WIC Breastfeeding Peer Counseling Study: Phase 2

USDA/NASS Review for USDA/FNS 9/8/2011- Reviewer- Matt Fetter

This is primarily a review of the document: Part B: Statistical Methods

Study statistical highlights as interpreted by the reviewer.

Universe- The subset of 1,810 Local WIC Agencies (LWAs) in the 50 states and the District of Columbia that have an active *Loving Support* Peer Counseling Program (n=675), and the pregnant WIC participants served by these 675 agencies (about 512,000 women per month).

Agency selection- Up to 8 volunteer agencies will be selected to participate, with the final number yet to be determined. (Sample is made up of volunteer agencies rather than a random sample). The selected LWAs will serve areas with a high population density and have a significant portion of clients belonging to populations with historically low breastfeeding rates. They will also have *Loving Support* Peer Counseling programs that are large enough to enroll a sufficient number of first time expectant mothers. An effort will be made to have at least one LWA from each of 4 major census regions (Northeast, South, Midwest, West) included in the study. Volunteering agencies will be pre-tested to determine their ability to carry out the study correctly before they are formally selected for the study.

The objective of the LWA selection procedure is to test the efficacy of the intervention in LWAs that have the strongest likelihood of implementing the intervention correctly. It is not to test its impact on a nationally representative sample of LWAs.

The treatment (intervention) being investigated- An enhanced version of the *Loving Support* program where women assigned to the treatment group will receive additional counselor follow-up contacts at birth and another face-to-face contact within 10 days after giving birth. The control group will not receive these additional contacts.

Requirements for study participants- WIC enrollees that are expecting their first child and sign up for the peer counseling program are eligible. They must be in their fifth, sixth, or seventh month of pregnancy and be at least 18 years old. Each client will be asked if they would volunteer to participate in the study as soon as possible after the client meets the eligibility requirements.

Study participant sample- The suggested sample size will be 1800 participants, with half being assigned to the control group and the remainder being assigned to the treatment group. Sample sizes have been calculated to give a minimum detectable difference of 6% for a one-sided test at α=.05. Sample size determination assumed about 10% of the variance in the outcome measures. These assumptions lean heavily on similar study results.

Participant assignment will be done randomly within each LWA in such a way that each LWA and each counselor within the LWA will have clients in both the control group and the treatment group.

Participants will be assigned to a counselor *before* the participant is assigned to the treatment or control group.

Outcome being measured- the intensity/frequency of breast milk being fed to the newborn. The intention of the treatment is to increase breastfeeding likelihood/ intensity.

Analysis – Descriptive analysis will be used to provide a comparison of baseline characteristics of participants across LWAs and across treatment groups. The similarity of characteristics between participants and their assigned counselors will be examined. Implementation analysis will be used to determine the nature of intervention implementation differences across LWAs and across individual counselors. These two analyses will be useful in interpreting the results of statistical analysis of the intervention impact. They will also be useful in determining the risk of potential biases incurred through participant attrition.

The estimation of the impact of the intervention will be made through logistic regression techniques using a set of covariates obtained from baseline and follow-up surveys of the participants.

Accounting for missing data- Response rates for LWAs and staff are expected to be 100%. A response rate of 85% is anticipated for study participants. For participant attrition, analysis will be conducted on available data to determine if drop-outs seem to differ systematically in some way from finishers. If it is determined that non-observation bias could be a problem, various methods such as multiple imputation or weight adjustments will be used to try to mitigate these bias problems.

***Comments*-** This reviewer feels that this study is well planned and the proposed analysis is sound. Useful covariates should be captured through baseline and follow-up data capture from the participants. Careful consideration appears to be given to many potential biases and procedures are put in place to reduce or eliminate them. Standard techniques are used to determine sample size and are based on results obtained by similar successful studies where appropriate. The choice of LWAs is largely dictated by practical considerations. The selection of participants to either the control or treatment groups appears well designed. The pilot test of LWAs volunteering for the study to determine each one's ability to carry out such a study successfully seems prudent. Response rates are always a little hard to predict, but standard procedures to deal with non-response are in place.

The intent of the study is not to project results to the entire population of potential participants, but to ascertain the effect of the intervention only on those that receive it. This reviewer feels that this study will likely accomplish this objective.