

PROTOCOL TITLE: Advance provision of postpartum emergency contraception and its effects on reproductive autonomy: a mixed methods study

PRINCIPAL INVESTIGATOR:

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STUDY SUMMARY:

Investigational Agent(s) (Drugs or Devices)	Ulipristal acetate (UPA)
IND / IDE / HDE #	N/A
Indicate Special Population(s)	<input checked="" type="checkbox"/> Children <input type="checkbox"/> Children who are wards of the state <input type="checkbox"/> Adults Unable to Consent <input type="checkbox"/> Cognitively Impaired Adults <input type="checkbox"/> Neonates of Uncertain Viability <input type="checkbox"/> Pregnant Women <input type="checkbox"/> Prisoners (or other detained/paroled individuals) <input type="checkbox"/> Students/Employees
Sample Size	75
Funding Source	Society of Family Planning, Emerging Scholars Grant
Indicate the type of consent to be obtained	<input checked="" type="checkbox"/> Written <input type="checkbox"/> Verbal/Waiver of Documentation of Informed Consent <input type="checkbox"/> Waiver of HIPAA Authorization <input type="checkbox"/> Waiver/Alteration of Consent Process
Site	<input type="checkbox"/> Northwestern Medicine Prentice Women's Hospital
Research Related Radiation Exposure	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
DSMB / DMC / IDMC	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

OBJECTIVES:

1. Understand the effects of advance provision of emergency contraception (EC) on factors beyond unintended pregnancy, in particular reproductive autonomy
2. Explore patient preferences in the postpartum period around contraceptive use
3. Assess use of EC in the postpartum period and the context that surrounds its use
4. Provide a patient-centered-and-controlled intervention to those who desire EC in the postpartum setting that facilitates contraceptive choice and access.

Hypothesis:

We hypothesize that providing an advance supply of EC will increase use and decrease barriers to use. Additionally, we hypothesize that, with thorough EC counseling, participants will develop an increased knowledge base of EC. With increased use and knowledge, we hypothesize that participants will experience greater reproductive autonomy over their contraceptive decisions.

BACKGROUND:

Emergency contraception (EC), an alternative or supplemental method that can be used in the event of having unprotected sexual intercourse, can offer people increased reproductive choice and freedom. Multiple pharmacologic options for EC now exist, with two available oral pills: levonorgestrel (LNG) and ulipristal acetate (UPA).¹ While the primary mechanism of both pills is to delay or inhibit ovulation, UPA has been shown to be more effective than LNG. Importantly, it can be used for up to 120 hours after unprotected intercourse compared to 72 hours for LNG. Though EC is overall less effective in overweight and obese patients, UPA still is more effective in these patients compared to LNG.²⁻³ To increase access to EC, in August 2013, the FDA ultimately approved the LNG pill to be provided over the counter without any age restrictions, but barriers to access still exist, such as unavailability, pharmacist resistance, and lack of knowledge within both patients and providers.⁴ Accessing UPA is even more difficult as it still requires a prescription, and many pharmacies in the United States do not have UPA readily in stock.⁵ Ensuring access to EC is a fundamental component of comprehensive contraceptive counseling and reproductive healthcare. Thus, strategies to increase access were introduced, including advance provision of EC, and it was hypothesized that increased access to EC would thereby decrease unintended pregnancy rates.⁶

Almost half of pregnancies in the United States are unintended, though this rate is declining.⁷ As a national public health issue, unintended pregnancy is associated with increased economic and emotional burden on mothers and families and impact our most marginalized communities.⁸ However, some scholars have criticized using unintended pregnancy as a measure for several reasons. The intendedness of a pregnancy is not always clear, and many people hold ambivalence over their pregnancy desires. Moreover, unintended pregnancies are not always adverse outcomes. Importantly, data showing higher rates of unintended pregnancy amongst marginalized communities can lead to further stigmatization, targeted and perhaps coercive contraceptive tactics, and shift of blame from structural inequalities to individual failures.⁹⁻¹¹

Ultimately, the effect of advance provision of EC on unintended pregnancy has had disappointing results. Multiple randomized controlled trials have overwhelmingly found no change in unintended pregnancy rates with advance provision of EC,¹²⁻¹³ with a few exceptions.¹⁴⁻¹⁵ In response, some proponents of EC have called for research efforts to be shifted towards effective strategies in decreasing unintended pregnancy, such as increasing the uptake of long-acting reversible contraception (LARC).¹⁶⁻¹⁸ However, given that rates of unintended pregnancy are highest amongst poor, black, Latinx,

young people, many reproductive justice scholars have thoughtfully raised concerns over the fine balance between contraceptive access and coercion.¹⁹⁻²³ Studies have reinforced the reality of reproductive injustice in this country, with providers changing their counseling based on race and ethnicity and patients of color feeling the pressure of contraceptive coercion.²²⁻²³ For many of the marginalized people that have lived through, directly or indirectly, the efforts to control their reproductive autonomy, LARCs may not represent the beacon of reproductive freedom that they are for others. Often, members of these marginalized communities prefer and choose methods where they are fully in control and are able to start, continue, and discontinue as they desire.²⁴⁻²⁵

Our project hopes to add depth to the literature through evaluating EC from a justice-focused framework. While having the capability of planning one's pregnancy can certainly be empowering, in what other ways can advance provision of EC further promote reproductive freedom and autonomy beyond the intendedness of a pregnancy? Studies have shown that advance provision of EC leads to increased and faster use, high acceptability and satisfaction, and increased knowledge of EC and other contraceptive methods.^{6, 12-13} Furthermore, providing EC prior to the "emergency" also allows for opportunities for healthcare providers to counsel on contraceptive use and sexually transmitted infections (STIs).¹² This study aims to use quantitative and qualitative methods to explore the effects of advance provision of EC on reproductive autonomy. However, our project will first focus our study population on postpartum patients, for the following reasons. First, few studies on advance provision of EC focus on the postpartum patient, though the antepartum and postpartum period is a rich opportunity for contraceptive counseling given increased motivation to prevent pregnancy and access to consistent reproductive healthcare.²⁶ Additionally, the risk of having another pregnancy is even more stark for these patients. Having a short interpregnancy interval, defined as less than 18 months from delivery to subsequent conception, is notably associated with increased maternal and fetal risk, including low fetal birth weight and preeclampsia. Out of all pregnancies, 35% occurred within 18 months of their prior birth, and 55% of these pregnancies were unintended.²⁷ Studying the impact of EC within this population can have important health effects on our patients and their families, while offering an opportunity to provide an empowering intervention.

In the face of increased access to EC on a legislative level, EC still remains underutilized, with multiple research studies showing its ineffectuality in successfully decreasing rates of unintended pregnancy. Using reproductive justice as our framework, our study hopes to provide an intervention to our patients who desire increased contraceptive choice, highlight the potential benefits of EC in promoting reproductive autonomy and freedom in a population highly motivated to prevent pregnancy, and add to the current body of literature on EC.

STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):

Study intervention: Provide advance supply of UPA (3 doses) prior to discharge from hospital after delivery. UPA is currently available through prescription and is FDA approved for emergency contraception. Therefore, it is not an investigational new drug

or device. Participants will have a prescription sent to the pharmacy. The pharmacy will fill this prescription for the patient, which will be delivered to the patient prior to discharge.

STUDY ENDPOINTS

- (1) Collection and analysis of EC use and knowledge via surveys
- (2) Collection and summarization of narrative verbatim transcripts of interviews

PROCEDURES INVOLVED / METHODS:

This project will be a prospective observational study, using a mixed-methods design to further explore the impact of EC use on postpartum patients' feelings of reproductive autonomy. We will aim to recruit 75 participants, with an expected 40-50 participants retained at 6 months, and 15-20 of those participants choosing to participate in an in-depth interview at 6 months. Participants will first be screened for eligibility on chart review. If any inclusion/exclusion criteria remain unclear in the medical record, these participants will still be approached to complete the eligibility survey if they are interested in participating in the study. All potential participants will confirm their contraceptive method prior to enrolling in the study. Participants who are undecided on their postpartum contraceptive plan will not meet inclusion criteria for the study. This is to avoid possible coercion or influence by the research study on patients' contraceptive choices.

If they choose to enroll in the study, they will undergo an informed consent and a baseline survey comprised of standard demographic questions, questions on reproductive and contraceptive history, knowledge on EC, and questions on reproductive autonomy. The section on reproductive autonomy is adapted from the Reproductive Autonomy Scale.²⁸ This survey will be designed to take ~10 minutes to complete. Participants will undergo standardized counseling on postpartum contraception. This counseling will include 1) best-practice recommendation for high-efficacy postpartum contraception, 2) recommendation for appropriate pregnancy spacing, 3) efficacy of contraceptive methods, and 4) types of EC and detailed instructions for use. They will receive a package of three doses of UPA prior to being discharged home along with educational material for EC. If participants need additional doses of EC, they would be able to call the clinic for additional doses. Participants will then complete surveys at 6 weeks, 3 months, and 6 months. In the 6-week survey, if they have used EC by that time, they will be invited to participate in a brief, 20-30 minute interview that will focus on their experience, comfort, and facilitators/barriers to their most recent EC use. In the 6-month survey, the participant will be invited to participate in an in-depth interview designed to further explore participant experiences with EC. The qualitative interview is expected to last ~1 hour and will discuss themes around EC use, acceptability, autonomy, contraceptive choice.

As the study intervention uses a drug that is FDA-approved for emergency contraception, participants are not expected to undergo additional risk with this intervention. The electronic medical record will be used to conduct a preliminary chart

review on possible eligible patients prior to approaching them for recruitment. The survey instrument and interview scripts are attached to this document.

This study will collect data from the surveys and the interviews. The surveys will be completed online, in person, or via the phone based on participant preference. The interviews will be in person and will be audio-recorded. Audio-recording of the interviews is necessary for this research in order to transcribe verbatim for data analysis. The audio recordings will only be used for data analysis and will be stored in a password-protected folder within the Northwestern Medicine secure departmental server. The password will only be available to the study team. Once the audio recordings are transcribed verbatim, they will be destroyed immediately.

STUDY TIMELINES

Participants will be recruited into the study on postpartum day #1. Then, they will complete surveys at 6 weeks, 3 months, and 6 months. At the 6 month survey, they will be invited to participate in an in-depth interview that would be scheduled within the following month. Therefore, the total duration of an individual's participation in the study would be 7-8 months, if they were to complete the study.

The investigators will be recruiting patients concurrently with primary data collection. We expect participant enrollment to occur from December 2021 – May 2022 (6 months). We expect primary data analyses to be completed by September 2022.

INCLUSION AND EXCLUSION CRITERIA

Participants will first be screened for eligibility through a chart review. Then upon first assessment on postpartum day #1, participants will complete a survey to confirm eligibility. If any of the inclusion or exclusion criteria are unclear on chart review, these participants will still be approached to complete the eligibility survey if they are interested in participating in the study.

Inclusion criteria:

- 16-40 years of age
- English-speaking
- In a sexual relationship with possibility of pregnancy
- Delivered a live infant
- Desire to delay pregnancy for at least a year
- A patient at Northwestern University Feinberg School of Medicine Department of Obstetrics and Gynecology
- Choosing no postpartum contraceptive method or a lower efficacy method: condoms, female condoms, diaphragm/cervical cap/sponge, fertility awareness method

Exclusion criteria:

- Allergy to UPA
- Those who have had tubal sterilization
- Those who conceived via assisted reproductive technology
- Those with inability to follow up

- Those taking drugs that interact with UPA (CYP3A4 inducers, abametapir, felbamate, fexinidazole, fusidic acid, griseofulvin, oxcarbazepine, progestins, topiramate)

Special populations

Excluded: adults unable to consent, currently pregnant women, prisoners

Included: Individuals who are not yet adults (teenagers between the age of 16-17).

Rationale: This study requires informed consent to participate, so adults without the ability to consent will not be approached for this study. This study aims to provide emergency contraception to postpartum patients, so currently pregnant women will not be approached. Incarcerated people do not receive obstetric care at Prentice Women’s Hospital, so they will not be approached for the study.

This study does include individuals who are not yet adults (teenagers who are 16 and 17 years old). However, given that these individuals will all have delivered a liveborn infant, they do not require parental permission to participate in the study, and they are able to consent to the study. Additionally, individuals who are under the age of 18 are allowed to consent to any and all contraceptive methods, including EC, without parental consent.

RECRUITMENT METHODS

Participants will be patients of Northwestern University Feinberg School of Medicine Department of Obstetrics and Gynecology. This includes the following clinics: Northwestern Medicine Faculty Foundation, Prentice Ambulatory Care, Maternal Fetal Medicine. These patients will be identified while on Labor and Delivery, prior to delivery. Potential participants will first be screened with a chart review. Patient without clear documentation on their postpartum birth control method will be included in possible recruitment.

Potential participants will be recruited on postpartum day #1 on the inpatient postpartum floors in Prentice Women’s Hospital. On postpartum day #1, they will undergo eligibility confirmation, informed consent, baseline survey administration, contraceptive counseling, and review of study logistics, including compensation. This visit duration will be around 30 minutes. As these patients will be approached while they are inpatient, they will not be compensated for completing this visit. Potential participants will be screened and recruited while they are inpatient, and there will not be additional recruitment materials, such as posters or flyers.

COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

Visit	Type of activity	Compensation
#1 (6 weeks)	10-minute survey	\$10
	Possible brief 20-minute interview	\$20
#2 (3 months)	10-minute survey	\$10

#3 (6 months)	10-minute survey	\$10
	Possible 1-hour in-depth interview	\$50

Participants will be compensated with Stored Value (VISA) cards. This card will be given to each participant upon joining the study on postpartum day 1. Compensation will be loaded onto the card upon completion of each study activity. Total possible compensation from this study, if the participant were to complete all components, would be \$100. In addition, if in-depth interviews are conducted in-person, compensation would be provided for transportation costs. A discounted research parking pass (valued at \$7 each) would be provided to those who are driving, and anyone taking public transportation or rideshare would be reimbursed on their Stored Value Card.

Participants will also be informed of any results of this study via their email.

WITHDRAWAL OF PARTICIPANTS

Any participant may be withdrawn from the study if the subject or the Investigator feels that it is not in the participant's best interest to continue. Participants may withdraw from the study at any time without penalization. Possible reasons for withdrawal include: subject withdrawal of consent, pregnancy, adverse event that would preclude continued participation in the intervention, inability to follow up/lost to follow up. To prevent undue pressure on contraceptive choice, participants will not be withdrawn if they were to choose or change their contraceptive methods, even if the method were to be a higher-efficacy option, such as an intrauterine device.

RISKS TO PARTICIPANTS

Physical risks of this study include possible adverse effects of taking ulipristal acetate, such as gastrointestinal symptoms (nausea, abdominal pain) or alterations to the menstrual cycle. This risk is minimized through excluding patients with an allergy to ulipristal acetate and thoroughly counseling patients on the medication and its side effects. Patients will additionally be able to contact their respective clinics through telephone, MyChart, or in-person visit, if they are concerned about any side effect. This is overall a reasonable risk to undertake, as UPA is an FDA approved medication for emergency contraception, and individuals are able to take this medication for this indication outside of this study. Psychological risks include potential discomfort or embarrassment with answering questions related to sexual activity and reproductive healthcare. This risk is minimized through providing an open and nonjudgmental environment and allowing participants to decline or refuse any question they are uncomfortable with answering. An additional psychological risk is the possibility of pregnancy even with taking emergency contraception, which may be more unexpected for the patient if they are undergoing this study. This risk will be minimized through clear counseling around EC and the risks of failure even with correct usage.

POTENTIAL BENEFITS TO PARTICIPANTS

For participants, a potential benefit is having a form of emergency contraception immediately available to them if it were necessary. Participating in this study may provide them with a feeling of increased control or autonomy over their reproductive decisions. Undergoing thorough counseling on emergency contraception may benefit participants through increasing their knowledge and awareness around emergency contraception.

DATA MANAGEMENT AND CONFIDENTIALITY

As a mixed-methods study, the target enrollment number of 75 participants is centered around adequate data saturation for a qualitative analysis. With 75 participants initially enrolled, it is expected that 45-60 participants will be retained at 6 months, with 15-20 participants choosing to participate in an in-depth interview. Fifteen to twenty, 1 hour, interviews will very likely yield sufficient data saturation for our qualitative analysis. For our quantitative analysis, our project will analyze EC use amongst our study population. We will also compare EC knowledge scores within each individual participant between their baseline survey and their 6-month survey.

Multiple steps will be taken to ensure data security. First, survey and interview data will be deidentified and will not include PHI. Participants will have a unique identification code assigned to them during the screening process. Participant names will only be recorded on Informed Consent Forms (inclusive of HIPAA authorization) and a master document that links identification codes with the participant, along with their contact information. Only designated study staff will have access to this master document. Any identifying information noted in the interview data will be substituted by their identification code or an appropriate label.

All documents will be both password-protected and stored only on the Northwestern Medicine departmental secure server. All audio files will be deleted immediately upon transcription. Passwords will only be shared with the study team, which will be composed of only individuals included on the IRB protocol who have undergone the required training. Once a participant has completed their research activities and the study is complete, all locator information will be destroyed, unless they wish to be contacted for, or be referred to, other studies conducted by the investigators or their colleagues.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS

Participants will only interact with members of the study team who have been appropriately recruited and trained for this study protocol. Additionally, the interviews will solely be conducted by the Investigator. In order to ensure maximum participant comfort with potentially uncomfortable questions and topics, participants will be informed that sensitive questions are optional, and they can decline to answer these questions. This will be emphasized at the beginning of every survey and interview. Additionally, participants are allowed to end a survey or interview early, if they feel the need to. Interviews will be conducted in a quiet, private space with only the interviewer and participant present. If participants are uncomfortable with any of the study team members, this concern will be seriously assessed, and participants may choose to not interact with certain team members. Members of the study team have access to all of

the research documents, and reviewing participants' medical records will be a necessary component of this study. However, study team members will only access information relevant to the study.

ECONOMIC BURDEN TO PARTICIPANTS

Potential economic burden is mitigated by participant compensation detailed above.

CONSENT PROCESS

Research staff responsible for providing informed consent will review study procedures, risks and benefits, as well as important study procedures and aspects of consent (i.e. voluntary nature of participation, confidentiality, right to withdraw, risks and benefits of participation, study procedures, etc.) with potential participants, and answer any questions they may have. Consent will take place in their private inpatient room on the postpartum floor, with care to minimize distractions as much as possible. The participants will be reassured that the information to be collected is solely for research purposes and will remain confidential to the research project personnel. They will be informed that they will be compensated for their time and effort at the rates specified in the consent. The participants will be informed of their right to refuse to answer any questions and their right to withdraw from the study at any time. Potential participants will be explicitly asked if they have any questions or need any component of the consent form to be repeated. Immediately after informing the participant, they will be asked to sign, initial, and date the informed consent form. The consent form will be co-signed and dated by the research staff in the presence of the participant. Duration of consent procedure will likely differ based on each individual participant, but average time devoted to the consent discussion should be 8-10 minutes.

PROTECTED HEALTH INFORMATION (PHI AND HIPAA)

This study will involve the use of Protected Personal Health Information. A HIPAA authorization will be obtained from all of the participants.

The following PHI will be used: name, date of birth, telephone number, medical record number, chart review

QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE

This study is supported by a number of resources that promotes the feasibility of completing this project. First, Northwestern Medicine Prentice Women's Hospital is a highly regarded, large-volume obstetric center in Illinois. With over 13,000 deliveries every year, this hospital is an optimal location to conduct research on postpartum and reproductive health. It is estimated that the clinics included in our recruitment comprise ~3,000 of those deliveries. Studies have shown that ~40-50% of postpartum patients choose no method or low efficacy methods after delivery.³⁰ Given our plan for recruitment over 6 months, we would have access to ~750 possible participants. We would therefore need to recruit 10% of these potential participants to meet our goal of 75 participants, which appears feasible.

In order to conduct and complete this research, I will be devoting ~10 hours weekly on this study. In addition, members of the study team will be recruited with clear expectations on time commitment. A full-time, paid research assistant, who is employed through Northwestern Medicine Faculty Foundation, will also be able to contribute to the study, especially during the recruitment process.

The facilities at Northwestern Medicine will be sufficient for the purposes of this study. The inpatient rooms allow for privacy to conduct the initial screening and baseline surveys. For any further in-person study activities, such as interviews, a private room in the same location as the OBGYN clinics can be reserved. Participants will remain as patients of their respective clinics during this study; if participants experience any adverse effects from the intervention, they will have access to the same clinical staff as prior to enrolling in this study.

All members of the study team will be fully trained on all aspects of the protocol and research procedures prior to starting their roles. In order to ensure this, I will conduct meetings with each individual team member to review the protocol, their role, associated duties and tasks.

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