

Clinical Practice Alert: Cervical Cancer Screening & Emergency Contraception
Questions & Answers
March 24, 2020

Cervical Cancer Screening Questions:

- **If a patient has a lot of vaginal discharge possibly abnormal, is it advisable to do Pap Smear?**
 - Yes. Liquid based cytology (LBC) technology is able to filter out excessive WBC that would otherwise make it more difficult to evaluate the squamous and glandular cells that were sampled. Excessive WBC used to be a problem with glass Pap “smears”, but this is no longer an issue with LBC.

- **What is your advice if result is always showing unsatisfactory for cytology using the liquid based cytology Thin PreP, collections were done correctly twice.**
 - ASCCP has guidelines for management of this problem. Their answer is:
In general, an “unsatisfactory” cytology should be repeated in 2-4 months. An exception is that when genotyping is done and shows HPV16+ or 18+, colposcopy is indicated. *Colposcopy is also recommended when two consecutive Paps are unsatisfactory.* Ref: <https://www.asccp.org/management-guidelines>

- **If a woman has cervical disease, are you doing anal paps?**
 - No. There are no national guidelines about the use of anal cytologic screening in women, including those who have abnormal cervical cytology results. Anal cytology is often done for males who are HIV positive and some clinics do this for routinely HIV-positive women, as well.

- **I was a bit surprised of the use of "virginal" within the webinar. It's not a medically accurate word as its too vague to clarify what type of individuals are considered "virgins" and doesn't distinguish well if the intention is just those never penetrated with a penis? But, how might other objects used for penetration differ?**
 - “Virginal” is the term that is used in the few guidelines that address the need for cervical cancer screening in females who have never had penetrative intercourse. In the vast majority of cases, HPV is transmitted to the cervix via skin-to-skin contact with the penis of an infected male owing to penetrative intercourse.
 - In females who have never had penetrative intercourse with a male, the risk of developing cervical cancer is extremely low, but not zero. In a very small percentage of cases, HPV may have been transmitted by penetration with a finger or device with HPV on the surface, or possibly, vulva-to-vulva contact. The exact percentages are unknown, which is the reason that current screening guidelines are intended to apply to all females 21 and older, irrespective of whether they have had penetrative sex with a male.

Emergency Contraception/Family PACT Questions:

- **If we as FFACT providers send an Rx to an outside pharmacy, will FFACT cover the EC at the pharmacy?**
 - Yes, but only if the pharmacy is currently contracted with Medi-Cal. All of the chain pharmacies and most of the independents are Medi-Cal contracted. If there is any question, call the pharmacy first to check.

- **Why does the Rx need to be written by a Family PACT provider to be covered by Family PACT?**
 - According to the PPBI (Policies, Procedures, and Billing Instructions), all prescriptions written for Family PACT clients must be done by providers who are enrolled in the program. Most health insurance policies (other than Preferred Provider Organizations) have the same requirement.

- **Would Family PACT cover 2 Plan B Rx in one day?**
 - No; only as needed in the client's current situation. The reason is that evidence (from 14 randomized trials) does not support the concept that "advance provision" of ECPs reduces the pregnancy rate any more than obtaining ECPs "as needed". According to the PPBI, all ECP products are restricted to one pack per dispensing, with a combined maximum total number of dispensing six packs per recipient, per year, any provider.

- **Pharmacists are now enrolling as Medi-Cal ORP...how can we extend this to Family PACT? Can a pharmacist at a pharmacy (like Target) see an established FFACT patient and prescribe onsite?**
 - Yes. Effective April 1, 2019, pharmacist services are reimbursable as a Family PACT Program benefit. These services include furnishing self-administered contraception, as authorized in Business and Professions Code, Section 4052.3.
 - CPT codes 99201 (evaluation and management of a new patient) and 99212 (evaluation and management of an established patient) are reimbursable with the following ICD-10-CM diagnosis codes:
Z30.011 (Initiate OCs) and Z30.41 (surveillance of OCs)
Z30.012 (Emergency contraception)
Z30.015 (Initiate vaginal ring) and Z30.44 (surveillance of vaginal ring)
Z30.016 (Initiate contraceptive patch) and Z30.45 (surveillance of patch).
Z30.09 (Encounter for contraceptive counseling and advice)

Emergency Contraception Questions:

- **Is 5 days the absolute outer limit to C-IUD placement for EC?**
 - Per the Centers for Disease Control, a Cu-IUD can be inserted beyond 5 days after intercourse as long as the insertion does not occur more than 5 days after ovulation. This requires that the timing of ovulation be estimated to the patient's best ability.
 - In patients with irregular menstrual cycles or in patients whom ovulation cannot be estimated, a Cu-IUD should only be used within 5 days of unprotected intercourse. This is because the benefit of the Cu-IUD as an emergency contraceptive agent is greatly reduced when more than 5 days have elapsed ovulation.

NOTE: A Cu-IUD can still be inserted in the luteal phase for long term contraception if patient's have been counseled about the risks of IUD placement in the setting of luteal phase pregnancy.

- **If the half-life for Plan B is 24 hours then if unprotected intercourse occurs 48 hours after taking Plan B it would be reasonable to give Plan B again 48 hours after the first dose, right?**
 - If an episode of unprotected intercourse occurs more than 24 hours after taking oral EC, another dose of oral EC should be taken.
 - Because oral EC works by delaying ovulation, women who have taken oral EC once in their cycle are still at risk of pregnancy later in that same cycle if multiple episodes of unprotected intercourse occur.
- **Patient gets the plan B and come back 2 hours later and said she lost her pills and want more. Should we give her again?**
 - Yes, patients can be given multiple doses of emergency contraception. Repeated use of EC is safe, even when taken in the same cycle. (See previous question.)
 - It is not harmful to take Plan B repeatedly, and in fact, patients are more likely to use EC after unprotected intercourse if they have it on hand.

NOTE: Family PACT covers EC (levonorgestrel or ulipristal acetate) one pack per event, with combined maximum 6 packs per year for clinic, and maximum of 6 packs per year for pharmacy. Earliest refill for clinic or pharmacy is as medically indicated up to the limit. Family PACT Policies, Procedures and Billing manual, *Benefits Grid section*.
- **If a patient takes oral EC and then returns in the next 5 days saying she had unprotected intercourse again, do you repeat the EC?**
 - Yes, the EC dosing should be repeated if the patient has another episode of unprotected intercourse more than 24 hours after taking oral EC.

Reference: Johansson E, Brache V, Alvarez F, Faundes A, Cochon L, Ranta S, Lovern M, Kumar N. Pharmacokinetic study of different dosing regimens of levonorgestrel for emergency contraception in healthy women. *Human Reproduction* 2002;17(6):1472-6.
- **Can you talk about how many times a female can take EC in one month?**
 - There is no upper limit to how many times a patient can take EC in one cycle. EC should be re-dosed if episodes of unprotected intercourse occur more than 24 hours after taking oral EC.
 - Repeated use is uncommon but safe. According to a 2006-2008 National Survey of Family Growth, 61% of emergency contraception uses had only used once.
 - Per the CDC and World Health Organization Medical Eligibility Criteria, repeated EC use is Category 1. There are no restrictions on repeated use for COCs, levonorgestrel, or ulipristal acetate for emergency contraception.
 - Patients with repeated EC use should be counseled about other more efficacious contraceptive options.

Resource: <https://www.cecinfo.org/publications-and-resources/icec-publications/repeated-use-emergency-contraceptive-pills-facts/>

- **Repeat Plan B okay, but repeat UPA not okay in one cycle is that true? and why?**
 - Use of UPA in the same cycle is safe. While the label for ulipristal acetate states that repeated use is not recommended, a prospective study published in 2016 demonstrated that repeat use is safe. Repeat doses of UPA in one cycle may delay follicular rupture and prevent pregnancy in the event of multiple episodes of unprotected intercourse. **Reference:** Jesam C, Cochon L, Salvatierra AM, Williams A, Kapp N, Levy-Gompel D, Brache V. A prospective, open-label, multicenter study to assess the pharmacodynamics and safety of repeated use of 30 mg ulipristal acetate. *Contraception*. 2016;93:310-16

- **Sometimes we've had a patient who used Plan B a few days ago but isn't sure of which day and then has had unprotected intercourse again. What advice would you give - safer to give Plan B now? What if the last Plan B was taken 3 days ago but the patient is obese? Ella?**
 - If a patient has unprotected intercourse more than 24 hours after taking oral EC, another prescription for oral EC should be given (or a Cu-IUD used for EC).
 - Levonorgestrel EC (Plan B) and ulipristal acetate should not be used within 5 days of one another.
 - If ulipristal is used for EC, levonorgestrel EC should not be used for at least 5 days if another dose of EC is required. A second dose of ulipristal can be used.
 - If the patient is obese, Ella should be always be used for EC.

- **With programs moving to alternate regimens related to COVID and trying to keep patients at home as much as possible, would you recommend progestin-only pills instead of patients coming in for their depo shot? AND, if so, would you recommend us also giving EC (one-step) at the time of the POP prescription?**
 - I would not advocate for switching contraceptive methods if the patient is on a method that works well for them.
 - The pros/cons of switching to an oral contraceptive can be discussed with the patient if there are significant concerns about a healthcare appointment for a DMPA injection or if an in-person appointment is unavailable.
 - **NOTE:** DHCS has *temporarily* allowed for pharmacy dispensing of DMPA-SQ directly to the beneficiary for self-administration at home, in addition to current Medi-Cal policy that allows administration by a health care professional. This policy also applies to the Family PACT program pursuant to the approval of a federal waiver allowing specific flexibilities related to the coronavirus disease 2019 (COVID-19) public health emergency. This is an alternative option for patients using DMPA IM who are able learn how to self-administer. Helpful clinical information regarding the use of DMPA-SQ can be found in the [NFPRHA DMPA-SQ Resource Guide](#).

- **There was such a big push to get Plan B to be accessible OTC. We know that there are all sorts of barriers to care, and needing a prescription is certainly a big one. Please forgive me if I missed it, but why exactly is it that Ella cannot be readily accessible OTC at this time? Do we foresee it to be available OTC in the foreseeable future?**
 - In the process of FDA approval, an agreement was made between the manufacturer and the FDA that Ella should be labeled for prescription only.
 - There is no obvious clinical reason why UPA should require a prescription and LNG-EC should be available over the counter. There is no contraindication to UPA use. Women

who are breastfeeding should be advised to delay breastfeeding for 24 hours after taking UPA.

- **It seems like the EC talk is emphasizing BMI instead of absolute weight. I've heard conflicting data (e.g., that weight over 165 is the cutoff for LNG vs UPA). Can you clarify?**
 - Most of the pharmacokinetic research investigating levonorgestrel and ulipristal as emergency contraceptive methods uses BMI categories.
 - In terms of weight categories:
 - Levonorgestrel
 - At weights <75 kg (165 lbs), the failure rate of LNG-EC is <1.5%
 - At weights >80 kg (176 lbs), the failure rate of LNG-EC is 6%, which is the same rate as not using any EC
 - Thus, at weight >176 lbs, levonorgestrel EC is unlikely to be effective.
 - Ulipristal acetate
 - Increased failure rate seen at weight >88kg (194 pounds) – less effective at weight >194 pounds

- **Can you help with counseling...if a young patient presents for emergency birth control, BMI 35, 72 hours post UPS and has never heard of an IUD...can you suggest some counseling segues to introduce the IUD as an option?**
 - The most important piece of contraceptive counseling is to review the patient's goals and preferences in regard to her fertility and family planning.
 - In addition to offering methods of emergency contraception, explore the patient's knowledge and/or desire to initiate a contraceptive method. Take a detailed menstrual history – does she have menorrhagia or dysmenorrhea and would be a poor candidate for a Cu-IUD?
 - If the patient is looking to start a long term highly effective contraceptive method and would also benefit from EC, the copper IUD can be introduced as an option to meet both of those needs.
 - If the patient would not be a good candidate for a Cu-IUD (personal preferences, heavy/painful menses, does not want long term contraception), then this method should not be used for EC and an alternative oral EC (in this case, UPA) should be prescribed.
 - A good resource for young patients exploring contraceptive options is www.bedsider.org