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Statistical Analysis Plan

ALTERNATIVE PROVISION OF MEDICATION ABORTION VIA PHARMACY DISPENSING

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STATISTICAL ANALYSIS PLAN

1. Study Design

We will conduct a prospective cohort study of patients receiving Mifeprex® dispensed by pharmacists after undergoing standard clinical evaluation. Women participating in this study will obtain Mifeprex® and misoprostol from the pharmacy instead of in the clinic. All clinical procedures will continue to be performed as they currently are. The only difference is that the Mifeprex® will be dispensed by a pharmacist in the study pharmacy rather than by the clinician in the clinic. In particular, patients will be evaluated for all contraindications to the method according to the label, and they will sign the Patient Agreement Form. A clinician who has completed the Prescriber Agreement Form will write a prescription for Mifeprex® 200 mg for the eligible patient. The patient will then go to a designated pharmacy to fill the prescription, where it will be dispensed by a trained pharmacist. The patient will then take the Mifeprex® at the time indicated by the prescribing clinician. Patients will be contacted on Day 2 and Day 14 to complete surveys about their experience, and they will undergo standard clinical follow-up. In addition, we will perform surveys and interviews with pharmacists before and after initiating the study, as well as monitor the number of pharmacists who refuse to dispense Mifeprex® at the study pharmacies.

2. Aims and Objectives

The proposed study aims to investigate the feasibility, acceptability, and effectiveness of pharmacy dispensing of Mifeprex®; safety data will also be collected.

Our primary objective is to assess the feasibility of pharmacist dispensing of Mifeprex® by measuring pharmacist satisfaction and the proportion of pharmacists who refuse to dispense the medication to patients.

Secondary objectives include assessing patient satisfaction with the pharmacy-dispensing model; describing clinical outcomes, including effectiveness and adverse events, with pharmacist-dispensed Mifeprex®; and comparing pharmacist knowledge about medication abortion before and after the intervention.

3. Analyses

3.1 Patient arm

We will examine three outcomes related to patient participants' clinical experience and satisfaction with the pharmacist dispensing model. These will include two clinical outcomes: 1) effectiveness of medication abortion and 2) adverse events, as well as an outcome from the patient perspective: 3) satisfaction with the pharmacy experience at day 2. Effectiveness of medication abortion is defined as the proportion of participants who have a complete abortion with medications alone and do not undergo vacuum aspiration. Given the accuracy of patient self-assessment of abortion completion, we will use self-reported survey data to document

abortion outcome if the participant does not have follow-up contact with the clinic. Adverse events will be captured up to 6 weeks after participants are recruited into the study, and any ongoing adverse events will be followed until resolution. Adverse events are defined as serious using the FDA criteria and include death, hospitalization, blood transfusion, and surgery. Information about adverse events will be collected from abstracted data from patients' charts and self-reported data in patients' surveys. The satisfaction outcome will be based on participants' ratings on a Likert scale. On the day 2 survey, we ask participants "Overall, how satisfied were you with your experience at the pharmacy when you got the abortion pill?" with response options "Very satisfied," "Somewhat satisfied, "Somewhat dissatisfied," and "Very dissatisfied." We will dichotomize responses by those who report being very satisfied compared with all other responses. All demographic variables and pharmacy experience responses will be collected from patient surveys except gestational age at the clinic visit, which will come from clinical charts. Missing survey data for age, race and ethnicity, and parity will be obtained from patients' clinical chart data when available. We will conduct all analyses using Stata 15 and report significance at $P<.05$.

3.2 Pharmacist Arm

We will examine two primary outcomes and one secondary outcome related to the pharmacist dispensing model. Primary outcomes will include: 1) pharmacists who object to dispensing Mifeprex® and 2) pharmacists who report satisfaction with pharmacy dispensing of Mifeprex®, and the secondary outcome will be: 3) pharmacists' knowledge related to medication abortion.

Number of pharmacists who object to participate in dispensing Mifeprex® will be based on information reported by pharmacy managers and site research staff as well as pharmacists' who self-report objecting to dispensing Mifeprex® in their baseline survey. Pharmacy managers and site research staff will track pharmacists' participation in the training and Mifeprex® dispensing and report the number of pharmacists who refuse to dispense Mifeprex® to the coordinating study team. Using these data, we will calculate the proportion of pharmacists who refuse to dispense Mifeprex® during the study.

Number of pharmacists who report being satisfied with pharmacy dispensing of Mifeprex® will be based on survey data reported by pharmacists. At follow-up, we will assess satisfaction with pharmacy dispensing of Mifeprex® (ranging from very satisfied to very unsatisfied).

Difference in pharmacists' mean knowledge score related to medication abortion will be based on data collected in pharmacists' baseline and endline surveys. Knowledge scores will be based on a set of 15 items related to medication abortion for which respondents will select answers from multiple choice response options. Topics include medication abortion dosing regimen, biological processes during medication abortion, clinical outcomes, and federal and state policies relating to medication abortion. For pharmacists who complete at least 50% of the items, we will calculate their average number of correct responses among completed items. All questions or statements include an "I don't know" response option, which we will code as incorrect.

We will first assess the internal consistency reliability of the 15 knowledge items and consider a Cronbach's alpha coefficient above .70 to be acceptable to examine the items as a combined score.[19] We will run descriptive summary statistics for baseline responses describing participant characteristics, as well as follow-up responses on satisfaction with the model. We will conduct a

series of multivariable logistic and linear regression analyses using Generalized Estimating Equation (GEE) models to assess whether study implementation is associated with pharmacists' overall medication abortion knowledge and on 15 individual medication abortion topics, ease and support of pharmacist dispensing of Mifeprex®. Coefficients in adjusted analyses examining overall medication abortion knowledge will represent the difference in mean knowledge scores between baseline and follow-up. We will conduct analyses in Stata 15.1 (StataCorp, College Station, TX).

We will also assess perceived benefits and challenges of pharmacist mifepristone dispensing. For perceived benefits, we will ask if this model "may improve access for women", "expands pharmacists' role in providing reproductive health services", and "may streamline delivery of medications", coding as dichotomous outcomes (yes/no). We will assess perceived ease of model implementation at baseline (anticipated ease) and follow-up (experienced ease) and personal support for pharmacist dispensing of mifepristone, measured on a four-point Likert scale, but coded dichotomously. We will code ease of implementation as very easy vs. somewhat easy/somewhat difficult/very difficult, and personal support for pharmacist dispensing of mifepristone as very supportive vs. somewhat supportive/somewhat unsupportive/very unsupportive.

For challenges, we will examine both anticipated (baseline) and experienced (follow-up) challenges (for example, lack of familiarity with medication or support from other pharmacists). At follow-up, we will assess how sufficient the medication abortion training and resources of the training were perceived to be (ranging from very sufficient to very insufficient), as well as satisfaction with pharmacy dispensing of mifepristone (ranging from very satisfied to very unsatisfied).