Official Tittle: A Study to Understand the Barriers in Referring Adolescent Women for the Etonogestrel Implant and to Evaluate Whether Intensive Coaching on the Management of Common Side Effects of the Implant Influences Referrals for the Implant

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Phase 2 Protocol

This study is designed to understand how coaching versus standard education impacts pediatric providers' recommendation of the etonogestrel contraceptive implant to adolescent girls considering contraception.

A cohort of 100 providers will be recruited. A pediatric provider is defined for this study as an MD, DO, PA, or APRN who is fully licensed in the state of Florida and graduated with the degree. To participate this individual must have a practice that provides care to female patients under the age of 18 in a pediatrics, family medicine, internal medicine or obstetrics/ gynecology practice that refers patients for or provides contraception in their practice. The provider must devote at least 50% of their practice to primary care or reproductive health. A provider can also see patients 18 years of age and older. More than one provider in a practice may participate. A minimum of 30% APRN or PA providers will be recruited.

By participating in the study, the pediatric provider is agreeing to participate in a 6-month long educational experience for the provider.

The cohort will be randomized into two groups. The control group is comprised of providers who will receive an educational activity and tip sheet. The experimental group is comprised of providers who will receive an educational activity and tip sheet plus an at-will coaching resource. Both groups will receive the educational activity together in a virtual platform as well as the same written tip sheet at the end of the educational activity. Both groups will be administered the same pre-test and post-test at beginning and end of educational activity via a redcap survey.

The educational activity was created based on Phase 1 of this study which identified the most common barriers in providing etonogestrel contraceptive implant to adolescents who reside in North & Central Florida and the areas of highest knowledge deficit. Topics included in this program are:

- Best practices in contraception counseling for teens
- Adolescent attitudes towards the contraceptive implant
- Parental attitudes towards the contraceptive implant
- Cost and access to contraception
- Physical characteristics of the contraceptive implant
- Indications and contraindications to receiving the contraceptive implant
- Understanding the implant placement procedure
- Most common side effects of the contraceptive implant
- Menstrual bleeding profile following placement of the implant
- Management of common side effects of the contraceptive implant
- Reasons to discontinue the contraceptive implant.

While participants in Phase 1 can participate in Phase 2 it is not required to have participated in Phase 1. Additionally, Phase 1 participants will not be directly contacted to participate in Phase 2. Instead, participants will be recruited through their response to a flyer and outreach done by the sponsoring institution's Education Events Office. After expressing interest in the educational event, providers will be contacted by email to determine if they are interested in participating in the study. If they are they will provide a phone number where staff can contact them staff to confirm their eligibility to participate in the study and seek their informed consent for participation in the study. Providers are welcome to participate in the educational session and receive continuing medical education credits regardless of their decision to participate in the study. If providers consent to participate in the study, they will receive an electronic copy of the informed consent that they can sign via DocuSign. The total educational session will be 1.5 hours with one hour dedicated to providing the educational session, questions and answers and 30 minutes dedicated to explaining the study and protocol. All study participants will receive 1 hour of continuing medical education credit for their participation in the educational event provided by the

sponsoring institution. Additionally, study participants who are physicians and hold board certification can elect to receive Part 4 Maintenance of Certification credit by participating in the activity. The educational session will occur virtually to mitigate the risk of contracting COVID 19 as well as include participants more widely in the state of Florida.

Each participant will receive an educational packet that will include: the slides and a troubleshooting tip sheet mailed to them prior to the date of educational event. The trouble shooting tip sheet will have the key take away points from the educational program. Participants who have consented to the study will additionally receive a contraception discussion tracking form, that will be color coded and labelled for each month of the study to indicate whether the participant has been randomized to the control group or the experimental group. As well as instructions on how to enroll in the MOC program. The referral form will have an email address at the bottom that the participant should use to return in their contraception discussion tracking forms. The tracking form will have the participant for each day record the number of patients under 18 who they discussed contraception with, the number who chose the implant, the number who chose another reliable contraceptive method, and number who chose no option. There will also be a place for the provider to record any reflections or questions they have. Each weekparticipants will receive an email reminding them to enter the information from the tracking form into the MOC portal. They will receive a survey on months 2,4, and 6via red cap asking them about practice changes and challenges experienced while trying to implement increased counseling. For participants in the experimental group their tip sheet has an email address they can use to access coaching. Additionally, this email will be included in all communication reminding them to enter their tracking form information into the MOC portal. Coaching is at will and is initiated by sending an email with a non-emergent question that will be answered within two business days. If the principal investigator is on vacation or unavailable, then the participant will be notified that coaching is not available and that they should proceed as they typically would without coaching. Questions will be categorized as to whether they are related to: indication, procedure question, post-placement bruising, post-placement breakthrough bleeding, post-placement weight gain, other post-placement side effect. These categories were selected based on data from Phase 1 questionnaire that showed these are areas that providers are less knowledgeable in addressing.

To assure the principal investigator remains blind to which participants are in the control vs experimental group several precautions will be taken. The principal investigator will not be involved in the check-in process of the educational program. Additionally, during data collection the tracking information will be routed to the study coordinator. Additionally, any questions initiated through coaching will route to an email that only the study coordinator has access to. The study coordinator will route the email to the PI without any identifying information. The investigator will return the email to the study coordinator with an answer, who will return the answer to the participant. This ensures the investigator will remain blind to which group the participants are in.

Over the course of 6 months the number of contraceptive discussions, number of patients who chose the implant, another reliable method, and no method will be tabulated for the experimental and control groups. Additionally individual providers trends over time for each of these variables will be analyzed for each group.

At the conclusion of the data collection period, five participants from each group will be selected at random to participate in a focus group. This focus group will last 1 hour. It will be audio recorded and analyzed to elicit narrative on barriers to counseling, referring, and managing patients with etonogestrel implant. Focus group participants will be compensated with a $100 gift card for their time.