IRB Protocol

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**The Impact of a Parental Health Literacy Book and its Efficacy on Reducing Non-Urgent Visits to the Pediatric Emergency Department: A Pilot Randomized Controlled Trial**

**Abbreviated Title: Health Literacy Book for Non-Urgent ED Visits**

## 1.) Purpose and Rationale

Emergency Department (ED) overcrowding from non-urgent visits can lead to an increase in wait times, utilization of resources and overall poorer health outcomes.[1,2] Lower socioeconomic status, lack of education and Hispanic ethnicity are risk factors for poor health literacy as well as predictors of non-urgent ED visits.[3] Because of the high proportion of native Spanish-speaking patients and parents who present to the New York Presbyterian-Morgan Stanley Children's Hospital (NYP-MSCH) ED, the lower health literacy in this population is particularly important for our patients.

In order to address the problem of health literacy in the pediatric population, multiple child health literacy tools have been developed and studied in different settings. According to a study of a self-care booklet mailed to every household in Uppsala County, Sweden, mothers who had read the booklet were less prone to seek medical care when their children had conditions for which medical care was not indicated.[4] A randomized controlled trial performed in the community surrounding NYP-MSCH showed that parents randomized to an educational intervention deployed through the Early Head Start program were significantly less likely to visit the Pediatric ED than parents in the control group.[5]

The health literacy book titled, *What to Do When Your Child Gets Sick* has been distributed in one Pediatric Emergency Department and in several Head Start programs across the country and has shown by pre- and post- intervention surveys to both increase health literacy in these populations and decrease non-urgent ED visits.[6,7,8] Until now, no randomized controlled trial has been conducted to evaluate the efficacy of this health literacy intervention. The purpose of this study is to perform a pilot randomized, controlled trial of this specific health literacy intervention on a population with perceived high rates of overutilization of Emergency Department services to assess health literacy and ED utilization rates before and after the intervention.

*Hypothesis*

The proportion of parents and legal guardians (hereinafter parents) that re-present at least once with their child to the ED for non-urgent illnesses in the 6 months after receiving an intervention that uses the health literacy book titled, *What to Do When Your Child Gets Sick* will be significantly less than the proportion of parents that re-present after receiving standard discharge instructions.

*Our specific aims are:*

a. To determine the proportion of parents of children who seek care at NYP-MSCH ED for non-urgent reasons who would be willing to participate in the study and 6 month follow up to establish the feasibility of a larger randomized controlled study in this setting.
b. To provide preliminary data on the proportion of parents in intervention and control groups that re-present at least once within a 6 month period. This pilot study will also help establish the potential effect size in the reduction of the median number of non-urgent ED visits, in the 6 months before and the 6 months after enrollment, among parents with their children in the intervention group as compared to those in the control group.
c. To obtain descriptive data on the perceived need of ED care among parents to better understand some of the reasons parents give for presenting with their children and the tools they use to decide what to do when their children are sick.

**2.) Design and Statistical Procedures**

We will conduct a pilot randomized controlled trial to determine the proportion of parents that re-present with their child to the ED for at least one non-urgent illness in a 6 month period when allocated to an intervention vs. a control arm.

Both the intervention and control group will be administered pre-intervention questionnaires at presentation and then called for post-intervention questionnaires at 6 months after enrolling in the study (see attached). The primary outcome measure will be the proportion of parents that re-present at least once to the ED with their child in 6 months after the intervention, based upon review of the electronic medical record and responses to questionnaires, using the number of visits to the ED in the 6 months prior to enrollment to control for pre-study differences between the control and intervention groups. Secondary outcomes will be generated by responses to the questionnaires to evaluate changes in perceived need for ED services as well as query the number of presentations at outside hospital ED locations to obtain the median number of ED presentations in both groups in the 6 month before and the 6 months following enrollment.

*Intervention*

The intervention group will be trained in the use of the book *What To Do When Your Child Gets Sick* in a 10 minute training session with a member of the study staff using training recommendations outlined in the *Teacher's Training Manual* distributed by the Institute for Healthcare Advancement.[9] The trainer will confirm understanding by asking parents to find information in the book to help them answer questions about hypothetical situations previously outlined in the pre-intervention questionnaire. Parents in the control group will be given routine discharge instructions and will receive neither the book nor training regarding how to use this health literacy tool.

*Outcomes*

The primary outcome measure will be the proportion of parents that re-present at least once to the ED in 6 months for non-urgent visits based upon review of the electronic medical record and responses to questionnaires.

Secondary outcomes will include changes in the median number of ED presentations in both groups in the 6 month before and the 6 months following enrollment.

Descriptive secondary outcomes are the reasons parents give for presenting with their children to the ED, as well as the tools they use to decide what to do when their children are sick.

*Sample Size*

This study is designed to be a pilot randomized controlled trial to provide data to adequately power a subsequent study. Prior data from an observational study suggest that the proportion of patients who re-present to the ED within 6 months decreases from 73% prior to receiving training in this book to 43% after training in the use of *What To Do When Your Child Gets Sick* in a predominantly Spanish-speaking population.[6] These prior data originate from a study that did not control for the possibility of decreasing ED visits as children age, did not address the seasonality of illnesses, and may not be relevant in our setting.

We will block randomize 20 parents and 20 respective children into each group. We based this sample size on the expected 2 month enrollment period and the availability of investigators. Five parents and children will be randomized to the control group and 5 will be randomized to the intervention group every 2 weeks for a total 8 week period. With only 20 patients in each group, the study is powered only to find a very large effect size, a decrease in proportion from 73% in the control group to 25% in the intervention group. However, this sample size will establish the feasibility of conducting a larger randomized controlled trial.

**3.) Study Procedures**

Study procedures include: 1) recruitment and consent in the ED, 2) administration of a pre-intervention questionnaire, 3) randomization and allocation, 4) intervention, 5) and 6 month post-intervention questionnaire and follow up.

During recruitment, a member of the treating medical team will ask the parent if they would be willing to learn more about a research study being performed in the Emergency Department. If that parent is interested, they will be approached by a member of the study staff and be given more information about the study and written informed consent will be obtained.

Upon consent, the research staff will administer the attached pre-intervention questionnaire which will collect contact information, demographics, and information about what parents do when their child is sick.

The parents and their respective children will be randomized and allocated to intervention or control group by block randomization using a computerized random number generator. Parents and their respective children in the intervention group will be trained in the use of the book described above and be provided a copy of this book in either English or Spanish based on the language primarily spoken at home. Parents and their respective children in the control group will be provided routine discharge instructions by the treating medical team.

At 6 months after this intervention, the study team (investigators or research coordinators) will conduct telephone follow-up for all parents using a standardized questionnaire. The study team will review each child's electronic medical record at 6 months after recruitment to determine the number of presentations to the NYP-MSCH ED. Any parents from control or intervention group who complete telephone follow-up will have a $10 NYC Metrocard mailed to their preferred address.

**4.) Study Drugs or Devices** - There are no study drugs or devices to be distributed with this study.

**5.) Study Instruments**

The health literacy intervention for this study is training in the use of the children's health education book, *What To Do When Your Child Gets Sick,* by Gloria Mayer, RN, and Ann Kuklierus, RN. Parents in the intervention group will all be given a copy in English or the Spanish-language translation of this book, *Qué Hacer Cuando Su Niño Se Enferma*, based on their preferred language, and will be trained in the use of this book to find health information relevant for their child.

**6.) Study Subjects**

40 parents and 40 of their respective children will be recruited from the NYP-MSCH Emergency Department.

- Inclusion criteria
    - Child between 6 months and 6 years of age registered in the NYP-MSCH ED
    - Child triaged as a non-urgent visit (level 4 or 5 in the standard Emergency Severity Index 5 level triage system) for an Upper Respiratory Tract Infection. This includes patients presenting with a chief complaint of cough, congestion, noisy breathing, or fever (if the parent endorses a symptom of URI on review of symptoms.)
    - Child lives in one of the following zip codes near NYP-MSCH: Northern Manhattan: 10026, 10027, 10030-10035, 10037, 10039, 10040 or Western Bronx: 10451-10457, 10463, 10468
    - Parent (legal guardian) primary language is English or Spanish
- Exclusion criteria
    - Child has substantial chronic illness (ever admitted to an intensive care unit, history of organ transplant, history of HIV infection, takes more than 2 prescription medications, or follows regularly with more than 1 subspecialists including cardiologist, pulmonologist, dermatologist, allergist, or rheumatologist.
    - Child presents with increased work of breathing, asthma exacerbation, shortness of breath, bony fractures, or skin lacerations
    - Treating provider orders lab or imaging study or prescribes outpatient medication, not including prescriptions for medications that are available over the counter
    - Child is moved to the acute side (more severely ill side) of the Emergency Department
    - Child is likely to be hospitalized
    - Parent typically presents for ED care at another hospital
    - Parent is not predominantly English or Spanish-speaking
    - Children in foster care or wards of state

**7.) Recruitment Process**

All parents will be recruited directly by study staff in the NYP-MSCH Emergency Department. Study staff will only approach parents that have already expressed interest in participating in research when asked by the treating medical team.

**8.) Informed Consent Process**

Upon arrival to the ED for non-urgent conditions, triage nurse will initiate appropriate medical management and medical team will assume routine care. A treating healthcare provider will ask the parent if he or she is willing to be considered for a research study. A member of the research team performing the study will approach the parent if they are interested and discuss the study. Parents will be asked to sign written consent to participate in the study and be provided printed information about the study, as well as IRB contact information.

**9.) Confidentiality of Study Data**

Questionnaires collected during enrollment and follow up questionnaires will be kept confidential in a secure location to which only the study research team will have access. They will be kept in a locked cabinet in a locked room maintained by study staff on CUMC and New York Presbyterian Hospital grounds. Follow up data from the EMR and questionnaires will be entered into a spreadsheet and saved on a secure computer that is password protected. Prior to statistical analysis, all data will be de-identified.

**10.) Privacy Protections –** see above.

**11.) Potential Risks**

There is a potential risk of loss of confidentiality, which will be minimized by restricting access of any personal information to the study team and keeping any personal information in a secure location. There is a theoretical risk that parents given our health education tool could become less likely to bring their children to the Emergency Department for a real emergent condition, but no research has shown a decrease in emergent presentations because of the use of health education tools.

**12.) Data and Safety Monitoring**

All data will be available upon request by the Authorities from Columbia University and New York Presbyterian Hospital, including the Institutional Review Board (IRB), and/or the Office of Human Research Protections (OHRP). Any adverse events will be reported to the IRB within 24 hours.

**13.) Benefits**

In the intervention group, participating parents of children presenting with non-urgent complaints will be provided a book with information on how to manage their routine health conditions. Participants can immediately begin using the book to educate themselves on routine pediatric health care at home. Participating parents in both groups will receive a $10 New York City Metrocard in the mail upon completion of the 6 month post-intervention questionnaire.

[1] Derlet, R.W., Richards, J.R. (2000). Overcrowding in the nation's emergency departments: complex causes and disturbing effects. Annals of Emergency Medicine, 35(1), 63-68.
[2] Krochmal, P., Riley, T.A. (1994). Increased health care costs associated with ED overcrowding. American Journal of Emergency Medicine, 12(3), 265-266.
[3] Walls, C.A., Rhodes, K.V., Kennedy, J.J. (2002). The emergency department as usual source of medical care: Estimates from the 1998 National Health Interview Survey. Academic Emergency Medicine, 9(11), 1140-1145.
[4] Rasmussen, F. (1989). Mother's benefit of a self-care booklet and a self-care educational session at child health centres. Social Science & Medicine, 29(2), 205-212.
[5] Stockwell, M., Catallozzi, M., Larson, E., Rodriguez, C., Subramony, A., Martinez, R., Martinez, E., Barrett, A., Meyer, D. (2014). Effect of a URI-Related Educational Intervention in Early Head Start on ED Visits. Pediatrics, 133, e1233-e1240.
[6] Herman, A., Young, K., Espitia, D., Fu, N., Farshidi, A. (2009). Impact of a health literacy intervention on pediatric emergency department use. Pediatric Emergency Care, 25(7), 434-438.
[7] Herman, A., Mayer, G.G. (2004). Reducing the use of emergency medical resources among Head Start families: A pilot study. Journal of Community Health, 29(3), 197-208.
[8] Herman, A., Jackson, P. (2010). Empowering low-income parents with skills to reduce excess pediatric emergency room and clinic visits through a tailored low literacy training intervention. Journal of Health Communication, 15(8), 895-910.
[9] Institute for Healthcare Advancement. Teacher's Training Manual, A Resource Kit for use with: *What To Do When Your Child Gets Sick*.