Alicia Chang, PGY-2
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Effect of a Health Literacy Intervention on Non-Urgent Return Visits in the Pediatric Emergency Department

A. Study Purpose and Rationale

Over the past decade, despite a decrease in the number of available Emergency Departments (ED) nationwide, the number of annual ED visits has increased, creating an overburdened system, increased costs and a scarcity of resources. Overcrowding from non-urgent ED visits exacerbates this growing problem, and studies quote a high incidence of pediatric non-urgent ED visits, ranging from 20-80%. Non-urgent medical problems addressed in the ED setting opposed to a doctor's office often leads to an increase in patient wait times, ED diversions, and increased health care costs. Non-urgent ED visits not only have systemic and economic consequences; young children are at risk for nosocomial infection, poor continuity of care, and increased number of missed school days from long wait times in the ED. Therefore, interventions aimed at decreasing non-urgent ED visits can both improve individual health care while lowering overall healthcare costs.

Studies have shown that Hispanic minority, low education level, low socioeconomic status (SES) and a poor perception of a child's overall physical health were all determinants of non-urgent ED visits. Health literacy, defined by the Healthy People 2010 initiative as, "the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions," has been a focus point for Headstart programs around the country as a means to decreasing poor health outcomes and unnecessary healthcare costs. One study, which implemented a health literacy book titled, "What to Do When My Child Gets Sick," followed approximately 9,000 families in 55 Head start programs around the country, and showed a 58% decrease in ED visits and a 41% decrease in doctor's visits over a 9 month period. Another study based out of the Kansas City Head Start program, implemented the same health literacy resource and found a similar reduction in both ED and doctor's visits. Moreover, in the intervention arm, these studies demonstrated a statistically significant decrease in both days of work missed by caregivers and days missed from school.

Studies have demonstrated a significant reduction in ED visits in families enrolled in a health literacy initiative in Head Start programs around the country. Further research is needed to study whether these initiatives would be equally effective in an ED setting. The emergency room has both an ideal patient population to target a health literacy initiative, and sub-acute wait times offer a unique opportunity for training and implementing a health care initiative. This will be the first study to show the utility of this intervention in an ED setting, and we hypothesize that, by using a

health literacy resource, there will be a reduction in the number of non-urgent return visits to the ED.

B. Study Design and Statistical Analysis

This study is a randomized control trial comparing non-urgent ED return visits of those who receive health literacy training and resources to those who have routine care in the ED.

The study participants will be caregivers of patients aged 6 months to 8 years old who receive a 4 or 5 triage level in the CHONY ED. Patients in this group will be assessed for basic literacy using the National Adult Literacy Screen (NALS) and if their home address falls into the CHONY ED catchment area. If a subject is deemed to be illiterate or whose home address falls out of the catchment area, the subject will be excluded from the study. Consent will be obtained to participate in the study. In the intervention arm, a trained community health worker will provide both visual and verbal training on how to use the health literacy book, "What to Do When My Child gets Sick" before being seen by a physician. The control arm will be given a handout on basic anticipatory guidance for each age group before being seen by a phsyician, thus trying to minimize the Hawthorne effect.

In this study, the primary outcome will be number of return non-urgent visits to the ED. Chi-square tests will be used to compare the categorical outcomes. We hypothesize a decrease in non-urgent return visits from 40% to 20% (effect size 50%). For statistical significance ($p=0.05$), the study will require 91 patients in both the intervention and control arms, respectively. Though a smaller effect size would likely be acceptable given a cost analysis, the time constraints of this study may limit enrollment, and we settled on a 50% effect size.

To study the relationship between intervention and time-to-event, a Kaplan Meier curve analysis will also be done at the end of the study.

C: Study Procedure: No procedures done

D: Study Drugs: No Drugs will be studied.

E: Medical Devices: None

F: Study Questionnaire: None

G: Study Subjects

Inclusion criteria will be:
- Caregivers of children ages 6 months to 8 years old whose child receives a level 4 or 5 triage at registration
- Ability to provide informed consent

- Permanent address in CHONY ED catchment area

Exclusion criteria will be:
- Illiterate or reading under 8th grade level as assessed by NALS survey
- Primary Language other than English or Spanish
- Living outside the CHONY ED catchment area
- Triaged lower to level 4 or 5 or requiring more complex care after being seen by a physician.

H: Recruitment of Subjects:

Subjects will be identified as they are registered and triaged by an RN in the waiting area of the CHONY ED. If the subjects meet inclusion criteria, the research team would approach the caregiver, explain the study and consent the patient. After enrollment, patients would be randomized to control and intervention arms. After being triaged into appropriate waiting rooms, the trained community health worker would administer the intervention to the appropriate study arm.

I: Confidentiality of Data

The following personal identifiers will be used for the purpose of this study: name, MRN, birth date, visit date, home address, both paper-based and electronically-based. Each patient enrolled will receive a study-specific indicator linked to their medical record number and all other patient identifiers will be deleted after the study indicator is assigned. This indicator will be used to track ED return visits for one year.
All the information will be stored in password protected computer spreadsheets and word documents, only accessible to the researchers in the study.
Dr. Chang will have access to the study data – data will be monitored by the Primary Investigator.

J: Potential conflict of interest: No conflict of interest exists in this study

K: Location of Study

The study will take place at New York Presbyterian Hospital- Columbia University Medical Campus Children's Hospital of New York Emergency Department.

L: Potential Risks

The only potential foreseeable risk to patients would be, after the intervention, not returning to the ED for an acute medical event. However, each intervention will come with a written disclaimer and each community worker will be trained to verbally instruct each participant on returning to the ED if such an event would occur.

M: Potential Benefits

The potential benefit to patients is a decrease in non-urgent return visit to the ED, which has risks such as nosocomial infections, decreased continuity of care, increased missed work days and school days.

N: Alternative Therapies: Non alternative therapies are available to our knowledge.

O: Compensation to Subjects: No compensation will be given to subjects.

P: Costs to Subjects: There will be no costs to subjects.

Q: Minors as Research Subjects: No minors will be used as research subjects.

R: Radiation or Radioactive Substances: There will be no radiation or radioactive substances used in this study

References

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