Last updated November 22, 2016

Analysis Plan: Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

Principal Investigator: Christine Dehlendorf, MD MAS

Intention-to-treat analysis

Participants who "cross over" from their assigned study arm (as determined by the provider they are likely to see) will be included in the final analyses in the arm in which they were initially assigned.

Modified intention-to-treat analysis: Post-randomization exclusion

Some participants may be excluded from analysis after being randomized:

- Participants who find out they are pregnant during their enrollment visit (and thus would have been ineligible had this been known prior to enrollment).
- Participants who enrolled in the study more than once (their second enrollment will be excluded).

Data Collection and Analysis

The outcomes of interest for this study have been divided into three specific aims, which dictate what type of data is collected and how it is analyzed.

Outcomes of Interest

Specific Aim 1: The primary outcome is a binary indicator of contraceptive continuation at 7 months and a secondary outcome is a binary indicator of contraceptive continuation at 4 months. For ambiguous cases for these outcomes, we used a blinded adjudication process and applied a standardized list of rules and assigned outcomes throughout the process of data collection. Potential outcomes for individuals are as follows: continuous users of chosen method, non-continuous users of chosen method, and missing but included and imputed.

For all variables, the analysis will use multiple imputation to deal validly with the missing values. Of note, specific variables were not collected from participants we collected data from more than 48 hours after their visit. Those variables will be analyzed in the same way as other missing outcomes.

- **Primary outcome:**
    - Continuation of the chosen method seven months after her visit, without a gap of four consecutive weeks or more. If participants completed a 4 month follow-up survey, they must have started their chosen method by the date of that survey to be considered continuous users. If they did not complete a 4-month follow-up survey and only completed a 7-month follow-up survey, they must have started their chosen method by 20 weeks post-enrollment (4 weeks after their 4-month follow-up milestone). Participants must be currently using their chosen method at the time of the 4-month follow-up survey to be considered continuous users, UNLESS they report this non-use as

part of a <4week gap at the time of the 7 month survey. Participants must be currently using their chosen method at the time of the 7-month follow-up survey to be considered continuous users.

- *Definition of continuation variable:* We will evaluate continuation based on the day of 7-month survey completion, within a 4-week window beginning 7 months after enrollment
- *Definition of chosen method:* In the primary analysis, continued use of any IUD among those choosing either IUD will be classified as continued use of the chosen method; we will conduct an additional sensitivity analysis in which only continued use of the type of IUD originally chosen will be classified as continuous.
- *Treatment of bridge method users:* For primary analysis, any combination of continuous bridge method use with or without subsequent use of the chosen method will be considered continuous; we will conduct a sensitivity analysis in which participants who never start their primary OR start their primary method after the 4-month follow-up survey are not considered continuous users of their chosen method.
- *Treatment of women who become pregnant.* Continuation at 7 months will be multiply imputed for participants who report a pregnancy before this point who had started their chosen method before 4 months and were continuing to use it at the time they became pregnant. Participants reporting discontinuation prior to pregnancy will be counted as non-continuers.
- *Continuous users of coitally-dependent methods*: For primary analysis, in addition to the standard definition of who is a continuous user of a chosen method, choosers of coitally-dependent methods will also be categorized as continuous users if they:
    - Did not have a gap of 4+ weeks during which they were sexually active and did not use a Tier 1 or Tier 2 method at any point since enrollment for four weeks or more OR
    - Report that they discontinued the method at the time of their survey BUT are not using anything else, have not had sex since discontinuation and say they would use this method if they were to have sex (note: no participants met this criteria) OR
    - Never started the method but haven't had sex since enrollment and would use the method if they started having sex (note: no participants met this criteria)

- **Secondary outcomes:**
    - Patient Contraceptive Counseling Satisfaction at post-visit survey
        - Factor analysis-validated survey created by the PI to assess patients' satisfaction with the contraceptive counseling experience.

        - In primary analysis, we will do top-scoring of the IQFP total score, i.e. a score of 55 versus all other scores
    - Patient Chosen Contraceptive Method Satisfaction at the post-visit survey, and 4 and 7 months
        - 5-point Likert scale question regarding patient satisfaction with contraceptive method chosen.
        - In primary analysis, we will do top-scoring for this questions
            - **Note:** Slightly different questions at baseline and follow-up:
                1) Baseline: How satisfied are you with your choice of birth control today?
                2) 4mo and 7mo: how much you agree with statement "I chose the best method for me at the time"
    - Experience with Shared Decision-Making (measured at post-visit survey)
        - Patient report of having engaged in shared decision making with their provider and their experience with the decision making process, as well as qualitative coding of contraceptive counseling visits. The qualitative coding will focus on the presence or absence of shared patient-provider decision making and patient engagement in the decision making process, drawing on concepts from observational measures of shared decision making, as well as insights into the counseling process gained through our previous observational study.
            - For the question regarding who made decision, we will collapse the responses into 3 categories
                1) Health care provider AND mostly health care provider
                2) Me and provider equally
                3) Mostly me AND me alone
            - For the question regarding whether the provider had a preference:
                1) "no preference" vs. other 4 categories
            - For the 5-point Likert scale question regarding satisfaction with support provided/how the provider helped you to choose, we will do top scoring
            - For the question regarding satisfaction with involvement of provider in the decision making process, we will analyze using the existing three categories (no collapsing)
            - For the question regarding satisfaction with the degree to which provider expressed preference, responses will be collapsed into 3 categories:
                1) A lot less strongly AND less strongly
                2) Exactly right
                3) A little bit more strongly AND a lot more strongly
    - Patient Decisional Conflict in Contraceptive Choice at the post-visit survey

        - Validated survey to assess patients' decisional conflict in medical decision making.
            - In primary analysis, we analyze this scale as a continuous variable. We will dichotomize if this violates linearity assumptions.
    - Patient Current Contraceptive Method Satisfaction at 4 and 7 months
        - 5-point Likert scale question regarding patient satisfaction with the contraceptive method they are currently using.
        - In primary analysis we will do top-scoring, i.e. a score of 5 versus all other scores
    - Patient Attitudes and Knowledge of Contraceptive Options and Features (post-visit survey)
        - Patient report of perceived knowledge of their options and questions derived from National Survey of Reproductive Contraceptive Knowledge and previous studies of contraceptive knowledge and attitudes.
        - In primary analysis:
            - Will analyze each of these questions independently. For the questions related to effectiveness and the questions related to knowledge of IUDs, we will also analyze as either answering all questions correctly vs. answering any incorrectly, and also examine the number correct as an ordinal outcome.
            - For all knowledge and attitudes question, unless otherwise specified below, we will analyze answered correctly vs. incorrectly or I don't know
            - Emergency contraceptive knowledge question:
                1) Primary analysis: selection of emergency contraception AND copper IUD vs. not selecting both of those
                2) Sensitivity analysis: for having copper IUD in their answer vs. not
            - For the "Heard of" question: we are pre-specifying interest in responses regarding IUDs (analyzed together), implant, vasectomy, female sterilization, patch, and ring, with a primary interest in IUDs
                1) IUD primary analysis: heard of an IUD (either one) vs. not having heard of it
                2) Equivalent analyses for other methods
            - For the "How would you rate for yourself?" question, we interested in all methods (specifying IUDs and implants)
                1) All methods (specifying IUDs- IUD type analyzed separately- and implants)
                2) Continuous variable for all methods; 11 point scale
            - Effect on fertility question
                1) Marked either IUD as yes or I don't know vs. marked both IUDs as no

2) Marked anything other than Depo as yes or I don't know, vs. marked everything other than Depo no (we will not factor responses to the questions about Depo into this variable)

- London Measure of Unplanned Pregnancy at 4 and 7 months
  - Incidence of unplanned pregnancy among study participants.
  - Definition of unplanned pregnancy: LMUP < 10;
  - *Justification: Barrett 2004 Journal of Epidemiology and Community Health*
- Use of Any Moderately or Highly Effective Method of Contraception at 4 and 7 Months Follow-up
  - Whether patient is using an effective contraceptive method at 4 or 7 months follow-up survey.
  - Definition of Moderately or Highly Effective methods: Tier 1 and Tier 2 methods
- Choice of a Highly Effective Method of Contraception at Baseline
  - Whether patient chooses a highly effective contraceptive method at baseline visit.
  - Definition of Highly Effective methods: Tier 1
  - Primary analysis: all highly effective methods (IUDs, implants, female sterilization, vasectomy) vs. everything else
  - Sensitivity analyses:
    - All reversible highly effective methods (IUDs and implants) vs. everything else
    - Excluding patients who indicate that they had to pay out of pocket for their birth control method
- Use of a Highly Effective Method of Contraception at 4 and 7 Months Follow-up
  - Whether patient is using a highly effective contraceptive method at 7 month follow-up survey.
  - Primary analysis: all highly effective methods (IUDs, implants, female sterilization, vasectomy) vs. everything else
  - Sensitivity analyses:
    - All reversible highly effective methods (IUDs and implants) vs. everything else
    - Excluding patients who indicate that they had to pay out of pocket for their birth control method

- Continuation of the chosen method 4 months after her visit.
  - Continuation of the chosen method four months after enrollment**,** without a gap of four consecutive weeks or more. In order to be considered continuous users. If participants completed a 4-month follow-up survey, they must have started their chosen method by the date that survey to be considered continuous users. If they did not complete a 4-month follow-up survey and only

completed a 7-month follow-up survey, they must have started their chosen method by 20 weeks post-enrollment (4 weeks after 4-month follow-up milestone). Participants must be currently using their chosen method at the time of the 4-month follow-up survey to be considered continuous users, UNLESS they report this non-use as part of a <4week gap at the time of the 7-month survey.

- *Definition of continuation variable:* We will evaluate continuation based on the day of 4-month survey completion, within a 4-week window beginning 4 months after enrollment
- *Definition of chosen method:* For primary analysis, we will collapse IUD types for chosen method; we will conduct an additional sensitivity analysis in which we do not collapse IUD types
- *Treatment of bridge method users:* For primary analysis, any combination of continuous bridge method use with or without subsequent use of the chosen method will be considered continuous; we will conduct a sensitivity analysis in which participants who never start their primary OR start their primary method after 4mo follow-up survey are not considered continuous users of their chosen method
- *Treatment of women who become pregnant.* Continuation at 4 months will be multiply imputed for participants reporting a pregnancy before this point who had started their method and continued to use it until they became pregnant and for those who never started their method before their 4 month survey. Participants reporting starting and then discontinuing heir chosen method prior to pregnancy will be counted as non-continuers.
- *Continuous users of coitally-dependent methods*: For primary analysis, in addition to the standard definition of who is a continuous user of a chosen method, choosers of coitally-dependent methods will also be categorized as continuous users if they:
    1) Did not have a gap of 4+ weeks during which they were sexually active and did not use a Tier 1 or Tier 2 method at any point since enrollment for four weeks or more (asked about a gap when were sexually active in the gap question) OR
    2) Report that they discontinued the method at the time of their survey BUT are not using anything else, have not had sex since discontinuation and say they would use this method if they were to have sex (note: no participants met this criteria) OR
    3) Never started the method but haven't had sex since enrollment and would use the method if they started having sex (note: no participants met this criteria)

Pre-specified covariates for patients for Specific Aim 1:

- Age
  - <20
  - 20-24
  - 25-29
  - 30-34
  - ≥35
- Parity
  - 0
  - ≥1
- Race/ethnicity
  - White
  - Black
  - Latina
  - Other
- Language
  - English
  - Spanish
- Parental education
  - ≤ High school
  - Some college
  - ≥ College

Pre-specified covariates for providers for Specific Aim 1:

- Age
  - <36
  - 36-50
  - ≥51
- Race/ethnicity
  - White
  - Other
- Professional Degree
  - NP
  - Non-NP

Specific Aim 2: Qualitative assessment of patient engagement and the presence of shared decision making between counseling provided before and after implementation of the decision support tool by providers randomized to the intervention group. As described above, the qualitative coding will focus on the presence or absence of shared patient-provider decision making and patient engagement in the decision making process, drawing on concepts from observational measures of shared decision making, as well as insights into the counseling process gained through our previous observational study.

Specific Aim 3:

- Qualitative assessment of providers' and staff members' experiences using interviews and focus groups
- Quantitative measures of consultation time and total clinic visit time
    - Total Clinic Visit Time
        - Total amount of time a patient spends in a clinic for a family planning visit, from check-in to check-out.
        - Time of visit end minus time of check-in (recorded in clinic tracking sheets)
    - Time Spent with Contraceptive Counseling Provider
        - Total amount of time spent with the provider that is providing contraceptive counseling.
        - Time of visit start minus time of visit end (recorded in clinic tracking sheets)
        - **Note:** this measurement will be different at PP Valencia because consultation time included time spent with RHS and clinician, rather than a singular contraceptive counseling provider as at other clinics
- Change in provider burnout, pre- and post-intervention, using the Maslach Burnout scale, measured prior to implementation of the intervention and at the end of the trial
    - Maslach Burnout Inventory:
        - Given to provider participants to measure emotional exhaustion, depersonalization, and personal accomplishment subscale scores.
        - In primary analysis, we will conduct 3 different analyses, with each subscale (emotional exhaustion, depersonalization, and personal accomplishment) as a continuous variable

Pre-specified covariates for providers for Specific Aim 3:

- Age
    - <36
    - 36-50
    - ≥51
- Race/ethnicity
    - White
    - Other
- Professional Degree
    - NP
    - Non-NP

Methods of Analysis

Patient and provider stakeholders will be involved in an iterative manner in all stages of planning of analyses and in data interpretation.

[IR-1] Data required for primary analyses will be inspected, cleaned, and locked before primary analysis is begun. Data checks will include examination of descriptive statistics for plausibility (e.g. plausible participant age, scale values fall within scale options given), distribution, and missingness. Values with errors will be replaced as missing or, if a correction is verifiable through review of an individual's record, replaced with the correct value in the dataset in Stata 14. For the primary analyses, individual record reviews will be performed for any participants with circumstances in which the primary outcome of contraceptive continuation may be complicated. These include all participants who selected DMPA (The Shot or "Depo") as their main or bridge method choice; participants who stopped their method before their 4-month survey and restarted it again before their 7-month survey; participants who transitioned from use of their bridge method to use of their main method for birth control during the course of the study; participants who became pregnant during the course of the study, after their day of enrollment; participants who were not reached to complete a 4-month survey, but did complete a 7-month survey; and participants with partially complete survey records at 4 or 7 months [IR-4]. Participants who are negative for the primary outcome (i.e. discontinuous) at the time of their 4-month survey will be considered negative for the primary outcome at 7 months, regardless of whether they completed a 7-month survey or not. Baseline outcomes will also be examined for individuals who accidentally completed multiple surveys at baseline, with priority given to the first survey completed. Reliability of scales will be assessed using Cronbach's alpha, as well checks for predictive and discriminant validity. [IR-4]. Reliability of scales will be assessed using Cronbach's alpha, as well checks for predictive and discriminant validity.

Specific Aim 1:

We will assess imbalance by treatment assignment using cross-tabulations and comparisons of within group means and medians. Inference for balance on provider covariates will use chi-squared, Fisher's exact, t, and Wilcoxon tests as appropriate, while differences in patient characteristics will be assessed using mixed effects models with fixed effects for clinic and random effects for provider. [IR-3] Primary analyses of treatment effects will be intention-to-treat, according to treatment assignment, and without regard to use of the tool or seeing an intervention provider. Treatment effects will be estimated using mixed effects linear, logistic, proportional odds, and multinomial models, with fixed effects for clinic and random effects for provider.

Missing data. [MD-1] Missing data will have been minimized by active follow-up of participants. [MD-4] Missing data rates for primary and secondary outcomes as well as important covariates will be reported, in combination with summaries of the reasons for missingness, including dropout and pregnancy. [MD-2] All analyses will handle missing data using 20-fold multiple imputation of missing outcomes, based on iterative chained equations. [MD-3] Summary effect estimates, averaged over the 20 imputed datasets, as well as confidence intervals and p-values, will be calculated using standard methods that account for imputation error.

Sensitivity analyses. [MD-5] Because informative missingness would violate the covariate-dependent missing at random (CDMAR) assumption of the standard multiple imputation procedure, we will conduct sensitivity analyses in which we multiply impute missing data under plausible informative missing data mechanisms – in particular, lower contraceptive continuation rates among participants with missing values of this outcome, in one or both arms. [DR-3] In addition, we will conduct sensitivity analyses controlling for any imbalanced pre-randomization characteristics (e.g., age and parity) that predict outcomes, using 5% changes in the coefficient for the intervention as the criterion for covariate inclusion in the adjusted model. To characterize the influence of individual providers, we will estimate best linear unbiased predictions of the provider effects, and also fit models with additional random provider-intervention interactions, to capture heterogeneity in the effects of the intervention. In all analyses, we will transform continuous outcomes as necessary to meet the normality assumption, model departures from linearity in the influence of continuous covariates, check for influential points, and identify potentially important interactions.

Heterogeneity of treatment effects. [HT-1] We will assess modification of the effect of assignment to the intervention by the following 5 pre-specified factors: age, race/ethnicity, language, parental education, and clinic. We will assess evidence for effect modification by adding the effect modifier and its interaction with the treatment assignment indicator to the primary analysis models specified above. To limit inflation of the type-I error rate, we will only estimate within-stratum treatment effects if the interaction is statistically significant at a Bonferroni-corrected P = 0.01, and will cautiously interpret findings. These analyses will use multiply imputed data and corresponding inference methods.

Specific Aim 2: For this aim, we will be assessing the effect of the intervention on counseling at the cluster (i.e., provider) level. We will use Dedoose software to analyze the audio recordings using modified grounded theory, with the coding performed by Dr. Dehlendorf, Reiley Reed, and Dr. Kimport, with input from patient stakeholder representatives. This coding will focus on the presence or absence of shared decision making and patient engagement in the decision making process. In conducting this coding, we will use concepts drawn from observational measures of shared decision making, including the OPTION scale and the Four Habits Coding Scheme, as well as insight into the counseling process gained through our previous observational study, to identify our initial thematic structure. We will perform iterative coding, with discussions between coders, the PI, and patient stakeholders to clarify concepts and resolve ambiguities. We will then, again in collaboration with stakeholders, qualitatively explore the extent to which the providers altered their behaviors following implementation of the intervention using memo writing, and ultimately compiling these into results.

Specific Aim 3: In order to determine the effect of the intervention on the experience of providing family planning care at the level of both the clinic and the provider, we will perform both qualitative and quantitative analyses. Quantitative analyses, including comparing consultation time and total clinic visit time for patients in the intervention and control group, will use similar methods to those described in Aim 1. We will also compare scores on each sub-scale of the Maslach Burnout Inventory (emotional exhaustion, depersonalization, and personal accomplishment), controlling for baseline values, between providers randomized to the intervention and those randomized to the control group in both bivariate

and multivariate analyses, again controlling for clustering by clinic. In addition, we will conduct a sensitivity analysis controlling for any imbalanced pre-randomization characteristics (e.g., age) that predict outcomes, using changes in the coefficient for the intervention as the criterion for covariate inclusion in the adjusted model. Thematic analysis of interview and focus group transcripts and recordings will again be performed using Dedoose software, using an iterative and collaborative process of coding as described in Aim 2.

Additional Analyses

Intervention arm patient participants' decision support tool data will be analyzed. Participant data input to the tool includes patient preferences around birth control characteristics, their recommended methods, and any questions for their provider.