Utilizing All Health System Contacts to Offer Postpartum Family Planning (PPFP) to Pregnant Women and Women within Twelve Months Postpartum in Ethiopia

Statistical Analysis Plan

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Analysis Plan

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This plan describes how data collected through different methods will be analyzed after cleaning in order to meet these research objectives:

1. Estimate the added effect of the community-based intervention by comparing uptake of PPFP through 12 months postpartum in intervention and comparison sites ("intent to treat" analysis)
2. Assess the effect of systematically integrating PPFP messages into contacts with the health system on uptake of PPFP through 12 months postpartum using a dose-response analysis based on the number of contacts ("per protocol" analysis)
3. Explore the feasibility of tracking PPFP and reviewing data at health centers and HEWs and volunteers using record keeping and review processes to track women's decision-making and contraceptive use from pregnancy through 12 months postpartum
4. Explore factors influencing women's/couples' adoption of PPFP during the first 12 months postpartum

Quantitative and qualitative data analysis will be triangulated to help interpret results and provide deeper insights on study objectives.

A. Quantitative interviews with Women:

After data have been thoroughly examined for quality, the study team will perform exploratory data analysis of key variables such as checking frequency distributions, measures of variability, central tendency, and data outliers. We will also check for incomplete data and consider strategies to handle missing values such as undertaking an imputation strategy and weighting adjustments for non-responses.

We will compare differences by study arm for key variables. Analysis will account for clustering of variables at kebele (village) level using the Taylor linearization method. Differences between the arms for categorical variables will be assessed using the Pearson chi-squared test with the Rao-Scott correction. Differences in continuous variables will be assessed using an adjusted t-test. In case of substantial differences between the study arms, we will perform propensity score matching and perform the analysis with inverse probability weights.

Key descriptive variables:

- Sociodemographic data such as age, marital status, education, and socioeconomic status (nationally representative SES will be determined using the EquityTool described here: http://www.equitytool.org/)
- (Baseline only) Proportion of pregnant women with non-first pregnancies (non-primiparous) who previously used family planning
- Number of health system contacts where FP was discussed or provided, by type of contact (ANC, PNC, immunization, etc) and provider (facility provider, HEW, volunteer)
- Proportion of postpartum women who chose a method prior to delivery, by method, and received chosen method
- Proportion of postpartum women who used FP during the first 12 months after giving birth, by method
- Reasons for starting and stopping contraceptive methods and duration of use

- Initiation and duration of exclusive breastfeeding and lactational amenorrhea (LAM); average/median duration of postpartum amenorrhea, PP sexual initiation/PP abstinence
- Partner communication about family planning

We will fit multivariable logistic regression models for the primary and secondary binary outcomes (see below) to examine differences between the study arms, adjusted for confounding covariates and clustering at kebele level. We will also conduct a "per-protocol analysis" by examining the "dose-effect" of health system contacts on the primary and secondary outcomes, regardless of study arm. We will run two dose-effect models, looking at the association between the outcomes and 1) the total number of contacts and 2) the number of contacts during which FP was discussed as reported by the woman. For the secondary outcome, we will only include contacts during pregnancy since contacts after the birth would not have a temporal effect on whether the woman chose a method prior to delivery.

- Primary outcome:
  - Proportion of interviewed postpartum women who used a modern family planning method within 12 months after giving birth
- Secondary outcome:
  - Proportion of interviewed postpartum women who chose a method prior to delivery

We will also conduct time-to-event analyses using life-table method and use a log-rank test to test for differences in survival distributions between the study arms in terms of the timing of FP uptake after birth. We will perform multivariable hazards model (Cox's proportional model or parametric model with Weibull distribution in case of non-normality in hazards function) for adjusting confounding covariates and clustering effects.

Additionally, we will run hazards regression models for women who initiated exclusive breastfeeding/LAM after birth to test for differences between arms in the duration of exclusive breastfeeding/LAM use.

B. Key Informant interviews, Focus Group Discussions and In-Depth Interviews: In-depth interviews, focus group discussions, and key informant interviews will be translated and transcribed, then coded and analyzed using the MAXQDA software to facilitate data management. *A priori* codes will be developed for broad areas of interest for this study (perception of quality of interactions between women and providers, feasibility of incorporating PPFP into community-based care, utility and feasibility of tracking tools, etc). Additional codes for themes and concepts that emerge within these broad categories will be developed using a Grounded Theory approach. Investigators will review transcripts together to develop a codebook. Investigators will then independently apply codes to several transcripts, compare results, discuss discrepancies, and make notes to enhance code definition and facilitate consistency in the coding process. Investigators will then code the remaining transcripts and analyze results for each theme.

C. Supportive Supervision Forms: Data collected during supportive supervision visits to all study health centers and intervention health posts will be analyzed:
   - Staffing changes, stock-outs and other service disruptions, completeness and use of data will be analyzed using descriptive statistics to assess fidelity to the intervention and implementation challenges
   - The quality of care will be analyzed by scoring checklists completed during observation of PPFP counseling sessions and IUD/implant insertions to ascertain if there were improvements over time in the quality of services provided

- Client exit interview responses will be analyzed using descriptive statistics to assess the acceptability of the intervention from the perspective of end beneficiaries
- Provider interviews (conducted at first and last supervision visits) will be analyzed using descriptive statistics to identify fidelity to the intervention as reported by providers, implementation challenges, and acceptability of the intervention from the perspective of providers. Changes in provider knowledge between the first to last supervision visit will also be assessed.
- Information on stock-outs and quality of counseling will be used in the “per protocol” analyses.

In addition, service statistics were extracted from facility records during supervision visits and will be used to analyze FP uptake by method over the study period to triangulate with information reported by women.