Patient-Reported Outcomes of Contraceptive Services Rendered by Community Pharmacists Using the Pharmacist Resource to Implement Services as Modules Platform: The PRISM-CS Study

6/20/2024

Informed Consent Form for OvaryIt LLC- English

This informed consent form is for patients invited to participate in the study: Patients Obtaining Hormonal Contraception by Pharmacists.

Part I: Information Sheet

Introduction

OvaryIt, a Florida-based LLC, has developed a proprietary contraceptive-specific EHR (Electronic Health Record) to provide affordable and convenient direct-to-consumer contraceptive and family planning telehealth services. The EHR was built to leverage the platform's efficiency to provide contraceptive services at affordable rates to self-pay patients, thereby increasing access to care for uninsured and underinsured women. Additionally, the platform was designed to improve patient safety by utilizing a rules-based engine and incorporating clinical decision support tools to assist providers in selecting the most appropriate contraceptive options for each patient. In previous studies, the application's safeguards increase patient safety by 40%. For this study, the OvaryIt team will utilize their proven platform in the pharmacy setting to allow for pharmacists to prescribe contraceptives.

Purpose of the research

Adapting the OvaryIt platform to integrate into the existing pharmacy setting could significantly increase pharmacist-prescribed contraceptive services and increase access to contraceptive care in the United States (US). Because 90% of the population lives within 5 miles of a pharmacy, pharmacists prescribing contraception could assist millions of individuals in obtaining access to care.

Type of Research Intervention

This research will utilize a multi-phase approach to obtain surveys, feedback, and concerns of patients wishing to obtain contraception consultations within a pharmacy setting. The Pilot Program will fund a contraception consultation with a pharmacist for 125 patients across 5 US pharmacies. Each enrolled patient will have an in-person contraception consultation at one of the participating pharmacies. The consultation will include contraceptive counseling, and if deemed appropriate by the pharmacist, may result in a prescription of an FDA-approved contraceptive medication. Following the consultation, the participating patients will be provided with two surveys. The first survey will be available immediately following the consultation and will contain questions regarding the quality of the consultation experience, attitudes towards pharmacist contraceptive services, and patient satisfaction. The second survey will be provided about 90-days after the consultation and will include questions about health outcomes, contraceptive satisfaction, and attitudes toward pharmacist contraceptive services. Enrolled patients will receive gift cards of $25 for each completed survey. The study will last approximately 97 days and will conclude after the submission of the second survey.

Participant Selection

You are invited to participate in this research study because patient feedback and understanding the patient's perspective are critical in discovering new approaches to increase access to quality contraceptive services. We believe that you can contribute to our understanding of these factors. Our goal is to recruit a diverse group of patients to join the study to make sure that the feedback is

inclusive of as many unique lived experiences as possible. To qualify for the study, you must be over 18 years old, be of reproductive age (have not yet had menopause), have a uterus, have the legal capacity to make your own informed decisions, want to join the study without being forced by another person, and speak enough English to be able to accurately fill out the forms and communicate with a participating pharmacist.

Voluntary Participation
Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you feel that someone is forcing you to participate, please notify a member of the study team.

Procedures
There will be about 125 participants in this study

You have the right to ask any questions to the participating pharmacy staff and/or a study team member and have the right to decide not to participate or withdraw from the study at any point without penalty. After you have consented to study participation and treatment, you will complete the pre-evaluation screening questionnaire and demographic surveys. After the completion of these surveys, you will be scheduled to receive in-person contraceptive services from one of the participating pharmacists free of charge. Your care will be focused on contraception and will not include non-contraceptive medical care. You will then be given a prescription for a contraceptive, family planning counseling, and/or a referral to another provider.

Following this, you will be asked to complete a quality of care and satisfaction survey. 90 days after the surveys, you will be asked to complete another survey designed to collect outcome data including contraception consistency rates, failures, side effects, and satisfaction with the contraceptive option you were given. You will be compensated with $25 gift cards after completion of each of the surveys.

If you have any medical questions following your participation, please contact the participating pharmacy where you received the contraceptive service. If you have any side effects from the prescribed contraceptive or experience any health concerns, please report them to the pharmacy where you received the care or to a member of the study team by calling (850) 608-0090. A member of the study team will reply within 48 hours if they are immediately unavailable. If you experience any potentially life-threatening or urgent medical issues, please call 911 or contact your local healthcare provider. After you are safe, please notify the pharmacy where you received the care or a member of the study team to let them know about the event.

Duration
This study will last approximately 90-97 days or approximately 3 months per patient.

Risks
The topic of contraception can be contentious in the current political atmosphere. There is a risk that you may choose to share some personal or confidential information or that you may feel uncomfortable talking about some of the topics. We will follow all medical and research regulations and cybersecurity best practices to help protect your health and demographic information, however, there is always a small risk to loss of confidentiality. We will never intentionally publish information

in a way that allows you to be identified as a participant in the study. We will never sell your data to third-party companies for marketing purposes.

All prescription contraceptives used in this study are FDA-approved for pregnancy prevention and have a long history of efficacy and safety outcomes reported in the US. It is important to know that contraceptives can lead to adverse events and side effects. Adverse events include any symptom, sign, illness, or experience that develops or worsens in severity during the course of the study. The types of adverse events change based on the contraceptive prescribed by the pharmacist. The FDA package insert for the medication prescribed to you will have information specific to that contraceptive including associated risks. You will have the chance to report any minor adverse events in the 90-day survey and any severe adverse events throughout the study.

Benefits

You may not have any direct benefit from participating in this study. Participating in this study will help the research team advance the literature regarding novel ways to implement contraceptive services in pharmacies which could increase access to contraceptive services and reduce the unplanned pregnancy rate in the US.

Reimbursement

You will be provided with a free contraceptive consultation and will receive a $25.00 gift card for each survey you complete after your consultation. If you complete both surveys, you will be reimbursed a total of $50.00. There is no additional cost to participants.

Confidentiality

We will not share your protected health information with anyone outside the participating pharmacy, direct research team, or Business Associate Agreement-covered third-party entities without your direct consent in compliance with HIPAA regulations unless we are legally required to do so. An example of a scenario where protected health information may be shared with your consent includes a referral to an outside provider for additional medical services. Your information will be stored in a medical database that is encrypted at rest and at transit, just like a database used in a traditional doctor's office.

The information that is collected from this research project will be stored in a de-identified manner that will not be able to be traced back to you. We will likely publish our findings including compiled demographic information about the study participants and collected outcomes data, but information that could lead someone to identify you personally will not be made publicly available.

HIPAA Authorization

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

<u>This is the information we will use and include in our research records</u>:

- Demographic and identifying information like: name, address, telephone number, and email address

- Related medical information about you like: allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure reading, heart rate, temperature, and lab results
- All tests and procedures that will be done in the study

How we will protect and share your information:

We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:

Members of the research team and University of Utah Health Sciences Center;

The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights;

The study sponsor: OvaryIt;

The National Institute of Health (NIH)

If we share your identifying information with groups outside of University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health Sciences Center.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

Sharing the Results

Nothing that you tell us will be attributed to you by name in any publication that results from the studies. Any published data will be de-identified and not be able to be traced back to you. It is your right to share with others that you were part of the study, but the research team will never disclose that information to any party unless legally mandated.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so. You may stop participating at any time. You may refuse to participate or discontinue participation without penalty or loss of benefits.

Whom to Contact
If you have questions about enrolling in the study or any questions or concerns during the study, please call (850) 608-0090 to reach a member of the study team who can assist you. You can also reach the study team by email using the information below. If you choose to email the study team, please do not include any protected health information in the email.

If you have questions, complaints or concerns about this study, you can also contact Dr. Rebecca Simmons at (801)-581-6170 Monday-Friday 9:00am to 5:00pm.

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.
Mary Kucek, PMP and Devin Bustin, MD are the Principal Investigators for OvaryIt, LLC:
marykucek@ovaryit.com; devinbustin@ovaryit.com

Part II: Certificate of Consent

I have been invited to participate in research about pharmacists prescribing hormonal contraceptives in the pharmacy setting.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions, and if asked, they have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

You will receive a signed copy of the consent document.

Print Name of Participant: _____

Signature of Participant: _____

Date: _____

Print Name of Person Consenting: _-

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Signature of Person Consenting:

_____

Date: _____