"Influencing Breastfeeding Rates Through the Use of Text Messaging Services"

Resident: Janine Bernardo, MD, MPH
Mentor: Tessa Scripps, MD
Additional Investigators: Kalpana Pethe, MD, Melissa Stockwell, MD, MPH

A Study Proposal and Rationale:

a. Breastfeeding is universally acknowledged as the optimal method for feeding infants. It is beneficial to both mother and child, particularly in boosting the infant's immune system, protecting against diseases such as obesity, atopy and cancer and many other advantages. Maternal advantages are also ample: bonding with the infant, lower rates of postpartum depression, and quicker post-pregnancy weight lost.[1] The American Academy of Pediatrics recommends exclusive breastfeeding for at least the first 6 months of life followed by continued breastfeeding as complementary foods are introduced.[i] Yet breastfeeding rates in the United States perpetually fall short of recommended targets. Healthy People 2020 set goals to increase the proportion of babies exclusively breastfed through 6 months of age to 25.5% and any breastfeeding at 6 months to 60.6%. Data from the Centers for Disease Control (CDC) and Prevention's Breastfeeding Report Card 2013, however, showed that breastfeeding rates are substantially below the above stated goals, with 6 months exclusive breastfeeding at 16.4%, and 6 months of any breastfeeding at 49%.
b. Furthermore, and of importance to the community of Washington Heights, breastfeeding rates differ substantially by race and socioeconomic status.[2] Data analyzed by the CDC from the 2004 National Immunization Survey (NIS) also showed that less educated mothers, single mothers and younger mothers all have lower rates of breastfeeding. This group of disadvantaged mothers would benefit from real-time access to healthcare providers to offer encouragement in times of self-doubt and to help trouble-shoot the widely known and addressable obstacles to breastfeeding. Breast-feeding self-efficacy scores have been found to be a modifiable factor associated with improved breastfeeding rates within the population this study intends to serve.[4]
c. Numerous interventions to increase breastfeeding rates have been implemented, such as support groups, home visits, telephone calls, and peer counselors. Text messaging services have been shown to effectively influence behaviors such as medication adherence, smoking cessation, and vaccination rates.[5-7] Text messaging services as they relate to breastfeeding have been explored in international setting,[8-10] but have not been completely evaluated in a domestic setting, nor in the specific population in which we work.[11] Data has also suggested that the ubiquity of text messaging is particularly relevant in populations with lower levels of income and education, which suggests that text messaging can be used as a powerful medium for communicating health messages to

underserved populations.[11] A previous national intervention, “Text4Baby” provided text messages to pregnant and postpartum women through a unidirectional means of communication at birth and one year.[12] This service, however, lacks a bidirectional mode of communication, and one that will provide support for women immediately postpartum, a critical time during which breastfeeding can take hold.

d. With this project we aim to study the impact of interactive two-way texting on breastfeeding initiation, duration and continuation rates. We also aim to assess maternal knowledge, attitude and beliefs regarding breastfeeding to assess if a texting intervention improves breast feeding self-efficacy scores.

B Hypothesis

a. We hypothesize that text messaging services provided to mothers up until 4 months will increase rates of exclusive and partial breastfeeding, as well as positively influence attitudes and beliefs surrounding breast feeding.

C Study Design and Statistical Analysis

a. Study design
    i. This project is a non-blinded randomized controlled prospective pilot study performed at a single center, urban tertiary care center. Goal recruitment will be 40 total patients based on power calculation to be randomized into two groups: (1) an intervention group who will receive text messages encouraging breastfeeding and a two-way exchange program and (2) a control group of mothers who receive standard care and education regarding breastfeeding.
b. Statistical analysis
    i. The primary outcome will be breastfeeding exclusivity based on the 5 point Likert scale at the 4-month visit defined as statistically and/or clinically significant increased scores overall. Secondary outcomes will include scores on the Breastfeeding Self-Efficacy Scale- Short Form (BSES-SF) survey at hospital discharge, 2 week, 1 month, 2 month and 4 month visits as well as scores on the breastfeeding exclusivity Likert scale at hospital discharge, 2 week, 1 month, and 2 month visits. We will compare these outcomes between arms using t-test for parametric data and Wilcoxon rank sum for nonparametric data.
c. Sample size
    i. Sample size was calculated based on detecting a one-point difference on the five point Likert scale for breastfeeding exclusivity at 4-months. Alpha was set at 0.05 and beta at 0.8. Sample size calculation indicated at least 17 participants in each group.
d. Subject selection
    i. Inclusion criteria: (1) English-speaking mothers being care for at the Well Baby Nursery at CHONY who (2) express interest in

breastfeeding and who (3) plan to bring their newborn for routine outpatient care at the Audubon Clinic. The ages of subjects will 18 years of age and older.

ii. Exclusion criteria: Non-English speaking mothers who do not express interest in breastfeeding will not be included.

e. Study Locations
   i. The main study location will be the Newborn Clinic (NBC) located at the main campus of CHONY, followed by Audobon Clinic, the Ambulatory Care Network (ACN) also on main campus. Historically, newborns from underserved backgrounds discharged from our nurseries had poor access to timely outpatient care, limited breastfeeding support, and inconsistent linkage to a medical home. NBC addresses these disparities by giving newborns an outpatient visit within 3-5 days of life, providing hands-on breastfeeding support, and facilitating medical home linkage. Newborns are eligible for NBC if they have/will have Medicaid insurance, and either do not yet have a medical home in the community where they can arrange for timely follow-up OR they plan on establishing their medical home at one of the ACN pediatric/family medicine sites.
f. Study Procedures
   i. The investigator will provide each recruited mother a handout and perform a brief discussion about the benefits of breastfeeding and trouble-shooting tips that address the most common barriers mothers encounter while breastfeeding. This is the standard of care that all study participants will receive. After consent, enrolled mothers will complete a short demographic survey (maternal age, parity, language, race/ethnicity, education) for baseline demographics
   ii. All mothers who consent will be randomized centrally 1:1 to intervention or control arms using a randomization scheme. Prior to hospital discharge, those randomized to the intervention group will engage in an initial 2-way text-message exchange with the health-care provider to establish a text-messaging rapport and they will be provided with information about access to the program. Those randomized to the control group will not receive further information than described above.
   iii. Text message support will include the following two interventions: (1) two-way text communications and (2) standardized texts. For the first intervention, the text program will provide participants enrolled in the intervention group a phone number where they can send text messages with inquiries about breastfeeding their child through the age of 4 months. All received text messages will initially be answered by text and a standardized protocol will be in place to determine if escalation to a phone call back is necessary. For the second intervention, standardized text messages will be sent weekly for the first month of life and twice per month after that until

4 mo of age to all participants of the intervention group that are informational, encouraging and tailored to specific breastfeeding barriers that correlate with the age of the child. The standardized texts will be generated using the "NYC Mother's Guide to Breastfeeding."

iv. All recruited mothers will be asked to evaluate breastfeeding exclusivity on a scale from 1 to 5 in which 1 is exclusive bottle feeding and 5 is exclusive breastfeeding. In addition, they will be asked to complete a validated tool known as the Breastfeeding Self-Efficacy Scale Short Form (BSES-SF) which rates a mother's confidence in her ability to breastfeed. This consists of 14 questions and uses a scale from 1 to 5 in which 1 = not at all confident and 5 = very confident. Surveys will be collected prior to hospital discharge and at the at the initial, 2 week, 1 month, 2 month, and 4 month visits for women enrolled in both arms. Investigators will text families to schedule appointments with providers if follow up visits are missed to ensure compliance with well visits and to ensure appropriate survey completion.

D Informed Consent Process:

a. RASCAL generated HPIAA and consent documents will be utilized in the consent of all patients.

E Confidentiality of Study Data:

a. The medical records of patients will be collected and all information will be kept at an encrypted computer site. Only the study staff will have access to the data.

F Costs:

a. Mothers will accrue the cost of the text messages.

G Potential Risks:

a. 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.

H Data and Safety Monitoring:

a. 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).

I Benefits:

a. The participants receiving text messages may have higher rates of exclusive and overall breastfeeding at the end of the study intervention.

J Alternatives:
   a. The alternative to the study is not participating.

K Research at External Sites:
   a. Not applicable.

References:

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