone owners saying they have used their phone to look up health or medical information.[57] Despite overall increases in access to and use of the Internet and mHealth technology, differences in access/use vary by race/ethnicity, age, income, education and urbanicity.[54, 58] Recent studies indicate a majority of urban, low-income parents use their cell phones to access the internet (71% own a smartphone) and are very interested in receiving health information via mobile technology.[59, 60]

Due to its popularity among URM populations, relatively low cost, and demonstrated efficacy in improving health behaviors, mHealth technology is uniquely well-suited for addressing pediatric health disparities. mHealth technology can have important public health impacts in pediatric settings, where clear and frequent communication between parents and providers is important for managing children's chronic diseases (e.g., asthma, diabetes). Parents [or other caregivers] serve as the intermediary between pediatric patients and providers; they determine when healthcare is sought and are primarily responsible for relaying information about their child's health to providers.[61] Thus, utilizing mobile technology to empower parents to more effectively communicate with their child's health care providers is a promising method for addressing disparities in childhood chronic diseases.

Rationale for Using mHealth to Expand the Scope of a Face-to-Face HC Interventions

Ongoing face-to-face tutorials with trained educators, as in the PEPAC study above, are labor intensive, costly and not easily generalizable, which limits this intervention's application

in additional settings and disease populations. Text messaging is a promising mechanism for delivery of our HC intervention because it addresses the practical limitations of a face-to-face intervention. First, text messaging has become a widely used form of electronic communication, especially among urban minority populations. 72% of adults send and receive text messages, and minorities send more text messages than their White counterparts.[10] Given high rates of mobile phone use, especially text messaging, in URM populations, this innovative approach to delivering important health-related information can reach those with the greatest healthcare needs. Second, messages can be sent asynchronously and received anytime, anywhere. This means that parents can easily refer to the message when the information is most useful, for example while they are discussing their child's health with their PCP, making it a more effective behavioral cue. Third, as it is less intrusive than a phone call and less effortful than in-person meetings, parents may be more receptive to information delivered via text. A survey of low-income parents of children under 6 years-old attending a Midwestern pediatric residency clinic indicated that the majority of this population is interested in receiving healthcare information (e.g., appointment reminders, test results, general health tips) via text messages from their PCPs.[62] Fourth, messages are easily mass distributed; once the protocol is developed, it can readily be scaled up to a population level without additional cost to program providers.

Potential for Advances in the Field

The proposed project is novel both in terms of the substance of the intervention and the means by which it will be administered, and as such, has implications for research and clinical practice.

Research Implications

This project fills several gaps in current research on pediatric asthma treatment, parent-provider communication, and mHealth methods for behavior change. First, this study directly addresses a pediatric health disparity. While studies have shown that mHealth can facilitate patient/parent-provider communication among children with asthma, [61] few focused on urban, low-income populations for whom asthma rates and morbidity are high. Our team has access to an inner-city, racially diverse, Medicaid-insured population of children receiving ED-based asthma care and has a proven track record of successfully engaging this population in research. Second, this study builds on previous successes (IMPACT DC and PEPAC) by using mHealth to expand access to and the scope of our HC intervention for urban, low-income parents of children with asthma to improve their adherence to treatment recommendations. The proposed text-messaging is personalized and interactive, but does not directly involve the PCP. Therefore, it circumvents provider time constraints and reduces the long-term costs of

administering this HC intervention. Third, this study advances research on mHealth for health behavior change by expanding the age range of children and testing longer- term efficacy. Most text message interventions in the pediatric setting have involved adolescents, who are themselves mobile phone users (see Kharbanda et al. for an exception [46,49,52,53]), but by delivering an intervention to impact parent behavior, we hope to affect asthma outcomes in a wide age-range of children. Fjeldsoe and colleagues noted that most text messaging interventions for health behavior change only assessed outcomes at the end of the intervention period, [8] but this study will examine longer-term efficacy with follow-up data collection up to 12 months post-intervention.

Clinical Implications

This HC intervention also advances clinical practice by targeting parent rather than provider communication, using a cost-effective technology for secondary prevention, and addressing a health behavior that is applicable across disease contexts. Part of effectively managing pediatric asthma is comprehensive and clear information transfer between patient (or more often their parents) and the healthcare provider. While some mHealth interventions are designed to improve patient-provider communication,[61] few have targeted the parents of low-income, medically underserved children,[63] despite their recognized role as the mediators of communication with healthcare providers.[61] Other interventions have shown effects of text message interventions on primary prevention behaviors among URM populations.49 Also, a text-messaging intervention has been shown to improve asthmatic children's disease management;[50] however, we propose using mHealth technology to impact prevention of asthma symptoms through primary care utilization. Finally, the proposed intervention advances clinical practice by establishing the feasibility and efficacy of a HC intervention that is not entirely disease specific. The study's goal of improving parents' communication self-efficacy and adherence to evidence-based guidelines in the care/management of a chronic pediatric condition can be applied to other chronic diseases (e.g., diabetes) for which there are health disparities.

Scaling up an Innovative mHealth-Enhanced HC Intervention

The overarching aim of the proposed project is to reduce a pediatric health disparity, specifically improving urban, low-income children's asthma-related health by empowering parents to more effectively communicate with providers and manage their children's disease. Improving parent communication and adherence to treatment recommendations in general could lead to positive child health outcomes for other chronic conditions such as diabetes, obesity and mental illness, further reducing health disparities. Based on the findings of the proposed study, the next step in this line of research would be to extend this mHealth-

enhanced HC intervention to parents of children with other chronic conditions. In addition, the expedience of scaling up a text-message protocol means that our intervention can easily be adapted to reach a broader audience in a cost-effective manner when compared to ongoing face-to-face interventions. If efficacy is demonstrated, another next step will be to expand the program to other healthcare settings, such as primary care practices.

Study Design

We propose to conduct a RCT with low-income parents of children with physician-diagnosed asthma, ages 2-12 years inclusive, who are seen in the Seattle Children's or Mary Bridge Children's ED [for asthma care] to test the efficacy of our mHealth HC intervention, T2B, primarily for reducing ED/urgent care visits for asthma care. Each hypothesis will be tested by contrasting parents receiving T2B with parents receiving only standard ED-based care for their child's asthma, over 12 months.

Study Schedule

Data on child and parent outcomes will be collected in-person at enrollment and by telephone interviews at 3, 6, and 12months post-enrollment. These telephone interviews will all be coordinated and conduction by the Seattle Children's study staff. Given the highly seasonal nature of asthma-related morbidity, the text message component of the intervention will continue for 12 months (3 months of biweekly educational interactive text messages; on-going parent-initiated access to key messages and reminder text messages for PCP follow-up/medication refills/annual flu vaccines) allowing for the capture of individual variability in disease course. (Figure 3).

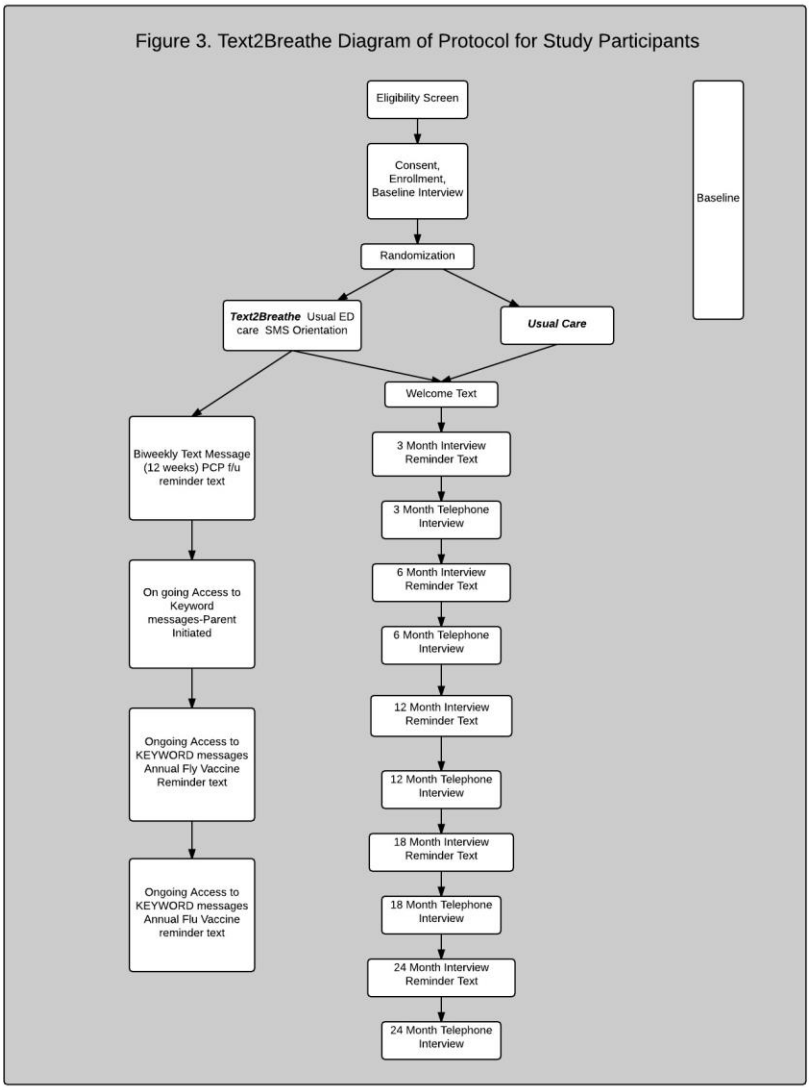


Figure 3

Study Population

The study population will be parents/guardians of Medicaid- insured patients seen in the Seattle Children's or Mary Bridge Children's ED for treatment of their asthma. These are patients whose asthma is not yet well controlled and who experience the greatest morbidity due to environmental and social factors and are thus the most resource-intensive group.

Inclusion criteria: Parents of Medicaid-insured children age 2 to 12 years inclusive with physician- diagnosed asthma for at least 12 months will be eligible. Older children/adolescents are excluded because they assume greater responsibility for asthma self-management, and their communication with providers becomes more independent over time. Parents must be

the primary owners of a mobile phone with text messaging service, which is anticipated to be at least 75% of parents in this population based on previous research on urban, low-income parents.[59, 60]

Exclusion criteria: Parents of children with significant medical co-morbidities (e.g., sickle cell disease, insulin-dependent diabetes mellitus) will be excluded because of their increased interaction with healthcare providers.

Recruitment and Randomization

CRAs will identify potentially eligible patients through electronic admission board and medical record diagnostic codes after intake into the ED, and they will describe the study to potentially eligible parents while they are waiting to be seen by a provider. Interested families will be screened for eligibility. If eligible, parents will complete the consent process. (See section 5.2.a for more details.) Then the CRA will administer a baseline questionnaire focusing on health care utilization, asthma self-management and morbidity, parental self-efficacy and outcome expectations. After the questionnaire is completed, participants will be randomized to usual care or the intervention group (T2B). Randomization will occur automatically via the RedCap database system. Time allowing, participants randomized to the intervention will receive brief education on the 3 Ss and orientation to the text message component (including an "opt-in" code) while in the ED or if necessary by phone within 48 hours. The text message education component will begin within 1 week after participants are randomized, allowing time for participants to enter the opt-in code.

Retention and Compensation

Parents will receive total compensation of $110 for participation in the study to be dispensed as: $20 gift card will be given to the parent after he/she completes the baseline interview and $30 gift cards will be sent after the 3, 6, 12 follow-up interviews; Based on previous studies conducted by our research team with similar populations, this amount should be sufficient to compensate participants for their time and offset the cost incurred for the text messages (if any), but it will not be coercive, minimizing participation solely based on financial gain.

To assist with subject retention, considering the transient nature of this community and the fact that phone numbers are frequently disconnected and/or changed, we will obtain up to 3 contacts' phone numbers from each participant at enrollment, and review and update contacts at each follow-up interview. Using this method in previous studies, our research team has successfully maintained 90% subject retention at 6-month follow-up.[15] In addition, Rip Road has extensive experience working with underserved populations [through public health departments] and pay-as-you-go service providers, and can thus nimbly respond and adapt to

any service interruptions. The window for follow up visits will be two weeks prior and post the due date for the 3 and 6 month follow up time points and 1 month prior and post the due date for 12month follow up time point. To enhance our ability to retain participants for, at each wave of follow-up, the system will send text message reminders to participants to alert them that their follow-up call is approaching and to contact the study coordinator to schedule. If a call has not already been scheduled as of day 1 of the open window, a CRA will contact the family. If no contact has been made as of the due date an online version of the follow up survey will be emailed to the provided email contact. If the participant misses a wave they will still be called for the next follow-up. Information for alternative contacts will also be collected at the time of consent. These contacts will be utilized when participants' provided phone numbers are inactive.

Data Collection

Trained CRAs will conduct structured in-person interviews after participants have consented and before randomization. Follow-up interviews, lasting approximately 30 minutes, will be conducted by a trained CRA blinded to participants' randomization. In cases when no blinded CRA is available an unblinded CRA may complete the survey. Unblinded status will be documented for each survey conducted. Electronic medical record review will be conducted by trained study staff at the site where the participant was enrolled. Measures of asthma outcomes for this study are aligned with the recent recommendations of the Asthma Outcomes Groups for standardization of definitions and data collection methodologies for asthma research studies and clinical trials.[75,76] All, but one of the following measures will be administered at each wave of data collection. The Asthma Self-Management Questionnaire will be administered at baseline and 12 months. (see appendix for Baseline Survey).

Distal Outcome Measures – Child Asthma Outcomes

ED visits for asthma care: Parents will report whether and how many times their child was taken to the emergency room because of asthma during the past 12 months using 2 questions administered in several national-scale surveys; [75] they will also indicate whether those visits included receipt of systemic corticosteroids.[76] We will validate a large portion of this data with EMR review because Seattle Children's is the primary ED utilized by young patients in the Seattle area and Mary Bridge Children's the primary ED utilized by young patients in the Tacoma area.

Asthma Morbidity: Asthma morbidity will be assessed by the questions used in the Inner City Asthma Consortium (ICAC)[73, 74, 77, 78] and applied subsequently in numerous studies, including the study validating the IMPACT DC intervention.[15] Morbidity will be measured as the number of days (or nights) of impairment in the prior 2 weeks.

Proximal Outcome Measures – Adherence to Treatment Recommendations

Primary Care Utilization: To maintain continuity in outcomes with the IMPACT DC RCT,[15] we will ask parents to identify their child's primary asthma health care provider, as well as their child's primary care provider. A computed variable will indicate whether the named PCP is the child's primary asthma heath care provider. In addition, we will ask parents about frequency of PCP visits for asthma care at each telephone follow-up interview.

Asthma Self-Management: For asthma, self-management involves of a number of tasks to prevent and manage symptoms, such as monitoring symptoms over time, avoiding known triggers, and taking medications properly. The Asthma Self-Management Questionnaire,[79] a newly developed measure recommended by experts convened for the Asthma Outcomes workshop,[80] includes 16 multiple-choice questions regarding knowledge of preventive strategies and controller medication use. Standardized scores (0-100) are generated, with higher scores indicating more knowledge of self-management. Cronbach's alpha was 0.71. Wording of questions will be revised (e.g., "you" = "your child") to be appropriate for parents of children with asthma.

Parental Self-efficacy: The Medical Competence Communication Scale (MCCS) measures patient's perceptions of their own communication during their most recent medical visits.[81] The patient version of the measure is used to assess information giving, seeking and verifying, as well as socio-emotional communication. The MCCS, patient version, consists of 23 items rated on a 5-point Likert scale (1= unimportant to 5= important) with a higher score indicating greater perception of communication competence. Cronbach's alpha ranges from 0.76-0.92 on the various subscales. Only the 16 self-competence items will be administered in this study. Wording of questions will be modified to state "my child's medical problem" rather than "my medical problem." The Parent Asthma Management Self-Efficacy Scale (PAMSES) is a valid and reliable instrument designed to measure parent self-efficacy in preventing and managing children's asthma attacks.82 The PAMSES consists of 13 items rated on a 5-point Likert scale (1=not at all sure to 5=completely sure) with a total possible score range of 13 to 65; higher scores indicate greater self-efficacy. Cronbach's alpha in a sample of primarily White mothers was 0.87.82

Parental Outcome Expectations: In accordance with other research of pediatric asthma interventions, to assess parents' beliefs about possible asthma quality of life for their child we will administer an 8-item measure of parental expectations for asthma treatment.[83] Parents respond to statements about their expectations (e.g., "I believe that my child can be symptom free most of the time.") using a 5-point Likert scale (1=strongly disagree to 5=strongly agree). Total scores are calculated by averaging across responses, and higher scores reflect more optimistic asthma outcome expectations (Cronbach's alpha = 0.70).

Study Intervention

The T2B intervention will consist of a personalized, interactive text-messaging program with asthma and health communication education (derived from IMPACT DC and PEPAC), as well as follow-up reminders for scheduling asthma care appointments with PCP and annual flu vaccines. Participants randomized to the control group will also receive reminder texts to schedule with their child's PCP and to get an annual flu shot. An algorithm of text message delivery will be determined for each participant (see appendix for Sample Algorithm content). The manual/intervention protocol and text messaging content will be refined and finalized during the start-up phase of the project (see Protection of Human Subject section for timeline). Within 24 hours of enrolling in the study, participants in the intervention will begin receiving a series of automated bidirectional text messages to their mobile phones based on the education components of IMPACT DC and PEPAC. In order to be oriented and familiar with the content of these messages participants randomized to intervention will also receive face-to-face PEPAC education, including the 3S tool kit card during their baseline visit. Messages will originate from the T2B program during the first 3 months, after which parents can text key words to repeat or receive additional messages/education at any time.

Text messages will be individually tailored to include child and parent initials and, child's gender, Parents will also choose one goal important for improving management of their child's asthma and for communicating with their child's PCP regarding asthma care. A component of their text message communication education content will be based on their identified goal. Information for the tailored messaging will be collected as part of the baseline survey and will be verified and updated at the 3, and 6 month telephone interviews.

Two to three education messages will be sent each week for the first 3 months, one focused on an IMPACT DC asthma education message and a second on a PEPAC health communication message. Parents in our focus groups indicated that this frequency of messages would not be burdensome but welcomed and useful. Parents will also receive text message reminders to follow up with their child's PCP for asthma care at appropriate times based on the asthma care guidelines and relative to the date of the ED visit/enrollment into the program. Parents will also be prompted to reply to the text confirming a scheduled appointment with their child's PCP. Some messages will 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 will send a subsequent text message with appropriate feedback. The program will also allow participants to send a variety of keywords at any time to receive additional messaging. This will allow parents, for example, to request the 3 S's during a visit with the PCP. Other messages may include an embedded link to a URL with additional relevant content (e.g., videos demonstrating proper inhaler technique, explanation of controller vs. rescue inhalers), which we anticipate most participants will be able

to access on their mobile device given the majority of urban, low-income parents in a recent study owned smart phones.[59]

Table 1. Text Message Healthcare Communication and Asthma Education Content

Theoretical Construct	Component of Intervention	Content	Week(s)
Outcome Expectations	Introduction to program	• Welcome to Text2Breathe. As part of this study we will be sending you messages 2x/week over the next 4 months. (interactive)	1-2
	Tailoring questions	• Participant's initials, Child's initials, , Child's gender •	
	Identification of personal goals (tailored)	• Fewer ED visits • Missing less school • Be more active • Follow-up with PCP every 3 months	
Facilitation	Education	• 2-3 messages/week – Personalized, Interactive • Examples will be based on stated information and goals (personalized) • Statement with response required about correct answer for example given (interactive) • *Asthma Education Example* –Controller medications should be taken every day. Choose a time a day that you and [child's initials] will remember. Txt MEDS 4 info. • *Health Communication Example* –Saying It Back is important 2 b sure you know your child's asthma plan. Txt 3SS for help on what to ask.	3-12
	Reminder Messages	• Reminder to follow-up with PCP, Influenza Vaccine • *Reminder Example* –Time 4 [child's initials] 2 follow-up with PCP. Did u make an appt? Reply YES or NO. Reminder to schedule study follow up call	
Self-efficacy	Keyword requests	(3SS) –Info from communication toolkit (PCP) – Reminder of when to follow-up with PCP (GOAL) - Reminder of parent's intervention goals (MEDS) – Info on difference between controller and rescue medications (TRIGGERS) – Info on common triggers	13-52 or On demand

Participants will receive a handout with instructions on how to interact with the text message intervention (including opt-in instructions and numbers to call for problems). In addition, parents will be informed that the text messaging system is automated and their responses will be sent to a secured computer system so they should not send text messages seeking medical care. Should the participant send a text message to the system that does not align with the algorithm response programming, they will receive a standard message with instructions to contact the T2B team, their health care provider or 911 if it is an emergency. Research staff will also have the capacity to monitor participant engagement with the system to

troubleshoot any problems. Participants randomized to T2B, intervention, group will also receive a wallet sized "tool kit" reminding them of the 3 S's and the key words to request text information.

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