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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.

Keywords

Translational research; Randomized controlled trial; Routine care; Breastfeeding; Health promotion

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

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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 I presents a brief overview of the projects, including how translational aspects of the trials' design and interventions were considered in the developmental phase. Section II describes implementation challenges and a corresponding "☑ Lessons Learned" summary.

I. 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 ($\approx 1,000$ 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 RA's 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. Study participants are given the RA's business card, in addition to PI and study coordinator contact information, at the time of enrollment, 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.

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 pre-natal 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.

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 Figure 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 nurse, providers see that there is a "message" regarding the patient. The "message" lists a series of questions for the provider to address during the patient's visit. At the bottom of the messages screen are two buttons—"Acknowledge" and "Turn Off" that can clear the messages. The study team met with providers prior to implementation to instruct them in how to respond to the prompts. Also, the study's principal investigator and Co-PI (then director of, Obstetrics and Gynecology at the teaching site), conducted a 1 day pilot of the prompts use with the site providers.

Interventions Designed for Translation Into Practice

The interventions have been *designed* to feasibly translate into practice. They are delivered by autonomous professionals-- certified nurse midwives, physicians, and the most highly trained

LCs,[20,21] minimizing supervision. Basing the interventions in an existing infrastructure and normal flow of routine primary care practice was designed to provide evidence for how successfully the interventions will translate into practice. In addition, this study design replicates the actual practice, of a routinely offered, primary-care based intervention. That is, the studies enroll and *offer* assigned interventions to all women regardless of prenatal or peripartum feeding intentions/behavior.

With regard to the LC intervention, mechanisms exist to fund primary-care based LC services. In practice, insurers, including Medicaid, have been reluctant to reimburse for non medical (i.e., physician, nurse-practitioner, or certified nurse midwife) providers.[22] There are diagnosis codes for maternal/ infant lactation problems and counseling,[23] though plans vary in their reimbursement policies. Lack of experience in billing for LC services has been a major barrier to reimbursement. Establishing LC services in routine care could address this barrier. [24] Furthermore, the modest scope of the LC intervention (2 prenatal, 1 hospital, post-partum phone follow-up, and home visits if needed) was designed to be effective, yet feasible.[25] Using non-medical providers to provide LC services, as is done in the study intervention, is more cost-effective than using medical providers.

With regard to the EP intervention, this too was designed to be effective, yet feasible. A pilot (albeit brief) of the EPs resulted in re-ordering of items and rewording of certain prompts. Apart from individual ‘detailing’ of the physicians and midwives about the EPs that would appear, and how to sign off on them, the intervention doesn’t require extra training. Lengthy provider protocols and/or those requiring specialized training are unlikely to be adopted and sustained in practice. EP interventions significantly increase the delivery of the preventive care message according to a systematic review of RCTs.[26]

II. Results: Implementation Challenges and Lessons Learned

Recruitment and Enrollment: Logistics

The study team’s first challenge was to plan the flow of recruitment and enrollment in busy prenatal care settings. Pre-implementation, the team met several times with administrators and clinical staff to develop a plan, including multiple iterations of a 20+ step flow diagram. The process that evolved through trial and error bore only minimal resemblance to these diagrams. The sequence of events, the where/when/whom of approaching eligible patients, and the method of obtaining provider approval of participants all evolved after the first few days and weeks in the field. For this project, the following effective and minimally intrusive (to the site) method of recruiting/screening/enrollment is as follows:

- * RA reviews patient charts at the nurse’s station (both sites) or precepting room (teaching site)
- * Potentially eligible women are approached in the exam room after completing their lab work, while waiting for the provider.
- * Alternatively, if there is another open office (e.g., HIV counseling room), the RA will call patients in from the waiting room. A drawback, compared with the above method, is that recruitment is interrupted when the woman is called for her appointment.

☑ Lessons Learned:

- ➔Flow of recruitment and participation must be worked out in practice
- ➔Assume interruptions will occur

On-Site RAs: Key to Enrollment and Retention Success

RAs clearly identify themselves as study staff, verbally and with identification badges. Nonetheless, participants associate them with the health center, and, by extension, their prenatal care team. This perception, along with the RAs' (almost) daily site presence maximizes contact with both prospective and current study enrollees. Prospective enrollees < the 12 week gestational age minimum, or who don't have time to enroll at a particular visit, often enroll at later visits as a result of having met and spoken with the RAs. RAs have also caught up with study enrollees at the sites, who would otherwise have been missed for the follow-up interview 'windows'.

The above strategy of a near daily presence at the site, and open access to all potential participants was developed after the Principal Investigator's (KB) experience in a prior trial of breastfeeding promotion interventions at two sites. At one site in the prior trial, RAs recruited from a 'mandatory' class for all new prenatal patients, held several times per week. However, attendance was sporadic, and interest in enrollment often reflected the most dominant participant's choice. At the other site, recruitment was reliant upon the health center's social work staff, who met with all new prenatal patients, to refer those who were interested to the RA. [11] Recruitment, which had been based upon both centers' total number of prenatal patients, fell below the target rate.

In the current studies, the RAs' comfort in the busy clinical setting, as well as their visibility and rapport with participants allows the team to exceed both the enrollment and follow-up goals. As of December 2008, 42.4% of trial participants were enrolled, compared with a projected estimate of 32.3%. Strong RA- participant rapport has also helped follow-up. Participants know who the RAs are when they call, and generally welcome the follow up interviews. The current 1, 3, and 6 month follow-up rates of 93%, 96%, and 98%, respectively, (Table 2), exceed the targeted rates, which assumes one-third less loss to follow-up, compared with the Principal Investigator's prior trial.

Of course, a range of strategies-- apart from RA presence and rapport contribute to these high retention rates. Two of the most successful include post-cards about upcoming interviews, and RAs meeting hard to contact participants either at their infant's visits or their own post-partum appointments, (The study is alerted to all such visits by the medical center's computerized scheduling system.) Meeting at these visits permits the RA to re-connect with the participant and update contact information for a future interview, even if a prior interview window was missed. Or, if the visit is in the last few days of the interview window, the RA will try to conduct the interview on the spot.

Lessons Learned:

- RA near-daily presence at study site engenders participant rapport
- RA rapport, in turn, aids in enrollment, receptivity to our LC intervention, and retention.

Health Center Staff/Administration: Rapport and Mutual Assistance

The RA's rapport with clinical staff is critical, as women are enrolled provisionally, contingent upon provider sign off. This requires the RAs to feel comfortable "pre-checking" with physicians about a woman's eligibility, to reduce the likelihood that an enrolled patient will later be disapproved for participation by her provider (and thus have to be disenrolled). The RA has become integrated such that the clinical staff, upon seeing an apparently eligible patient, expects that the patient will be recruited for the study and refers her to the RA.

Provider and staff rapport has been further developed at the faculty practice. Nurses and physicians routinely request the RA's help in translating for Spanish-speaking patients, when

the sites' bilingual English/Spanish nurses are unavailable. The increase in requests for the RA's services as an interpreter has built the rapport with staff.

Rapport building began with informational meetings with staff at all levels prior to implementation. In the first month or two on-site, simple gifts such as fruit bowls and bagels in staff common areas were surprisingly effective at increasing site staff receptiveness during this critical phase-in period. In addition, the fact that many staff have a favorable view of what the study team is trying to accomplish, aids rapport. At the teaching site, either the principal investigator, project director, or LC attend the monthly staff meeting. (The faculty practice does not have a comparable meeting.) While this meeting is devoted to operational and clinical care issues, their presence: a) allows them to appreciate the challenges of clinical care, b) exemplifies their being team players and c) when time permits, allows them to provide study updates.

☑ Lessons Learned:

- Ability of study staff to assist site staff is a plus and engenders rapport
- Rapport with site staff requires on-site study staff to have strong interpersonal skills.

Health Center Staff/Administration: Study Provides "Value Added Time"

An unanticipated study benefit was identified by the training site's administration: 'Value Added Time'. That is, engaging patients for recruitment, and (for those assigned to an LC intervention group) LC education and counseling, during what would otherwise be down time, is viewed as a service. The administrators note that the concept of value added time is derived in part from a framework that they and other federally qualified health centers employ. Value added time is the rationale behind health promotion videos in waiting rooms-- patients receive constructive information, while being distracted from the length of the wait. The time spent by patients in the exam rooms is invariably down time. Recruitment during this time engages a patient in an activity, and they receive a financial incentive. In fact, the teaching site encourages nursing and tech staff to engage in brief, casual conversation with patients waiting in the exam rooms during less busy periods. The LC intervention during this time provides clear educational benefit.

☑ Lessons Learned:

- Studies can benefit patients by providing 'value added time' during long waits
- Such benefits can accrue from both the study interviews, and the interventions

Research Role vs. Service Conflict: Sites Eager for Study LCs' Services

Sites initially expressed interest in study LCs assisting women outside the study, effectively raising the "standard of care". If women outside the study could receive LC services, while, study participants not randomized to an LC group could not, then the latter would receive *less* than the site's standard of care. Such a situation is contrary to a basic tenet of RCT design--that Controls not receive less than the standard of care. This was explained to the sites. The project staff also explained to the sites that RCTs begin from a position of clinical equipoise. That is, despite a priori hypotheses, it can't be assumed that an intervention will yield statistically significant improved outcomes, compared to standard care.

As an alternative, the project team developed a BF resource guide for the site staff to use. This brochure is a list of referrals for BF support (e.g., free classes) and services (e.g., where to rent a breast pump) offered by area hospitals, WIC sites, and private organizations. Literature suggests that this resource is unlikely to interfere with the ability to detect the interventions'

effects.[27] In the first 6 months, site staff still referred non-study patients and Control group participants to our LC's, though referrals ceased soon thereafter.

☑ Lessons Learned:

- ➔Valued study interventions will be sought by providers and staff for patients
- ➔Providers and other site staff may not initially comprehend the ethical problems of providing interventions to non-study patients, or Control group participants

Research Role vs. Service Conflict: Participants Eager for Study LCs' Services

Study RAs are clear about the randomness of group assignment—explaining it in different ways when they review the consent--and the fact that all groups receive study gift incentives. Still, several prospective enrollees cite receipt of LC services as a reason for joining. For example, a 35-year-old mother of a 6-year-old girl, told her daughter to “cross [her] fingers so mommy can get in the mother-baby specialist group”. A few women expressed disappointment about being randomized to regular care; one asked the RA to switch her group. At the 1 month phone follow-up, one such regular care group participant said she felt “left out” by the study. After giving birth, she was expecting “somebody from the study to show up and help her with the baby” She had milk production problems the first few days, was upset that she “had to find help on her own,” and said she felt like a “guinea pig”. Of note, no participant has refused to participate after learning of her treatment group.

☑ Lessons Learned:

- ➔Controls in an RCT may expect a (valued) intervention, despite research team's description of random assignment in lay terms.

Delivering Study Interventions In Routine Care

Electronic Prompt (EPs)

At the study's inception, many providers were unclear about how to work with the EPs' message section- even though the messages section is used for clinical care reminders. If one clicks “Acknowledge” rather than “Turn Off,” EPs are temporarily cleared from the screen but continue to pop up—cumulatively-- each time the record is opened. This has exasperated busy clinicians, one of whom stated, “This keeps on popping up, all of these prompts. It's ridiculous. How can I be expected to ask 15 questions at one visit?” Actually, only 1 EP, featuring 2-3 questions to ask the patient, appears if the EP was handled properly at the previous appointment.

Providers who complain of difficulty working with computers require the RA's assistance, as do new providers who rotate in at the teaching site. Emails and flyers have proved ineffective, so the on-site RAs to train the providers when they are at the screens. Even with this, the study coordinator has had to clear one-third of the prompts herself, by clicking “Turn Off” once the woman has given birth. Table 3 shows how often providers address prompts.

A focus group with residents at the teaching site, held 7 months into the study, affirmed the above logistical frustration. Additionally, just half of the residents knew the study was going on, even though a statement about the study appears with each prompt. Further, the EPs, while designed to be brief, were felt by some to promote a discussion that they did not feel qualified to engage in. One stated “I don't know what to answer back to them.... I don't know what I should be clarifying and saying.”

These findings point to the difficulties of implementing point-of-service health promotion cues. Study investigators had been advised to keep any such cues brief. In practice, however, providers may feel ill-equipped to respond to participant queries. The single day of pilot testing

at the site prior to the field phase, was insufficient for deriving needed feedback. Rather, a run-in period, with adequate time for feedback would have benefitted the providers, who needed the time to become familiar with the process.

☑ Lessons Learned:

- ➔ Provider-administered study interventions must be a) minimally burdensome, b) “stand alone” (contain needed cues/information), and c) part of routine clinical care
- ➔ Incorporate an adequate pilot and run-in phase for the interventions involving site providers/staff.
- ➔ Site providers/staff administering interventions need on-site study team support.
- ➔ Provide frequent opportunities for site feedback

LC Intervention in Clinical Practice: Space and Scheduling Challenges

Selection criteria for the current project sites included: a) dedicated LC intervention space at least 1-2 days/week, and b) desire/commitment to incorporating LCs into the prenatal care process, including scheduling. In the PI’s prior related trial, the LCs were not integrated into the clinical setting. Meetings occurred in the health centers’ waiting areas, neighborhood coffee shops, or participants’ homes. This arrangement reduces the likelihood that participants will perceive the LC to be part of routine prenatal care. Consequently, 36% of Intervention group participants did not meet with the LC prenatally, and 75% were not seen in the hospital[11] This experience led to the selection criteria regarding space and LC integration for the current projects.

Space and scheduling are more of a challenge at the larger teaching site. Providers are frequently shuffled among exam rooms during a session because the patient flow is so great. RAs and LCs have access to dedicated space adjacent to the prenatal care service 1-2 days/week. On other days, LCs meet with participants in the exam rooms, adjacent hallways, or social work room. While this approach provides “Value Added Time” for patients, the intervention contact is interrupted when the provider knocks on the exam room door. (Such interruptions occur in the dedicated space as well, when the patient is paged for her appointment.) The LCs must ‘track’ participants before, throughout, and after their appointments, as described by one LC at the teaching site:

“The mother’s appointment was at 12:45 and she was there at 12:45. We started talking before she was called in and we moved and paused our conversation with her visit with the midwife and the nutritionist. I finally finished talking to her and left the center at 4:00pm....”

At the faculty practice, recruitment is restricted to the 2 days each week when dedicated space, a private room just off of the waiting area, is available. Patients of physicians who are in session those days are recruited. Thus, the follow-up visits at which the LC intervention would be delivered, occur on days set aside to have dedicated intervention space. This approach would not work at the teaching site where provider schedules are more fluid, and the weekly recruitment goals for the study are higher.

In the first few weeks, LC visits were scheduled 30 minutes prior to the next prenatal care visit. However, this created longer wait times, which diminishes patient satisfaction and our rapport at the sites. Patients, aware of the sites’ long wait times, were reluctant to arrive beforehand. Thus, most just arrived at their regular appointment times anyway. Indeed’ patients’ willingness to enroll often hinges on whether or not it will add extra time to their visit. In addition, scheduling the LC for 30 minutes before the prenatal care visit would still result in

interruption or displacement, as neither site could afford yielding an exam room. Scheduling the LC visit at the regular prenatal appointment time has worked out at both sites.

Despite the challenges, study LCs are successful at negotiating space. Just 8% of LC group women had no prenatal visits, while 70% had ≥ 2 visits (Table 4). LC group women have also been receptive to hospital (75%) and phone follow-ups (70%), in part, because the LCs are associated with their prenatal care setting. This perception is fostered by the routine, on-site presence of both the RAs and the LCs, which validates the LC as part of the care team.

Some participants complain to the LCs about the interruptions and room changes. Yet, none have mentioned this as a problem in the limited (n=10) qualitative exit interviews at 6 months post-partum the team has conducted thus far. Instead, they appreciate the convenience of twinning the LC meeting with their prenatal care visit. In response to exit interview queries about the scheduling and site of LC meetings, participants stated:

“It was great. It was convenient.” [faculty practice, subject P163]

“....And the scheduling was awesome because it was at the same time as my prenatal appointment.... just pulled me in while I was waiting.” [teaching site, subject B222]

☑ Lessons Learned

- ➔ Study Interventionists must be flexible and able to work around site staff and providers
- ➔ Tailor intervention schedule and recruitment goals to site’s capacity.
- ➔ Enrollment procedures and interventions at the site of clinical care, that don’t add extra visit time, increase enrollment and adherence to the intervention.

DISCUSSION

This paper reports on the first year implementing an RCT of BF promotion interventions, designed to translate into practice, and delivered during routine prenatal care. One of the interventions—electronic medical record prompts (EPs) to address BF at prenatal visits—is delivered by the providers themselves. The other intervention is delivered by study lactation consultants (LCs), in the midst of regularly scheduled prenatal care appointments. LC group participants meet with a study LC at their scheduled appointment time, in an exam or counseling room at the site.

Key lessons are summarized in Table 5. The steady presence of the studies’ skilled and personable RAs and LCs helped build rapport with the site staff. As noted by others, research team members’ use of personal influence, motivation, and retraining and instrumental assistance are key to intervention uptake and implementation.[28] This team’s experience affirms this finding and extends it to the recruitment and study interview process as well.

Burden and time emerged as key concepts for participants and the sites. Consenting and the prenatal baseline interview together take about 15 minutes. This is nearly always completed in the exam room, while the patient waits to see the provider. (Our post-partum phone interviews take 5-15 minutes.) The LC intervention, which occurs at visits subsequent to enrollment, takes an average of 30 minutes. Thus, the LCs are more likely than the RAs to be interrupted, and have to track the patient through her visit. On a few occasions, the LCs have asked a participant to stay after her visit.

Another salient concept that emerged was “Intervention as Resource”. Initially, the site’s nurses and nursing technicians were not comfortable with withholding the study LCs’ services from women who specifically asked for BF assistance. The team addressed their concerns by a) emphasizing that without a Control group, one can’t be certain the intervention yields improved

outcomes and b) developing a guide to free or low cost BF services. Conversely, because the LC is viewed as a valued resource, the sites appreciate that at least some patients have access to it.

Finally, “Value Added Time” is how the teaching site’s lead administrator describes the study engagement of patients (for recruitment and intervention) during down time. In fact, nursing staff are encouraged to do the same during less busy hours, in an effort to maximize patient satisfaction. This study thus implements a strategy consistent with the site’s goals. Researchers can increase a potential site’s receptivity to hosting a study by identifying opportunities for value added time.

The research described here is “T2” translational research, according to Steven Woolf’s “T1” and T2” designations. In contrast to” T1“ -- traditional bench-to-bedside translational research-- T2 research is aimed at ”...helping clinicians and patients to change behaviors and make more informed choices, providing reminders and point-of-care decision support tools, and strengthening the patient-clinician relationship.”[2] T2 research, such the described studies, is not conducted under ideal laboratory conditions. Rather, it takes place in the settings in which successful findings would be applied, thereby increasing the likelihood of translation into practice. For example, at the faculty practice site, recruitment and follow-up days are dictated by when there is a free room. At the teaching site, the LC intervention may be interrupted mid-stream, and the LC will have to find the participant after she sees her providers. On the other hand, both sites appreciate the value of the research, as well as the intervention to (a subsample of) participants, and are pleased to host the project staff.

As noted earlier, the two settings are quite different. One is a fast-paced teaching practice that serves a predominantly low-income patient population. The other is a faculty practice whose patients are socioeconomically diverse. And yet, the experiences in the first year of the trial transcend the particular social and organizational dynamics of each. Thus, the checklist offered, below, can guide researchers testing the adoption of innovative practices across varied care settings.

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Figure1. Electronic Prompt Message as Displayed to Providers

Table1
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? 3. What have you heard about how long and how much to breastfeed? Clarify: 6 months, only breast milk, is the goal.
2	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? 8. How have your breasts changed since you've been pregnant?
4	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

Table 2
Follow-Up Interview, Completion vs. Target Rate*

Post-Partum Interview	Completed (N)	Missed (N)	Actual Completion Rate	Target Completion Rate
1-Month	215	17	92.7%	89.7%
3-Month	159	6	96.4%	84.6%
6-Month	52	1	98.1%	80.0%

* Represents first 450 of expected 941 participants.

Table 3
EP Groups Prompts Addressed by Provider *

Electronic Prompt Series **	Prompts Addressed by Provider (N, %)
1	137 (84.5%)
2	118 (72.8%)
3	104 (64.2%)
4	90 (55.5%)
5	71 (43.8%)

* Based on 162 participants

** Each series of electronic prompt messages appeared at a specific visit

Table 4
LC Intervention Contacts (LC Groups Only)

Type of Visit	Given Birth (N= 128) [*]
0 Prenatal	8 (6%)
1 Prenatal	22 (17%)
≥ 2 Prenatal	98 (77%)
Hospital	93 (73%)
Post-Partum[§]	98 (77%)

^{*} A total of 470 women are expected to be randomized to an LC group by the end of the study.

Table 5
Clinical Translational Researcher ‘Checklist’ for Maximizing Site Collaborations

<i>Build Rapport</i>	☒ Project team's: On-site presence + interpersonal skills + ‘pitching in’ at site → Enhances recruitment and negotiation of space.
<i>Minimize Participant Burden</i>	☒ Enrollment procedures and interventions that don't add extra visit time increase enrollment and intervention adherence
<i>Minimize Site Burden</i>	☒ Successful implementation of study interventions by site providers is maximized if they: a) ‘stand-alone’ and b) require only minimal deviations from routine practice. ☒ Site personnel need timely, competent support from project team when carrying out study-interventions or procedures.
<i>Intervention as Resource</i>	☒ Participants allocated to standard care may be disappointed/resentful. ☒ Site may seek intervention for non-study patients. ☒ Highlight a) RCT rationale, and b) subset of patients' receives intervention
<i>Value-Added-Time</i>	☒ Study enrollment & interviews that engage patients during visit ‘down time’ provide VAT (study gift incentives a “+”). ☒ Study interventions that engage patients during visit ‘down time’ provide VAT