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OVER-THE-COUNTER APPROVAL OF PROGESTIN-ONLY PILLS

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Mentor: Dr. Whitney Calkins
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Oral contraceptives are one of the most frequently used contraceptive options, especially among younger people who can get pregnant.

There can be many barriers to accessing contraceptive care. These barriers include, but are not limited to, cost, insurance, communication, policy, transportation, and access to healthcare.

In July 2023, the FDA approved OPill, a progestin-only pill (POP), for non-prescription use. However, progestin-only pills have a short half-life and need to be taken at the same time each day for maximal efficacy.\(^1\)\(^2\)

Description of need:

There is a need for education surrounding non-prescription POPs to help people of childbearing age decide whether this is the right contraception option for them and to optimize prevention of pregnancy with this method.

AHEC Focus Areas:

- Social Determinants of Health
- Current and Emerging Health Issues
SLIDE 3: PUBLIC HEALTH COSTS

- As of 2019, 65.3% of women of child-bearing age (15-49) in the United States were currently using contraception. The most common reversible contraceptive method is the oral contraceptive pill (14.0%).

- The oral contraceptive pill usage is most popular in younger women. 19.5% of women ages 15-19 and 21.6% of women ages 20-29 reported using oral contraceptive pills during the 2017-2019.

- The population that consistently uses contraception makes up 5% of unintended pregnancies in the United States. Meanwhile, 95% of unintended pregnancies are due to lack or inconsistent use of contraception.

- In 19 states, minors must meet certain criteria or obtain parental permission to receive access to contraceptive care.

- As of 2016, one-third of women in the United States who tried to obtain or fill a contraception prescription reported a barrier to access.

- The total cost of unintended pregnancies in Vermont in 2010 was $31.4 million between the federal and state governments. The cost nationwide in the same year was $21.0 billion.
SLIDE 4: COMMUNITY PERSPECTIVE

Social Work Case Manager for Labor and Delivery and Mother-Baby Units at UVMMC

• “[Over the counter approval of contraceptive pills] can remove a lot of the barriers, such as transportation barriers, getting to doctor's appointments, and other things that some folks struggle with. Especially if you have a big family, maybe you're not prioritizing your own appointments and your own health. Picking something up from the pharmacy seems a lot easier than setting up an appointment.”

• “A good amount of women have trauma related to either OB/GYN care or their bodies in general. So, it’s a less invasive way to access contraception rather than having to go into the doctor's office, [which some] people get anxious about. It's nice to be able to remove that if that's a barrier for folks too.”

Health & Sexuality Educator at the University of Vermont

• In the college population, both shame and surveillance (via parentally-controlled insurance) are two major barriers to contraceptive care that will be lessened by the availability of OPill.

• “Just because this type of birth control method has been approved for over the counter, it does not mean that it's the right birth control method for everyone. I worry that people will default to it for its convenience … but then will have to deal with side effects they don't want to experience or that are really negative and [they feel like they] don't have another option. I want to make sure that this is shown as one option, not the only option.”
SLIDE 5: INTERVENTION & METHODOLOGY

- **Background:** People who can get pregnant in the age range of 15-29 are the most likely to use oral contraceptive pills. Sexual health materials in the format of small booklet, colloquially known as a zine (meaning mini magazine), have been previously successful in disseminating important health information to students at the University of Vermont. This is an 8.5”x11” sheet of paper that is folded into an eight-page booklet.

- **Intervention:** A zine has been created to share important information about OPPill. This booklet includes information targeted to a college-aged audience with information about OPPill, side effects, other options, and how to most effectively take a POP to prevent pregnancy.

- **Methodology:** These materials will be distributed to students by the sexual health educator at the University of Vermont and will be available in the sexual health zine library. It will also be available for virtual download.
To evaluate the effectiveness of this intervention, a survey would be implemented to assess understanding of the over-the-counter progestin-only pill and confidence in decision making around contraception.

**Study Design:**

- Each group would first receive a pre-survey on their knowledge of progestin-only pills and their confidence in deciding whether to use this birth control method.
- The intervention group would then receive the intervention (the zine) and the brand’s box information on OPill. The placebo group would only receive the box information.
- Participants would then take a post-survey describing their knowledge and confidence in decision making.
SLIDE 7: EVALUATION OF EFFECTIVENESS & LIMITATIONS

- Due to the limited time frame of this project, the study design was not yet implemented to evaluate the effectiveness of the intervention.

- While this project is intended to reach the college population at the University of Vermont, there are other groups who would also benefit from information on the non-prescription progestin-only pill.

- OPill is currently scheduled to become available on pharmacy shelves in early 2024, so distribution of the zines will likely be delayed.

- The statistics and costs available and reported in this presentation about contraception and unwanted pregnancy on a state and federal level refer to cisgender women. This may leave out important information about usage of contraception by non-binary and transgender people who can get pregnant.
Creation and distribution of zines for other pertinent sexual health topics, such as:
• Obtaining prescriptions for combined oral contraceptive pills from pharmacists, which is legal in Vermont and 21 other states
• Other types of birth control options, including long-acting reversible contraceptives
• PrEP (pill and injectable options)
• HPV vaccine

Extension of this or similar projects to other communities who will be affected, such as:
• Local high schools
• Other Vermont colleges

As O Pill will not be available on pharmacy shelves until early 2024, and the price has not yet been set, there may be further barriers to access or other downstream effects that are not yet readily apparent and will be an important point of future study.


