**(insert AGENCY name)**

Reproductive Health Program

Clinical Practice Standard

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| **Subject:** Vaginal Spermicides and pH Modulators | | **No.** |
| **Approved by:** |  | **Effective Date:** |
| **Revised Date:** January 2018, January 2019, January 2021, **October 2022** | | |
| **References:** U.S. Medical Eligibility Criteria (U.S. MEC), 2016; U.S. Selected Practice Recommendations for Contraceptive Use (U.S. SPR), 2016; Contraceptive Technology, 20th Ed | | |

**POLICY:** This Clinical Practice Standard follows the recommendations of the U.S. MEC, 2016; U.S. SPR, 2016; and Contraceptive Technology, 20th Ed.

**PURPOSE:** This Clinical Practice Standard provides direction for reproductive health clinics to assist clients in their use of vaginal spermicides and pH modulators.

Spermicides prevent fertilization by interfering with the sperm transport by mechanically blocking or killing sperm. Spermicidal preparations consist of two components: 1) a formulation (gel, foam, cream, film, suppository, or tablet), also called a carrier or base; and 2) a chemical that kills sperm in different doses and concentrations. The active chemical agent in spermicidal products in the U.S. is nonoxynol-9 (N-9). This surfactant works by destroying the sperm cell membrane.

Spermicides are available without a prescription.

The first vaginal pH modulator (Phexxi®) was approved by the FDA for contraception in 2020. It is not considered a spermicide, but it is used in a similar way. This product works by maintaining a low vaginal pH even in the presence of semen, thus lowering sperm motility. The active ingredients are lactic acid, citric acid, and potassium bitartrate, which are suspended in a bioadhesive, viscous gel base.

Phexxi® is available by prescription only.

Spermicides are some of the least effective contraceptive methods; in typical use, 28 out of 100 people who use them experience an unintended pregnancy within the first year of use. With typical use of vaginal pH modulators, 14 out of 100 people experience an unintended pregnancy within the first year of use.

Spermicides do not protect against sexually transmitted infections (STIs). Vaginal pH modulators are also not approved for the prevention of STIs; however, there is promising data showing significant reduction of urogenital chlamydia and gonorrhea acquisition in patients at high risk for STIs, and Phexxi® has been granted Fast Track Designation by the FDA for this new indication.

**STANDARD:**

1. (**insert AGENCY name**) MDs, NPs, PAs, DOs, and NDs may provide/prescribe spermicide and/or vaginal pH modulators to any client who requests this method and has no U.S. MEC category 4 risk conditions.
2. (**insert AGENCY name**) RNs may dispense spermicide and/or vaginal pH modulators to any client who requests this method and has no U.S. MEC category 3 or 4 risk conditions.

**PROCEDURE:**

1. Follow the [*Core Reproductive Health Services* *CPS*.](https://www.oregon.gov/oha/PH/HEALTHYPEOPLEFAMILIES/REPRODUCTIVESEXUALHEALTH/RESOURCES/Documents/Clinical-Practice-Standards/CPS-Core_RH.docx)
2. Follow the [U.S. MEC](https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/appendixk.html) to determine client eligibility for use of spermicides. (Currently, vaginal pH modulators are not addressed by the U.S. MEC. The prescribing information advises against using Phexxi® in clients with history of recurrent UTIs or urinary tract abnormalities):
3. RNs may initiate the client’s contraceptive method of choice as long as the client has no U.S. MEC category 3 or 4 risk conditions for its use.
4. If client has any MEC category 3 conditions, an NP, PA, DO, ND or MD *may* prescribe the method according to their clinical judgement, if requested by the client. Documentation must show that the client understands the risks of the method and finds other, lower-risk methods unacceptable. RNs may not dispense the method unless under explicit verbal order after discussing the client's case with the prescribing provider.
5. Clients requesting a method for which they have a category 4 risk condition will be offered lower risk methods and referred to an OB/GYN or specialist provider.
6. Each client will receive client instructions regarding warning signs, common side effects, risks, method of use, alternative methods, use of secondary method, and clinic follow-up schedule. Document client education and understanding of the method of choice.

**PLAN:**

1. Spermicides and vaginal pH modulators may be initiated at any time.
2. Spermicidal gels, creams, and foam are commonly marketed for use with a diaphragm but may be used alone for contraception.

* Different concentrations of N-9 are available depending on the product.

1. Spermicidal suppositories can be used alone or with a condom.

* Adequate time between insertion and intercourse (10-15 minutes) is essential for the spermicide to dissolve and disperse.

1. Spermicidal film can be used alone or with condoms, diaphragms or cervical caps.

* The sheet must be inserted on or near the cervix at least 15 minutes before intercourse for the sheet to melt and disperse.
* Placing the film on top of the penis is not recommended as the film will not have adequate time to dissolve or may not be placed against the cervical os properly.

1. Contraceptive sponge is a single-use vaginal spermicide.

* Its concave shape is designed to fit over the cervix, and this decreases the chance of displacement during intercourse.
* It is moistened with tap water prior to use and inserted deep into the vagina.
* The sponge protects up to 24 hours, no matter how many times intercourse occurs.
* After intercourse, the sponge must be left in for 6 hours before it is removed.
* It is not recommended to be left in longer than 24 to 30 hours because of the rare risk of Toxic Shock Syndrome.

1. Vaginal pH modulators may be used alone or in conjunction with any other method of contraception except vaginal rings.

* Phexxi® gel comes in single-use applicators for vaginal insertion. The gel can be inserted immediately before or up to 1 hour prior to intercourse. If more than one hour passes, a new applicator should be inserted. If a person has intercourse more than once in an hour, another applicator should be used before each episode of intercourse.

1. Provide client with a supply of spermicides or vaginal pH modulators.

**ROUTINE FOLLOW-UP:**

1. The recommendations listed below address when routine follow-up is recommended for safe and effective continued use of contraception for healthy clients. Although routine follow-up is not necessary for the use of spermicides, recommendations might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple conditions may benefit from more frequent follow-up visits.
2. Advise a client to return at any time to discuss side effects or other problems, or if the client wants to change the method being used.
3. At other routine visits, healthcare providers should do the following:

* Assess the client’s satisfaction with the contraceptive method and whether the client has any concerns about method use; and
* Assess any changes in health status, including medications that would change the appropriateness of using spermicides for safe and effective continued use on the basis of the U.S. MEC.

Managing Problems:

* + - 1. Recurrent vaginal or vulvar irritation are common side effects of spermicides and vaginal pH modulators but may indicate an allergy or sensitivity to the product; providers may suggest client try another product or contraceptive method.

1. If symptom(s) persist after discontinuing method reevaluate for other etiology (e.g. STI exposure, yeast vaginitis, or bacterial vaginosis).
   * + 1. Counsel client that urinary tract infections may occur, especially when using spermicides 2 or more times a day.

**CLIENT EDUCATION:**

1. Advise client to call clinic if they have any questions or concerns regarding their contraceptive method.
2. Advise client that spermicides and vaginal pH modulators must be used every time vaginal intercourse occurs.
3. Counsel the client that using more than 3 applications of N-9 spermicides per day increases the risk of HIV compared to placebo**.**
4. Inform clients who are using the contraceptive sponge of the signs and symptoms of Toxic Shock Syndrome (clients should be informed to seek immediate care if any warning signs are noted):
5. Sudden high fever;
6. Chills;
7. Vomiting;
8. Diarrhea;
9. Muscle aches;
10. Sunburn-like rash.

**REFERENCES:**

Cates, W. & Harwood, B. 2011. Vaginal Barriers and Spermicides, In Deborah Kowal (Ed) *Contraceptive Technology*, 20th Ed. Pg 391-407. Ardent Media: Atlanta, GA

Centers for Disease Control and Prevention. 2016. U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf>

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Prescribing Information for Phexxi, July 2022. <https://22077562.fs1.hubspotusercontent-na1.net/hubfs/22077562/Phexxi_July2022/PDFs/PhexxiUSPI.pdf>