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Clinical translational research hits the road: RCT of breastfeeding promotion interventions in routine prenatal care

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ABSTRACT

Translating evidence-based research into practice requires data from clinical trials in real world settings. This paper presents "lessons learned" from the implementation of an RCT of breastfeeding promotion interventions at two busy, urban, prenatal care sites. Data were obtained via direct observations, qualitative interviews, and study statistics.
Primary challenges include: time and space burdens, "research vs. service" mission conflict, and the provider learning curve for conducting interventions. Primary facilitators include: researcher presence for enhancing rapport with participants and staff, site staff labeling of both the research interview and intervention as "value added time," and the ability of research staff to assist the clinic beyond the scope of the clinical trial.
Specific suggestions are given for building collaborative bonds between the research team, clinicians, administrators, and staff in busy urban practices.

1. Introduction

Researchers and funders recognize that scientific discoveries must be translated into practical applications if they are to improve health [1,2]. This is as true for basic science research as it is for behavioral interventions aimed at health promotion and disease prevention. Yet, the "lack of generalizable, effective and sustainable interventions that have been translated into health promotion practices" is problematic. [3] In fact, US patients receive only about 50% of "best practices" recommended for acute and chronic care. Education and counseling (behavioral interventions) per health care guidelines fare even worse, with only 10% being implemented as recommended [4].

One study team's experience implementing research that was specifically designed to be translatable into wider practice is the focus of this paper. Presented are experiences from the first year of implementing an RCT of breastfeeding (BF) promotion interventions, which are offered as part of routine prenatal care. Recruitment of study participants from two prenatal care sites affiliated with an urban medical center began in early 2008. The two interventions being tested include a) Lactation Consultant (LC) and b) Electronic Prompt (EP). Both are further described in the next section.

As background, a comprehensive evidence report of the short and long term effects of BF on maternal and infant health outcomes in developed countries finds a reduced risk of many diseases [5]. The studies described are measuring BF levels at 1, 3, and 6 months post-partum, and infant illness through the first year of life. Healthy People 2010 goals include a 60% exclusive BF rate at 3 months, with continued BF rates of 50% at 6 months and 25% at 12 months. [6] Thus, these trials test behavioral interventions in line with national public health goals.

Section 1 presents a brief overview of the projects, including how translational aspects of the trials' design and interventions were considered in the developmental phase.

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Section 2 describes implementation challenges and a corresponding "Lessons Learned" summary.

1.1. Methods: study description and rationale

Recruitment for the two studies (separately funded NIH RCTs) [7,8] began in early 2008. Both test routine prenatal care based interventions to increase BF intensity and duration in multiethnic women in urban settings. The two study sites vary in design and setting, though both are at health centers affiliated with the same academic medical institution.

Study A (hereafter, "Teaching Site") is a large teaching practice (≈1000 birth/year) where midwives and OB/GYN residents (precepted by an attending physician) provide care to routine, low-risk prenatal patients, the majority of whom are low-income (89% covered by Medicaid) black and Hispanic women. Many of the women are recent immigrants from Latin America, Africa or the Indian subcontinent, and language barriers are not uncommon. As the designated referral site for the affiliated medical center's high-risk prenatal patients, the site has a large number of patients with complex medical and psychosocial needs. At this busy site, patients face an average wait time of over an hour. Staff commitment to their patients is evident, but the effects of this pace and burden upon the staff is palpable.

Study B (hereafter, "Faculty Practice") is being conducted at a faculty practice, serving a more socio-economically (59% covered by Medicaid) and educationally diverse patient population. For example, study participants enrolled from this site include a resident from the affiliated medical center, as well as women receiving public assistance. The site operates similarly to a private practice, where patients can expect to see the same doctor at every appointment. Two smaller, separate waiting areas lend a somewhat calm feel to the site.

While each study site is unique, offering particular insights into both the research process and what such interventions would look like in regular, non-research practice, the lessons learned at each site, which are the subject of this paper, have largely coincided.

Study research assistants (RAs) enroll, randomize, and administer the baseline interviews at the sites. Study RAs are Spanish/English bilingual females with at least bachelor's level education, and previous clinical research experience. Contact information for the study coordinator is made available to all patients in posters and informational pamphlets displayed at the site. At the time of enrollment, study participants are given the RA's business card in addition to PI and study coordinator contact information to use in the event of questions or to provide notification of change of address or phone number. Many patients will approach the RAs with questions about the study at subsequent appointments.

RAs conduct follow-up interviews at 1, 3, and 6 months post-partum to obtain infant feeding patterns. Gift checks are handed to participants after completing the baseline interview, and mailed after the completion of each follow-up.

Two interventions are being tested: a Lactation Consultant (LC) and an Electronic Prompt (EP), compared with a Control standard of care. Neither site has a childbirth education class or any explicit BF promotion and support programs. Any specific education or counseling about infant feeding is at provider discretion.

1.1.1. Lactation Consultant (LC)

The rationale for the LC intervention is based upon a systematic review showing the effectiveness of combined pre- and postnatal interventions, and individual-level professional support. [9] Face-to-face, sustained, [10] technical assistance the LC's provide is highly effective. [11] Both US [12] and Canadian Task Forces [13] call for BF trials assessing routine provider, primary-care based interventions.

The project employs 3 specially trained health professionals with advanced training in counseling, management and support of BF. Women assigned to the LC intervention are scheduled for at least 2 prenatal LC sessions at the site. LCs attempt to visit every woman in an LC group at least once during her hospital stay. Post-discharge, the LCs make weekly phone calls through three months post-partum, and home visits when indicated.

1.1.2. Electronic Prompts (EP)

The rationale for the EP intervention is based upon literature showing that prenatal care provider support and information [14,15] affects feeding plans, which then affect feeding behavior. [16–19] The studies test an intervention that standardizes such support via EPs in the electronic medical charts. The study EPs consist of 5 prompts that appear throughout the pregnancy (see Table 1). Each prompt contains 1–2 brief open-ended questions that portray BF as the norm (e.g., "What are your plans for BF?"), or ascertain and clarify participants' understanding of current guidelines regarding BF.

RAs insert the prompts into the electronic medical chart for women assigned to the EP intervention. See Fig. 1 for a screen shot of how they appear. The first EPs appear at the next visit after study enrollment; four additional EPs appear throughout the woman's prenatal care. Upon entering the exam room, where the patient's electronic chart has been opened by a

Table 1
Electronic Prompt questions by prenatal visit.

Prenatal visit	Electronic Prompt questions
1	1. What are your plans for breastfeeding? 2. What are your concerns about breastfeeding?
2	3. What have you heard about how long and how much to breastfeed? Clarify: 6 months, only breast milk, is the goal. 4. What have you heard about breastfeeding and infant health? Clarify: Babies fed all breast milk for 6 months have less respiratory and stomach illness, may also reduce risk of overweight later.
3	5. What ideas about feeding babies are specific to your family or culture? 6. If you breastfed before, do you have any concerns from this experience? 7. How does your partner/family feel about you breastfeeding?
4	8. How have your breasts changed since you've been pregnant? 9. Do you have concerns about how medications, or any smoking, alcohol, or substance abuse might affect breastfeeding? 10. Who will help out at home after the baby is born?
5	36 weeks encourage BF best practices — Immediate skin-to-skin contact — Limit mom/baby separation (room in) — BF right away, whenever possible — Ask for help!! Nurse to watch entire feed