

UCLA

UCLA Previously Published Works

Title

Seeking the female (internal) condom in retail pharmacies: Experiences of adolescent mystery callers

Permalink

<https://escholarship.org/uc/item/7220c6w4>

Journal

Contraception, 101(2)

ISSN

0010-7824

Authors

Hsu, Ruth

Tavrow, Paula

Uysal, Jasmine

et al.

Publication Date

2020-02-01

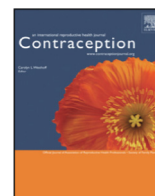
DOI

10.1016/j.contraception.2019.10.006

Copyright Information

This work is made available under the terms of a Creative Commons Attribution License, available at <https://creativecommons.org/licenses/by/4.0/>

Peer reviewed



Seeking the female (internal) condom in retail pharmacies: Experiences of adolescent mystery callers^{☆,☆☆}



Ruth Hsu^{1,*}, Paula Tavrow, Jasmine Uysal², Amy E. Alterman

Department of Community Health Sciences, Fielding School of Public Health, University of California at Los Angeles, 650 Charles E. Young Dr. S., Los Angeles, CA 90095, United States

ARTICLE INFO

Article history:

Received 11 August 2019

Received in revised form 17 October 2019

Accepted 17 October 2019

Keywords:

Female condoms
Internal condoms
Adolescents
Pharmacy
Contraception

ABSTRACT

Background: Female (internal) condoms could be viable alternatives to male (external) condoms. Our objective was to describe barriers that adolescent mystery callers encountered when trying to access female condoms in U.S. pharmacies.

Methods: In mid-2016, university students seeking “condoms for girls” called retail pharmacies in Arizona, California, New Mexico and Utah. We evaluated differences in product availability and callers’ experiences by pharmacy type.

Results: Of our final sample ($n=1475$), only eight outlets (0.5%), all national chains, definitely stocked female condoms. Of those not (or probably not) stocking female condoms, 11% tried to be helpful (e.g., offered to special order), 59% made no substantive comment, and 30% were unhelpful (e.g., dismissive, rude, gave wrong information). National chain employees were significantly more unhelpful (34% vs 22%, $p < .01$).

Conclusion: Almost no pharmacies in four southwestern states stocked female condoms in mid-2016. Pharmacy staff frequently were unhelpful, which could deter adolescent use of female condoms even if new types become available.

© 2019 Elsevier Inc. All rights reserved.

1. Introduction

Condoms are the only form of birth control that simultaneously protect against sexually-transmitted infections and unintended pregnancies. However, less than half of adolescents in the U.S. used a condom the last time they had sex [1–3]. Some barriers to using male (external) condoms – such as loss of pleasure, inconvenience,

and partner opposition – are mitigated with the female condom [4], which is also called an internal or universal condom because it can be used in male-to-male sexual activity.^a The sole FDA-approved female condom (FC2 Internal Condom)^b consists of an enclosed nitrile pouch held together by two rings, which women insert through the vagina up to the cervix. Female condoms have a 95% effectiveness rate in preventing pregnancy when used correctly, and are 75–82% effective in normal use [4–8].

Although female condoms could be a viable alternative to male condoms, adolescent uptake in North America remains low. High cost, low availability and awareness, and provider bias have prevented female condoms from gaining popularity. A fall 2014 survey of 1128 outlets in Philadelphia found that only 1% carried female condoms, whereas 77% sold male condoms [9]. Another study found that many healthcare providers had little knowledge and did not recommend female condoms because they believed their patients would not like them [10].

Yet studies indicate that with appropriate instruction and promotion, female condoms could be highly acceptable among adolescents, women, and heterosexual couples [4,11–16]. For example,

[☆] Declaration of Competing Interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

^{☆☆} Funding: This study was funded by the Bixby Center on Population and Reproductive Health at the University of California, Los Angeles (UCLA).

* Corresponding author.

E-mail address: ruthrhu@ucla.edu (R. Hsu).

¹ Present Address: Mathematica Policy Research, 955 Massachusetts Avenue, Cambridge, MA 02139, United States.

² Present Address: Center on Gender Equity and Health, University of California, San Diego, Department of Medicine, Division of Global Public Health & Infectious Disease, UC San Diego Central Research Services Facility, La Jolla, CA 92093, United States.

^a Because this paper focused on heterosexual adolescent sex, we have adopted the nomenclature of “female condoms.” However, the gender-neutral “internal condoms” is becoming more common because these devices also offer protection for men who have sex with men. See: <https://www.bedsider.org/methods/internal-condom>. Accessed June 14, 2019.

^b By prescription or direct order through FC2 website: <https://www.FC2.us.com>. Accessed June 14, 2019.

one study found that after adolescent heterosexual girls participated in a sexual health workshop that discussed female condoms, half of the participants tried the product for one month. Eighty-five percent of those who tried it said they would continue using female condoms [12]. Another study found that adolescent girls liked the dual protection and lack of hormonal side effects [13].

For this study, we wanted to assess female condom availability by pharmacy type in southwestern states and describe heterosexual adolescent experiences when inquiring about female condoms, after first asking if there were any products to prevent a pregnancy after unprotected sex. This approach allowed us to document real barriers that young people face when phoning retail outlets.

2. Methods

2.1. Study design

We used a mystery-caller approach to evaluate young people's experiences in obtaining information about pregnancy prevention and female condoms from retail pharmacy outlets in four southwestern states: Arizona, California, New Mexico, and Utah. To generate a sample of pharmacies, we systematically selected every third zip code for each state. Then we entered each zip code with the word "pharmacy" into Google search engine to approximate how youths would identify nearby pharmacies. This produced pages of pharmacy listings, of which the callers would phone the first six non-duplicative numbers [17].

From March to April 2016, we recruited 15 university students (5 male and 10 female) to pose as 16-year-olds seeking to avoid a pregnancy and learn about female condoms. The students only gave their age if asked. We created a structured script to guide their calls (Fig. 1). Immediately afterwards, callers filled out a Google form and recorded verbatim any comments made. All quantitative and qualitative data were later uploaded from Excel to SPSS for coding and analysis. We instructed callers to hang up if pharmacies put them on hold for more than five minutes, and to call back if they experienced what seemed to be an accidental hang-up.

Callers began by explaining that they had unprotected sex and asking how to avoid a pregnancy. If the pharmacist told them about emergency contraception, the caller asked additional questions (results reported elsewhere) [17]. Next, callers inquired if the pharmacy carried any "condoms for girls," which is how some

heterosexual teens refer to female condoms [18,19]. We calculated female condom availability based on whether pharmacies affirmed they had female condoms and answered subsequent questions (e.g., cost, location).

From mid-April to mid-June 2016, mystery callers phoned 1707 pharmacy listings. After removing duplicate calls, wholesale outlets, and out-of-service numbers, our final sample consisted of 1475 pharmacies. We classified the pharmacies as national chains (e.g. Rite-Aid, Walgreens) and individual retailers (which also included a few regional outlets). Male students called 52% of the pharmacies and female students called 48%, with no difference by pharmacy type.

2.2. Analysis

We analyzed the data using SPSS version 24. For pharmacies not stocking female condoms, two of us (who were blinded to pharmacy type and caller gender) coded pharmacy staff responses into three categories: (1) helpful, (2) made no substantive comment, or (3) unhelpful. We considered pharmacy staff "helpful" if they gave specific suggestions on where to obtain female condoms or made positive comments. We categorized calls as "no substantive comment" if staff simply stated that the product was not in stock or gave non-specific suggestions. We classified staff as "unhelpful" if they were rude, negative about the product, not knowledgeable, or not willing to check their stock. Any discrepancies between coders were resolved through discussion. We analyzed differences using the Chi-square statistic.

This study was granted an exemption from the UCLA Institutional Review Board.

3. Results

3.1. Availability of female condoms

Of our sample, 983 were national chains and 492 were regional/individual pharmacies. Only eight (0.5%) pharmacies, all national chains, carried female condoms at the time of the call, as verified through follow-up questions (Table 1). In another 7.6% of the outlets, we could not determine if the product was available, because the staff would not check on product availability or price (5.6%),

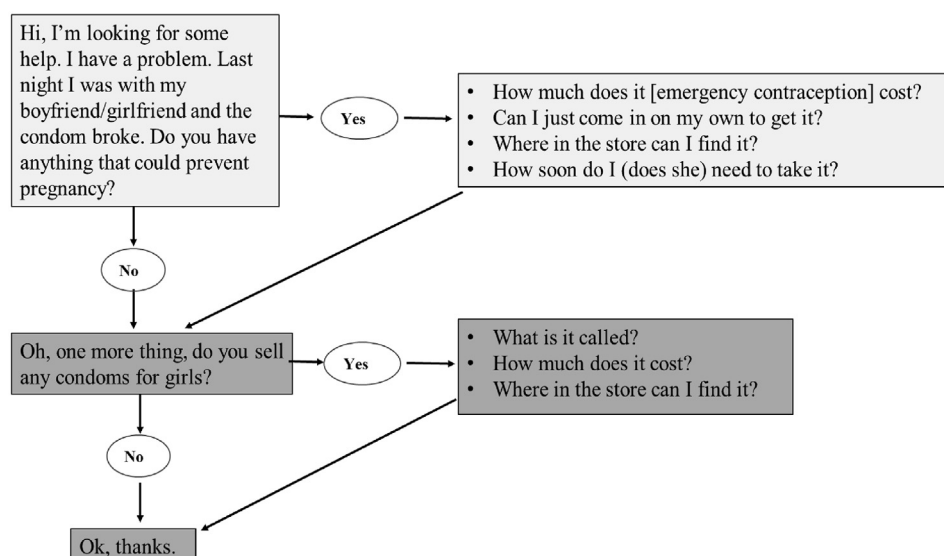


Fig. 1. Script flowchart for adolescent mystery caller.

Table 1

Female (internal) condom availability in pharmacies in four southwestern states and adolescent mystery caller experiences, by pharmacy type, April–June 2016.

	National Chain N %	Regional or Individual N %	Total N %
Yes, in stock	8 (0.8%)	0 (0.0%)	8 (0.5%)
Indeterminable ¹ , staff were unhelpful to caller	99 (10.1%)	12 (2.4%)	111 (7.5%)
Not in stock, but staff tried to be helpful to caller	109 (11.1%)	54 (11.0%)	163 (11.1%)
Not in stock, staff made no substantive comment ²	535 (54.4%)	329 (66.9%)	864 (58.6%)
Not in stock, staff were unhelpful to caller	232 (23.6%)	97 (19.7%)	329 (22.3%)
TOTAL	983 (100.0%)	492 (100.0%)	1475 (100.0%)

¹Could not determine availability because staff refused to check or hung up on caller.²Staff simply stated that female condoms were not in stock and/or suggested the caller try elsewhere, without being rude or giving any specific information.**Table 2**

How pharmacy staff were unhelpful to adolescent mystery callers seeking female (internal) condoms, by pharmacy type, April–June 2016.

Pharmacists were unhelpful if they...	National Chain (n = 983)	Regional or Individual (n = 492)	Total (N = 1475)
Refused to check on product availability or price	75 (7.6%)	6 (1.2%)	81 (5.5%)
Were rude to caller (e.g., dismissive, insulting, hung up)	101 (10.2%)	51 (10.3%)	152 (10.3%)
Initially said they had female condoms, but after checking stock realized they had none or the wrong product	62 (6.3%)	10 (2.0%)	72 (4.9%)
Said they had never heard of female condoms	39 (4.0%)	14 (2.8%)	53 (3.6%)
Were negative about female condoms (e.g., recommended against it)	54 (5.5%)	29 (5.8%)	83 (5.6%)
TOTAL unhelpful	331 (33.6%*)	110 (22.1%)	441 (29.9%)

*Different from other outlets, $p < 0.01$.

hung up on callers, or placed them on indefinite hold (2.0%). Hence, up to 8% of the outlets may have stocked female condoms.

3.2. Caller experience

We also assessed caller experience in trying to obtain female condoms. We found that about 11% of staff were helpful, 59% made no substantive comment, and 30% were unhelpful and/or negative. Caller experience differed by pharmacy type (Table 2). After controlling for pharmacy type, no difference in caller experience was found by gender of the caller or gender of the pharmacist. However, pharmacy personnel were less helpful during weekends and in the afternoons, probably because they were busier then.

3.2.1. Helpful or neutral

Being helpful to the caller occurred infrequently. An example of a helpful comment was: *“Female condoms sound like a great thing. We don’t carry it, but we’ll see how we can probably stock some.”* We also considered pharmacy staff helpful if they offered to do a special order, suggested other contraceptive products, and did not disparage the female condom when making their recommendations. In addition, we labelled suggestions with specificity as helpful, such as: *“We don’t carry them, but Planned Parenthood might have them for free.”* These contrasted with no substantive comment, where pharmacist merely told callers the product was unavailable or suggested to check a national chain.

3.2.2. Unhelpful and/or negative

We characterized experiences as “unhelpful and/or negative” when callers encountered pharmacy personnel who were dismissive, refused to check on the product or price, gave inaccurate information, laughed at the caller, or were negative about the product. As shown in Table 2, pharmacy staff at national chains were significantly more likely to be unhelpful than those in regional/individual pharmacies (33.6% vs. 22.1%, $p < 0.01$).

In one out of ten outlets overall, callers reported that the pharmacy staff were rude or dismissive. In some cases, pharmacy staff put the caller on hold for an extended period, hung up on them, or required them to speak with multiple people. In other exchanges, pharmacy staff expressed annoyance, rushed the caller, were unwilling to provide any specific information, or gave inaccurate information. For example, one caller reported that the pharmacy staff refused to give any specifics about female condoms in the store, declaring: *“There are a lot of brands and they all have different prices.”* This was impossible as the FDA had approved only one brand. Another caller reported that the pharmacy staff was very impatient and *“tried to end the call several times.”*

We labelled staff as unhelpful if they claimed they had female condoms, but refused to check their stock when asked about brand and price. Other staff gave vague answers when asked about female condom availability or price, telling the caller just to come to the store. We considered these encounters unhelpful because for young people with limited funds, their time and effort would have been futile if they reached a store only to find the product was unavailable or unaffordable.

We also considered pharmacy staff unhelpful if they initially stated they had female condoms, but when probed for brand or price, they checked and found they did not stock it. Since many young people might feel too embarrassed to ask further questions, they would be inconvenienced if they acted upon the pharmacy staff’s initial response that female condoms were in stock.

[I was] transferred to customer service from Pharmacy. At first he said yes, but it turned out that he was telling me about sponges. . . I had to describe that it works the same way as the male condom, but for girls. Second time, he checked and realized they do not carry it.

While some pharmacy staff corrected their initial answer and clarified they actually did not carry female condoms, others insisted that their products were female condoms or near enough.

These products included spermicide, vaginal films, or creams (e.g. Encare, VCF, and Vagisil). For example, one pharmacy staff said, *“Actually, we have spermicide. Yeah, I would count that as a female condom.”* In some calls, pharmacy staff clearly had mistaken the female condom for another product, mainly a diaphragm. These staff told callers they needed a doctor’s appointment to get the female condom fitted and prescribed. A few pharmacy staff had never heard of female condoms. Callers reported that this led to awkward encounters that might humiliate an adolescent. As one caller recorded: *“She asked me, ‘Is this a joke?’”* Another noted: *“[The] pharmacist did not know what it was ... said he never heard of it and even laughed.”*

Lastly, some staff voiced a negative opinion about female condoms, such as that the female condom was inherently inferior to the male condom or had other (inaccurate) unappealing features. For instance, one pharmacist said: *“I don’t recommend it. It may get dislodged in the vaginal area.”* Others said that they *“slip a lot,”* are *“not nearly as effective as regular condoms,”* or *“have a short shelf life.”* This misinformation sometimes was used to explain why the female condom was unavailable.

All told, the study revealed a substantial amount of confusion, misinformation, and negativity from pharmacy staff when a young person asked whether their outlet stocked “condoms for girls.”

4. Discussion

4.1. Availability

Our study’s main finding was that female condoms were unavailable in almost all retail pharmacy outlets in the four southwestern states in mid-2016. Despite the female condom being promoted as an alternative to the male condom, our findings were similar to Cavanaugh’s in Philadelphia [9]. Until female condoms are in wider supply, promoting the product – as is often done in comprehensive sex education programs – will have little effect. Even though pilot programs to introduce female condoms have been relatively successful in some countries, a persistent myth is that the product is not an acceptable barrier method [20]. The result is a vicious cycle in which retailers do not stock female condoms, providers do not recommend them, and clients are unaware of them and therefore do not demand them [8]. The current use of female condoms by U.S. women is less than 0.2% [21].

In 2017, after our study was conducted, Veru, the U.S. manufacturer of the only FDA-approved product, discontinued retail distribution in favor of making the product available through prescription or direct purchase on their website. The stated reason was to reduce the price to consumers [22–24]. The female condom at retail is about double the price of a male condom (0.70) [25]. But unless FC2 is well-advertised, healthcare providers are unlikely to suggest the product and adolescents would not know to request a prescription. Compounding this knowledge gap is the lack of information about female condoms on health-related websites. For instance, one study found that only 60% of U.S. municipal health department websites mentioned the female condom as an effective barrier method, and many of those contained numerous inaccuracies about the product [26].

4.2. Unhelpfulness of pharmacy staff

Our other main finding was that retail pharmacy staff’s knowledge and attitudes may be a barrier to female condom uptake, since nearly one-third were unhelpful. Regardless of FC2’s status, pharmacy staff often are the first people to whom adolescents speak when seeking information about sexual and reproductive health products [27,28]. Pharmacy personnel can provide informa-

tion confidentially and may be a more accessible source of health information for teens than healthcare providers because no appointment or fee is required.

Besides information giving, another concern is how young people are treated. About 10% of the adolescent mystery callers in our study experienced dismissiveness or rudeness. These behaviors may be especially consequential to young people, because teenagers are often embarrassed and uncomfortable when talking about sexual matters [29]. A negative calling experience might inhibit an adolescent from visiting a pharmacy and obtaining needed products.

4.3. Regulatory changes

In September 2018, the FDA announced that it would designate female condoms as Class II medical devices, by renaming the product as “single-use internal condoms.” Prior to this change, the FDA had designated female condoms as Class III medical devices, which meant it was a multiple-use device and would thus require more regulatory processes and clinical trials [30]. This inhibited the development and approval of new forms of female condoms, which may have prevented market competition. By reducing the regulatory burden on manufacturers, this ruling will make it easier for products already in use elsewhere to get FDA approval, which could lead to more competition and lower prices.

4.4. Limitations

This study had two main limitations. First, having questions about emergency contraception precede those on female condoms may have affected some aspects of the callers’ experiences. Possibly, this contributed to pharmacy staff’s impatience and rudeness. Second, due to the nature of a mystery-caller study, we cannot be certain whether outlets stocked female condoms. By instructing callers to probe for product details, we were better able to determine if the product was indeed a female condom, but we could not tell if staff who recommended going to the doctor were mistaking the female condom for a diaphragm.

4.5. Implications

Although it is one of only two barrier methods protecting against sexually-transmitted infections and pregnancy, female condoms were essentially unavailable in pharmacy outlets in four southwestern states in mid-2016, even before Veru had announced that their product would be prescription only. This is concerning because it is valuable for youths who dislike the male (external) condom to have an alternative [31,32]. Moreover, many young people seeking the method encountered considerable discouragement and misinformation. In light of the recent announcement from the FDA, new female (internal) condom products will likely enter the market, so pharmacy outlets will continue to play a key role in providing information about and access to female condoms [33]. To have a public health impact, it is necessary to break the cycle of low availability, low awareness, and low demand.

Acknowledgement

We thank the UCLA student interviewers for their assistance in data collection.

References

- [1] Centers for Disease Control and Prevention (CDC). Sexual Risk Behaviors: HIV, STD, & Teen Pregnancy Prevention. Div Adolesc Sch Heal Natl Cent HIV/AIDS,

- Viral Hepatitis, STD, TB Prev 2018. <https://www.cdc.gov/healthyyouth/sexualbehaviors/> (accessed June 10, 2019).
- [2] Kann L, McManus T, Harris WA, Shanklin SL, Flint KH, Queen B, et al. Youth risk behavior surveillance — United States, 2017. *MMWR Surveill Summ.* 2018;67:1–114.
 - [3] Child Trends Databank. Condom Use. Child Trends 2016. <https://www.childtrends.org/indicators/condom-use> (accessed June 10, 2019).
 - [4] Narrigan D. Women's barrier contraceptive methods: poised for change. *J. Midwifery Womens Health* 2006;51:478–85.
 - [5] Beksinska M, Smit J, Joanis C, Potter W. New female condoms in the pipeline. *Reprod. Health Matters* 2012;20:188–96.
 - [6] Exner TM, Tesoriero JM, Battles HB, Hoffman S, Mantell JE, Correale J, et al. A randomized controlled trial to evaluate a structural intervention to promote the female condom in New York state. *AIDS Behav.* 2012;16:1121–32.
 - [7] S. Hoffman, J. Mantell, T. Exner, Z. Stein, The future of the female condom. *Perspect. Sex Reprod. Health* n.d.; 36: 120–126.
 - [8] Vijayakumar G, Mabude Z, Smit J, Beksinska M, Lurie M. A review of female-condom effectiveness: patterns of use and impact on protected sex acts and STI incidence. *Int. J. STD AIDS* 2006;17:652–9.
 - [9] Cavanaugh C, Mial K, Tulloch D. Assessing and mapping the availability of the female condom in the Philadelphia metropolitan area. *AIDS Behav.* 2016;20:2845–9.
 - [10] Mantell JE, West BS, Sue K, Hoffman S, Exner TM, Kelvin E, et al. Health care providers: a missing link in understanding acceptability of the female condom. *AIDS Educ. Prev.* 2011;23:65–77.
 - [11] Welbourn A. Sex, life and the female condom: some views of HIV positive women. *Reprod. Health Matters* 2006;14:32–40.
 - [12] Raphan G, Cohen S, Boyer AM. The female condom, a tool for empowering sexually active urban adolescent women. *J. Urban Health* 2001;78:605–13.
 - [13] Latka MH, Kapadia F, Fortin P. The female condom: effectiveness and convenience, not “female control” valued by U.S. Urban adolescents. *AIDS Educ. Prev.* 2008;20:160–70.
 - [14] Weeks MR, Coman E, Hilario H, Li J, Abbott M. Initial and sustained female condom use among low-income urban U.S. women. *J. Womens Health (Larchmt)* 2013;22:26–36.
 - [15] Weeks MR, Hilario H, Li J, Coman E, Abbott M, Sylla L, et al. Multilevel social influences on female condom use and adoption among women in the urban United States. *AIDS Patient Care STDS* 2010;24:297–309.
 - [16] Witte SS, El-Bassel N, Gilbert L, Wu E, Chang M, Hill J. Promoting female condom use to heterosexual couples: findings from a randomized clinical trial. *Perspect. Sex Reprod. Health* 2006;38:148–54.
 - [17] Uysal J, Tavrow P, Hsu R, Alterman A. Availability and accessibility of emergency contraception to adolescent callers in pharmacies in four southwestern states. *J. Adolesc. Health* 2019;64:219–25.
 - [18] Do they make condoms for girls? Seventeen Mag 2008. <https://www.seventeen.com/health/sex-health/q-and-a/a2351/do-they-make-condoms-for-girls/>. (accessed June 10, 2019).
 - [19] How come there are no condoms for girls? Quora 2019. <https://www.quora.com/How-come-there-are-no-condoms-for-girls>. (accessed June 10, 2019).
 - [20] Peters A, Jansen W, van Driel F. The female condom: the international denial of a strong potential. *Reprod. Health Matters* 2010;18:119–28.
 - [21] Daniels K, Abma J. Current contraceptive status among women aged 15–49: United States, 2015–2017. *Natl. Cent. Heal. Stat. Data Br.* 2018.
 - [22] M. Kempner, Female Condoms, Used by Women and Men for HIV Prevention, Will Now Be Prescription Only - HIV Prevention Resource Center - TheBody.com. Body 2017. <http://www.thebody.com/content/80020/female-condoms-used-by-women-and-men-for-hiv-preve.html> (accessed June 10, 2019).
 - [23] M. Kempner, Advocates and Female Condom Maker Spar Over Changes to Access - Rewire.News. RewireNews 2017. <https://rewire.news/article/2017/10/06/advocates-female-condom-maker-spar-changes-access/> (accessed June 10, 2019).
 - [24] Kaiser Family Foundation. Minimum Contraceptive Coverage Requirements Clarified by HHS Guidance | The Henry J. Kaiser Family Foundation. Kaiser Fam Found 2015. <https://www.kff.org/womens-health-policy/issue-brief/minimum-contraceptive-coverage-requirements-clarified-by-hhs-guidance/> (accessed June 10, 2019).
 - [25] H. Worley, Obstacles Remain to Wide Adoption of Female Condom - Population Reference Bureau. Popul. Ref. Bur. 2005. <https://www.prb.org/obstaclesremaintowideadoptionoffemalecondom/> (accessed October 14, 2019).
 - [26] Ventura-DiPersia C, Rodriguez K, Kelvin EA. Failure of many United States Department of Health Web sites to provide accurate information about the female condom. *Contraception* 2015;92:40–5.
 - [27] Gonsalves L, Hindin MJ. Pharmacy provision of sexual and reproductive health commodities to young people: a systematic literature review and synthesis of the evidence. *Contraception* 2017;95:339–63.
 - [28] Peters LM, DiPietro Mager NA. Pharmacists' provision of contraception: established and emerging roles. *Inov. Pharm.* 2016;7.
 - [29] Hoopes AJ, Benson SK, Howard HB, Morrison DM, Ko LK, Shafii T. Adolescent perspectives on patient-provider sexual health communication: a qualitative study. *J. Prim Care Community Health* 2017;8:332–7.
 - [30] Food and Drug Administration, Health and Human Services. Obstetrical and Gynecological Devices; Reclassification of Single-Use Female Condom, To Be Renamed Single-Use Internal Condom. 2018.
 - [31] Fennell J. “And Isn't that the point?": Pleasure and contraceptive decisions. *Contraception* 2014;89:264–70.
 - [32] Sanders SA, Hill BJ, Crosby RA, Janssen E. Correlates of condom-associated erection problems in young, heterosexual men: condom fit, self-efficacy, perceptions, and motivations. *AIDS Behav.* 2014;18:128–34.
 - [33] Chen BA, Blithe DL, Muraguri GR, Lance AA, Carr BR, Jensen JT, et al. Acceptability of the Woman's Condom in a phase III multicenter open-label study. *Contraception* 2019;99:357–62.