

## **EMERGENCY CONTRACEPTION TOOLKIT**

A RESOURCE FOR PROVIDERS AND ADMINISTRATIVE STAFF PROVIDING EMERGENCY CONTRACEPTION (EC) TO PATIENTS IN AMBULATORY AND POSTPARTUM SETTINGS.

PICCK IS AN INNOVATIVE CLINICAL AND PUBLIC HEALTH PROGRAM DESIGNED TO PROMOTE CONTRACEPTIVE CHOICE AND QUALITY CONTRACEPTIVE COUNSELING ACROSS THE COMMONWEALTH OF MASSACHUSETTS.



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#### Why Emergency Contraception?

Emergency contraception gives people a chance to prevent pregnancy in the case of unprotected intercourse or birth control method failure. Why is this important? Any contraceptive method can fail and emergency contraception provides a way to intervene. Why do methods fail? There are a range of reasons: challenges related to method use (missed oral contraceptive pills, delayed contraceptive injections), bad luck (condom breakage, IUD expulsion) or other circumstances (insurance problems, appointment delays). Emergency contraception has a critical role to play when contraceptive methods are not working as intended. Emergency contraception can also provide a bridge to ongoing, more effective methods of birth control. Finally, emergency contraception is an easy, safe, accessible method of contraception for those at risk for pregnancy who are not using an alternate method of contraception.

#### What is Emergency Contraception?

Emergency contraception (EC) is birth control that prevents pregnancy after vaginal intercourse with a sperm-producing partner. There are two forms: oral emergency contraception pills and intrauterine devices (IUDs). EC makes it much less likely that a patient will get pregnant from a particular instance of intercourse. Oral EC is sometimes referred to as "the morning after pill," although it may be used anytime from immediately after vaginal intercourse until five daus (120 hours) after. There are multiple oral EC pills on the market in the U.S. and all work by inhibiting or delaying ovulation. They do not interrupt an established pregnancy and therefore do not cause abortion. According to the CDC U.S. Medical Eligibility Criteria for Contraceptive Use, there are no situations in which the risks of oral EC outweigh the benefits.<sup>1</sup> No serious complications to patients or fetuses have been linked to oral EC, including with repeat use. The IUD (copper IUD and levonorgestrel 52 mg IUD) is another form of EC that works up to five days after unprotected sex and then provides ongoing, highly effective birth control, if desired.

#### **Options for Emergency Contraception in the U.S.**

#### Progestin emergency contraceptive pills

Progestin-only EC pills are just that—pills that contain only progestin—and only one particular progestin, levonorgestrel. Only levonorgestrel has been studied as stand alone oral EC. After studies showed that a single dose of 1.5 mg was as effective as two 0.75 mg doses 12 hours apart, the FDA approved a one-dose formulation in 2009 and it has now generally replaced two-dose levonorgestrel oral EC pills in the U.S. The progestinonly products available in the United States are Plan B One-Step (1.5 mg) and multiple generic forms, all of which are available at pharmacies without a prescription. The generic forms are equally as effective as the Plan B

brand and common names for them are Take Action, My Way, Option 2, Preventeza, AfterPill, My Choice, Aftera, and EContra.<sup>2</sup>

#### Ulipristal acetate emergency contraceptive pills

The second-generation anti-progestin ulipristal acetate (30 mg in a single dose) is a highly effective, well tolerated form of oral EC that has been available in Europe since 2009. Ulipristal acetate was approved by the U.S. FDA in 2010 and is available for sale by prescription only, marketed under the brand name Ella.

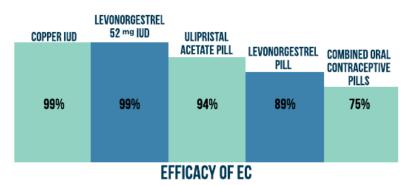
#### Copper IUD

The IUD is the most effective method of emergency contraception available in the U.S. The copper IUD can be inserted by a provider up to five days after intercourse. If desired, the IUD can continue to be used as ongoing contraception, or it can be removed with the next menstrual period.

#### Hormonal IUD

New evidence shows that hormonal IUDs with 52 mg of levonorgestrel are equally effective EC as the copper IUD.<sup>3</sup> Using the hormonal IUDs for EC has the same profile as the copper IUD for EC, including efficacy, time-frame, and the option to be ongoing contraception. IUDs with the brand names Mirena and Liletta have 52 mg of levonorgestrel and can be used as EC. The Skyla and Kyleena hormonal IUDs have not been studied and are not indicated for use as forms of EC.

#### How well does EC work?



It is challenging to study EC's efficacy, as estimates of efficacy depend on accurate predictions of the risk of getting pregnant from one instance of vaginal intercourse. If the risk of pregnancy is overestimated, efficacy of EC may also be overestimated. Importantly, all EC products appear to be better at preventing pregnancy than using nothing. Available studies suggest that combined oral contraceptive pills are the least effective method of EC and still prevent about 75% of predicted pregnancies<sup>4</sup> (see EC: then and now on page 3), whereas the copper IUD and the levonorgestrel 52 mg IUD are the most effective methods of EC and prevent

#### EC around the world

The oral anti-progestin mifepristone, used in many countries for early firsttrimester medication abortion, is also highly effective for use as emergency contraception at lower doses. It works well as oral EC up to five days after unprotected intercourse without a decline in efficacy. However, mifepristone's dual role as abortion pill and EC may limit its acceptability, and it is currently available as EC only in Armenia, Moldova, Ukraine, China, Russia, and Vietnam.

about 99% of predicted pregnancies.<sup>3</sup> Studies show that the efficacy of ulipristal acetate (Ella) oral EC is greater than levonorgestrel (Plan B) oral EC when taken 72-120 hours (3-5 days) after unprotected intercourse and for people with an elevated BMI.<sup>5</sup> For these reasons, Ella is preferred over Plan B when coverage and access do not pose obstacles to use.

#### Indications for EC use

- Unprotected vaginal intercourse in the last 5 days (<120 hours) or
- Vaginal intercourse with method failure:



Condoms: Rips or slips so that semen could be in the vagina



Pulling out: Some semen could be in vagina, if ejaculation started prior to withdrawal

Combined hormonal pills: 2+ missed active pills in a row



Progestin-only pills: Active pill missed or taken too late according to directions (late pill directions vary by brand)

Spermicide, Sponge, Phexxi, Diaphragm, or Cervical Cap: Concern about proper placement before sex

Fertility awareness: Difficulty or concerns about tracking body changes or irregular periods

Ring: Left out for 3+ hours or late replacing it according to directions (changing ring directions vary by brand)

Patch: Off for 24+ hours or late replacing it according to directions (changing patch directions vary by brand)

Shot: 14+ weeks since last shot

IUD: Expelled

#### Side effects of and contraindications to EC

Side effects after taking oral EC are uncommon and short-lived. There are no contraindications to oral EC other than a known allergy. Some people experience nausea and, less commonly, vomiting after taking emergency contraceptive pills. Other side effects include headache, fatigue, dizziness, lower abdominal pain, and breast tenderness. Some people also experience unexpected vaginal bleeding or changes in menstrual timing. If vomiting occurs within 3 hours of taking oral EC pills, another dose of oral EC should be taken as soon as possible. Use of an antiemetic can be considered, but routine use of an antiemetic is not recommended. A study comparing levonorgestrel and ulipristal acetate oral EC showed similar side

#### EC: then and now

The first oral emergency contraceptive regimen used ordinary birth control pills and was described by Albert Yuzpe, a Canadian physician, in the 1970s. The "Yuzpe method" uses specified combinations of combined oral contraceptive pills containing the estrogen ethinyl estradiol and a progestin. The regimen consists of one dose followed by a second dose 12 hours later, where each dose consists of 4, 5, or 6 pills, depending on the brand of combined oral contraceptive pill.

Progestin-only EC pills have now largely replaced the older combined EC pills because they are more effective and cause fewer side effects. Plan B was FDA approved in 1999 - before that, there was no product packaged and labeled for EC use in the U.S. A one pill version of EC (Plan B One-Step) was approved in 2009, and a generic version of Plan B (Next Choice) was also approved in 2009. However, pharmaceutical companies have not marketed the products to the same degree as most contraceptive products. Lack of marketing likely impacts the number of people who know about and have used EC. Among people aged 15-44 who have ever had intercourse, the percentage who had ever used EC increased from 4% in 2002 to 20% in 2011-2015.8

In August 2013, Plan B One-Step finally became available without prescription to males and females regardless of age. One-pill generics are now approved for sale on the shelf as well. Cost varies but is in the range of \$15 to \$50. In most pharmacies, EC is located on the shelf in the family planning aisle; some pharmacies have chosen to keep it in a locked cabinet.

effects for the two medications. About 20% of people in each group reported headaches after oral EC use, 13-14% experienced pain with menses, and 11-12% experienced nausea. Persons using both types of oral EC reported shifted menses by 1-2 days, on average.<sup>6</sup>

Side effects of the copper IUD include post-insertion cramping, longer periods, heavier periods, and stronger cramps with periods. Contraindications to copper IUD use for EC are the same as for routine use, and include known pregnancy, Wilson's disease, copper allergy, distorted uterine cavity, cervical or uterine cancer, unexplained suspicious vaginal bleeding, active cervical infection or pelvic inflammatory disease, and pelvic tuberculosis.<sup>1</sup>

Side effects of the levonorgestrel 52 mg IUD include post-insertion cramping, spotting between periods, and lighter, irregular, or no periods.<sup>7</sup> It is clinically safe to experience amenorrhea. Contraindications to levonorgestrel 52 mg IUD use for EC are the same as for routine use.<sup>3</sup>

## **SPECIAL CONSIDERATIONS FOR ORAL EC USE**

#### Repeat oral EC use

While there are no studies on the long-term safety of repeat use of oral EC, available data suggest that the risk is low. There is good data confirming the safety of long-term use of combined or progestin-only oral contraceptive pills. A study of repeated use of ulipristal acetate every seven days for eight weeks showed no safety concerns, suggesting that this method can be safely used more than once per cycle.

#### Patient body mass index (BMI)

Oral EC pills may be less effective among persons with a higher BMI, though no safety concerns exist. The available evidence are more specific for levonorgestrel EC, suggesting that people with BMI  $\geq$ 26 kg/m<sup>2</sup> experience an increased risk for pregnancy after use of levonorgestrel EC compared to persons with BMI <26 kg/m<sup>2</sup>.<sup>9</sup> Two analyses suggest obese people (BMI  $\geq$  35 kg/m<sup>2</sup>) might also experience an increased risk for pregnancy after use of ulipristal acetate compared with nonobese people, although this increase was not found in another study.<sup>10</sup> The effectiveness of the copper IUD and the levonorgestrel 52 mg IUD is not impacted by weight.

Early research has found that doubling the dose of levonorgestrel EC (from 1.5 mg to 3.0 mg) for overweight people, appeared to produce serum concentration levels similar to those in not overweight people who had taken the regular dose (1.5 mg).<sup>11</sup> However, recommendations for dosing have not yet changed based on these findings.

#### Hormonal IUD as EC

In January 2021, *The New England Journal of Medicine* published results from a clinical trial by researchers at the University of Utah. The study was a noninferiority trial with 711 participants randomized to either Paragard or Liletta for EC. Researchers found that the levonorgestrel 52 mg IUD was just as effective for use as EC as the copper IUD.<sup>3</sup> Because the Mirena and Liletta IUDs contain the same dose and hormone, both are now considered acceptable as EC.

#### Oral EC use in pregnancy

There are no known safety concerns for the use of oral EC in the setting of pregnancy.<sup>12, 13</sup> Studies of pregnant persons who have used levonorgestrelonly EC, ulipristal acetate, or combined oral contraceptive pills during their pregnancies repeatedly show no increased risk of birth defects.

#### Use of oral EC when breastfeeding

Studies have shown that there are no adverse maternal or infant effects and no effects on continuing breastfeeding for people who take oral EC. The CDC therefore states that oral EC can be safely recommended in the setting of lactation, as benefits outweigh risks (Category 1).

Consistent with the recommendation of the InfantRisk Center<sup>17</sup>, PICCK recommends that all forms of EC are compatible with breastfeeding and breastmilk does not need to be discarded after taking ulipristal acetate. This recommendation is based on the limited infant safety data available. Out of caution with the limited evidence base, the CDC recommends that breastfeeding persons discard pumped milk for 24 hours after taking ulipristal acetate.<sup>1</sup> This recommendation is due to the presence of ulipristal acetate in breastmilk, with the highest concentrations in the first 24 hours after ingestion.<sup>18</sup> However, the CDC recommends that breastfeeding persons can safely take levonorgestrel oral EC because levonorgestrel passes into breastmilk in minimal quantities.

#### Time since unprotected intercourse

Progestin-only EC works best to prevent pregnancy within the first 72 hours of use. While progestin EC still has benefit in preventing pregnancy 72 to 120 hours after unprotected intercourse, ulipristal acetate works better than progestin-only EC to prevent pregnancy 72 to 120 hours after intercourse. Both the copper IUD and the levonorgestrel 52 mg IUD work better than both forms of oral EC to prevent pregnancy within 120 hours of unprotected intercourse.

#### Starting hormonal contraception after oral EC

Ulipristal acetate is more effective than progestin-only EC in several scenarios, but use of this oral EC method poses one addition clinical question: when to resume hormonal contraception after use of EC? Ulipristal acetate has the potential to interfere with ongoing use of hormonal contraception via its mechanism of action as an anti-progestin. The CDC recommends that people start or resume their hormonal contraception no sooner than five days after use of ulipristal. For methods requiring a visit to a health care provider, the CDC recommends considering starting the method together with ulipristal acetate EC; the risk that the regular contraceptive method might decrease the effectiveness of ulipristal acetate must be weighed against the risk of not starting an

#### EC myths and facts

**Myth:** People using oral EC will not use other forms of contraception as well.

**Fact:** Use of oral EC does not impact other contraceptive use.<sup>14, 15</sup>

**Myth:** Availability of EC leads to decreased condom use and more STIs.

**Fact:** Young people obtaining oral EC from a pharmacist have been shown to be no more likely to get an STI.<sup>16</sup>

**Myth:** Giving oral EC in advance of need is risky.

**Fact:** Receiving oral EC in advance of need does NOT increase risk-taking behavior. Advanced provision of oral EC does not decrease condom use and does not increase one's number of sexual partners. Advanced provision of oral EC does increase use and increases earlier use, when EC is more effective.<sup>16</sup>

Myth: Oral EC will cause an abortion.

**Fact:** Oral EC has no impact on an existing pregnancy.

## **SPECIAL CONSIDERATIONS FOR ORAL EC**

ongoing hormonal contraceptive method. People should abstain from sexual intercourse or use barrier contraception for the next seven days after starting or resuming regular contraception or until their next menses, whichever comes first.<sup>19</sup>

If a patient wants to begin a longer-acting contraceptive method (injection or implant) on the same day as taking ulipristal, they should not be discouraged from using these methods. Counsel them to abstain from intercourse or use a barrier method for the next 12 days to ensure contraceptive efficacy after the effects of ulipristal have waned.

Use of levonorgestrel oral EC has no impact on the efficacy of hormonal contraception and any contraceptive method can be quick-started right away, with a follow-up pregnancy test recommended. See Appendix 1 for further information.

#### **Oral EC as contraception**

Oral EC has not been recommended as a primary method of birth control. However, there may be people for whom oral EC is a logical choice to use as a primary method. Those who have sex infrequently, such as those who are or have a partner in the military or who lives far away, may find that occasional yet regular use of oral EC provides excellent contraception. Patient-centered counseling is often the best approach to weighing the pros and cons of any given contraceptive method. Counseling can include the following:

- Oral EC is less effective for long-term contraception than all hormonal forms of birth control and the copper IUD.
- Frequent use of levonorgestrel EC results in exposure to higher total levels of hormones than ongoing use of either a combined or progestin-only oral contraceptives.
- Frequent use of oral EC is likely to result in more side effects, such as bleeding irregularities and nausea.

If a patient decides to use oral EC as their primary method of contraception, they should be provided with a prescription for as many refills as is allowable per their insurance. Encourage them to always have a supply of oral EC on hand, to expedite the use of the medication as soon as possible after intercourse.

## Challenges for adolescents and EC access

Adolescents face particular challenges when it comes to EC access. Many adolescents don't know about EC and, among those who are aware it exists, many don't know that it should be taken after unprotected intercourse. This is not surprising, given that few pediatricians discuss and prescribe emergency contraception. Adolescents trying to access EC may have difficulty obtaining a confidential prescription or device, affording the cost of overthe-counter EC, dealing with myths surrounds adolescents and IUDs, or interacting with pharmacists who may be unwilling to dispense EC to minors or to males.

One of the concerns cited about adolescents using oral EC is that it will increase non-use of other methods of contraception and therefore increase the likelihood of adolescents having unintended pregnancies. However, use of oral EC has increased among teens over time in the US and pregnancy rates have not.<sup>20</sup> The American Academy of Pediatrics (AAP) and the Society for Adolescent Health and Medicine (SAHM) strongly endorse access to and increased awareness of EC for adolescents.<sup>21</sup>

Adolescents may benefit from particular counseling about EC and routine advanced provision of oral EC. As adolescents are exploring contraceptive methods for the first time, the majority of adolescents report not using a highly effective method of contraception during last intercourse. Adolescents are also likely not to use hormonal contraception at the onset of sexual activity and between partners. In addition, adolescents often must contend with the issue of maintaining confidentiality.

## **IMPLEMENTING EC IN CLINICAL SETTINGS**

#### Triage: urgent response to EC request

Telephone requests, or, increasingly, patient portal requests for EC should be treated as urgent by staff on the receiving end of such communication. If the request comes in first to non-clinical staff, it should be urgently transferred to nursing triage. Requests for EC should NOT follow the protocol for "routine" prescription requests or prescription refills.

Requests for EC during business hours should be handled actively by the on-call or provider-of-the-day existing system for same-day patient needs. Weekends or after hours requests should be transferred to the provider oncall. Please see Appendix 2 for a Telephone Triage Protocol for EC.

#### Counsel about the IUD as EC up front

Nursing triage has an important role to play when it comes to educating patients that a copper IUD or a levonorgestrel 52 mg IUD can be used for EC. Many patients are not aware of these options, and may call for EC expecting that a pill is the only possibility. While many patients will prefer the ease of filling a prescription and avoiding an office visit, those who want the most effective EC option may be interested in hearing about the IUD.

Below is a sample script:

"I am so happy you called. We offer both oral emergency contraception pills and IUDs as emergency contraceptive options. There are two types of IUDs that can be used for emergency contraception—one is hormonal and one is non-hormonal. IUDs are birth control as well as emergency contraception. Both IUDs are 99% effective at preventing an unplanned pregnancy and can be used as birth control for up to 10 years. Plan B and Ella, commonly known as 'the morning after pills,' are about 90% effective. We can see you today, send in a prescription for you, or set up an appointment in the next few days at a time that is convenient for you. Plan B is also available over the counter without a prescription at full price." Please see Appendix 1 for additional information.

#### **Postpartum EC**

Up to 50% of people will have vaginal intercourse prior to their six-week postpartum visit. For that reason, people who leave the hospital postdelivery without an effective method of contraception should be offered a prescription for oral EC. Both oral ECs are safe and compatible with breastfeeding. However, ulipristal acetate is preferred over levonorgestrel EC for persons with a BMI over 26.

#### Ella vs. Plan B

Now that ulipristal acetate (Ella) and levonorgestrel (Plan B) EC are both readily available, many clinics that provide oral EC face the following question: should we give or prescribe Plan B or Ella to patients when they request oral EC? Because Ella and Plan B have virtually the same side effect profile and the major consideration with oral EC is how well will it work (since it is usually an one time dose), the answer to this question is: usually Ella.

Ella works better than Plan B for all people 72-120 hours (3-5 days) after an episode of unprotected intercourse and for those with a BMI over 26. The situations that might change this decision relate to cost, access, and whether a patient plans to start hormonal contraception after taking EC.

Plan B, as an over-the-counter medication available without prescription, is more readily available to all people, especially those who may want oral EC without clinician interaction. Some pharmacies and clinics may not carry Ella and ordering Ella could delay EC use. Ella may cost more than generic levonorgestrel EC. Finally, use of Ella has the potential to decrease the effectiveness of ongoing hormonal contraception use and this should be considered for patients quick-starting hormonal methods of contraception or those planning to continue a hormonal method after Ella use (like those who are taking the birth control pill and used Ella due to missed pills).

## **IMPLEMENTING EC IN CLINICAL SETTINGS**

#### EC post-sexual assault

Emergency contraception must be offered by law to all survivors of sexual assault in Massachusetts. Any victim of penile sexual assault who is capable of reproduction (has a uterus, not in menopause) should be offered EC. An IUD or ulipristal acetate should be recommended, as they are the most effective forms of EC. If patients are using hormonal birth control whose efficacy may be impacted by EC, this should be taken into consideration.<sup>22</sup>

#### Advanced provision of oral EC

The World Health Organization (WHO) states, "Any woman of reproductive age may need emergency contraception at some point to avoid an unwanted pregnancy."<sup>24</sup>

Studies show that people are more likely to take EC and are more likely to take EC sooner when it is prescribed in advance of need.<sup>26</sup> The CDC recommends that providers consider supplying oral EC pills to people in advance of need so that EC is available when needed and can be taken as soon as possible after unprotected sexual intercourse. Any patient of reproductive age who is not seeking pregnancy should be counseled about EC and offered advanced provision of oral EC, as birth control methods can be discontinued or fail at any time. Like all medications, oral EC pills have an expiration date. Generally the shelf life is about four years. Pills should be stored in their original packaging in a dry area at room temperature.

# Ulipristal acetate and breastfeeding

The CDC recommends that breastfeeding persons refrain from breastfeeding and discard pumped milk for 24 hours after taking ulipristal acetate.<sup>1</sup> This recommendation is out of caution with the limited evidence base.

European guidelines state that breastmilk should be discarded for one week after taking ulipristal acetate, consistent with the recommendations from the manufacturer.<sup>23</sup> Planned Parenthood recommends that breastfeeding persons taking ulipristal acetate should "pump and dump" for 36 hours.<sup>25</sup> The strongest concentration of ulipristal acetate in the breastmilk occurs for 1 to 3 hours after taking it, so some providers recommend "pumping and dumping" only once.<sup>27</sup>

However, no infant safety data is available for use in lactation. The manufacturer reports that after this medication was given to 12 breastfeeding women for EC the mean concentration of ulipristal and its metabolic monodemethyl-ulipristal acetate in milk were 22.7 mg/mL and 4.49 mg/mL in the first 24 hours. Using this mean ulipristal concentration in the first 24 hours of therapy, the relative infant dose is 0.8%.<sup>28</sup>

InfantRisk Center recommends that all forms of EC are compatible with breastfeeding and breastmilk does not need to be discarded after taking ulipristal acetate because there is no infant safety data available and the levels in the milk appear to be very low.<sup>17</sup> PICCK's recommendations align with those of the InfantRisk Center.

#### 13 things your practice can do to improve EC access

- Prescribe oral EC in advance of need.
- Write oral EC prescriptions with the maximum number of refills.
- Send prescriptions for oral EC to patient's pharmacy to decrease cost as a barrier.
- Have a protocol that allows for access to EC ASAP.
- Have a call system/provider-of-the-day who addresses EC requests in the moment.
- Stock copper and levonorgestrel 52 mg IUDs, progestin-only EC pills, and ulipristal acetate for same day clinic, hospital, and emergency department administration.
- Make all patients aware that they can get EC from you.
- Patient financial services office or pharmacy staff should offer assistance with seeking reimbursement if a patient with insurance purchases oral EC over the counter.
- Make sure patients know that the IUD is the most effective form of EC.
- For oral EC users, recommend ulipristal acetate unless a patient is using/starting hormonal contraception.
- Have order-sets that include EC provision post-sexual assault, postpartum, and for all family planning visits.
- Include counseling about EC in the assessment and plan section of family planning note templates.
- Have a best practice alert to preferentially prescribe ulipristal acetate for patients with a BMI over 26.
- Offer all postpartum patients a prescription for oral EC upon hospital discharge if they do not have another contraceptive plan.

## REFERENCES

- 1. Centers for Disease Control and Prevention. U S. Medical Eligibility Criteria for Contraceptive Use, 2016. MMWR 2016;65:1-108.
- 2. What's the Plan B morning-after pill? Planned Parenthood. www.plannedparenthood.org/learn/morningater-pill-emergency-contraception/whats-plan-b-morning-after-pill. Accessed May 27, 2021.
- 3. Turok DK, Gero A, Simmons RG, Kaiser JE, Stoddard GJ, Sexsmith CD, Gawron LM, Sanders JN. Levonorgestrel vs. Copper Intrauterine Devices for Emergency Contraception. *New England Journal of Medicine*. 2021;384(4):335-344. doi:10.1056/nejmoa2022141
- 4. Trussell J, Rodríguez G, Ellertson C. Updated estimates of the effectiveness of the Yuzpe regimen of emergency contraception. *Contraception*. 1999;59:147-51.
- 5. Glasier A, Cameron S, Fine P et al. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomized non-inferiority trial and metaanalysis. *The Lancet* 2010; 375:555-562
- 6. Raymond EG, Goldberg A, Trussell J, Hays M, Roach E, Taylor D. Bleeding patterns after use of levonorgestrel emergency contraceptive pills. *Contraception*. 2006;73:376-81.
- 7. What are the side effects of IUDs? Planned Parenthood. www.plannedparenthood.org/learn/birth-control/iud/iud-side-effects. Accessed May 27, 2021.
- 8. Center for Disease Control and Prevention. National Center for Health Statistics. Key Statistics from the National Survey of Family Growth- E listing. https://www.cdc.gov/nchs/nsfg/key\_statistics/e.htm#emergency
- 9. Festin MP, Peregoudov A, Seuc A, Kiarie J, Temmerman M. Effect of BMI and body weight on pregnancy rates with LNG as emergency contraception: analysis of four WHO HRP studies. *Contraception*. 2017;95:50-4.
- Glasier A, Cameron ST, Blithe D, et al. Can we identify women at risk of pregnancy despite using emergency contraception? Data from randomized trials of ulipristal acetate and levonorgestrel. *Contraception*. 2011;84(4):363-367. doi:10.1016/j.contraception.2011.02.009.
- 11. Edelman A, Cherala G, Blue S, Erikson D, Jensen J. Impact of obesity on the pharmacokinetics of levonorgestrel-based emergency contraception: single and double dosing. *Contraception.* 2016;94:52-57.
- 12. Zhang L, Chen J, Wang Y, Ren F, Yu W, Cheng L. Pregnancy outcome after levonorgestrel-only emergency contraception failure: a prospective cohort study. *Hum Reprod.* 2009;24:1605-11.
- 13. Levy DP, Jager M, Kapp N, Abitbol JL. Ulipristal acetate for emergency contraception: postmarketing experience after use by more than 1 million women. *Contraception* 2014; 89: 431-3.
- 14. Belzer M, Sanchez K, Olson J, Jacobs AM, Tucker D. Advance supply of emergency contraception: a randomized trial in adolescent mothers. *J Pediatr Adolesc Gynecol.* 2005;18:347-54.
- 15. Gold MA, Wolford JE, Smith KA, Parker AM. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *J Pediatr Adolesc Gynecol.* 2004;17:87-96.
- 16. Raine TR, Harper CC, Rocca CH, Fisher R, Padian N, Kluasner JD, Darney PD. Direct access to emergency contraception through pharmacies and effect on unintended pregnancy and STIs: a randomized controlled trial. *Journal of American Medicine.* 2005; 293(1):54-62
- 17. InfantRisk Center, https://www.infantrisk.com/breastfeeding
- 18. Gainer E, Massai R, Lillo S, Reyes V, Forcelledo ML, Caviedes R, Villarroel C, Bouyer J. Levonorgestrel pharmacokinetics in plasma and milk of lactating women who take 1.5 mg for emergency contraception. *Hum Reprod.* 2007;22:1578-84.
- 19. American Society for Emergency Contraception. Providing Ongoing Hormonal Contraception after Use of Emergency Contraceptive Pills. November 2016. Available at: http://americansocietyforec.org/uploads/3/4/5/6/34568220/asec\_fact\_sheet-\_hormonal\_contraception\_after\_ec.pdf

## REFERENCES

- 20. Center for Disease Control and Prevention. Reproductive Health: Teen Pregnancy. https://www.cdc.gov/ teenpregnancy/about/index.htm
- 21. What do experts say about EC? International Consortium for Emergency Contraception. https://www.cecinfo.org/ about/endorsements/
- 22. Emergency contraception information for providers. https://www.mass.gov/info-details/emergency-contraception-after-sexual-assault
- Trussell J, Raymond EG, Cleland K. Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy. Princeton University. https://ec.princeton.edu/questions/EC-review.pdf. Published January 2019. Accessed July 20, 2021.
- 24. World Health Organization. Emergency Contraception. 2018. https://www.who.int/news-room/fact-sheets/detail/ emergency-contraception
- 25. Emergency Contraception. Planned Parenthood of Michigan. https://www.plannedparenthood.org/planned-parenthood-michigan/healthcare/emergency-contraception. Accessed July 20, 2021.
- 26. Gold MA, Wolford JE, Smith KA, Parker AM. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *J Pediatr Adolesc Gynecol.* 2004;17:87-96.
- 27. Can I take emergency contraception if I am breastfeeding? Nurx. https://www.nurx.com/faq/can-i-take-emergencycontraception-if-i-am-breastfeeding/. Accessed July 20, 2021.
- 28. Drugs and Lactation Database (LactMed) [Internet]. Bethesda (MD): National Library of Medicine (US); 2006-. Ulipristal. [Updated 2021 Jun 21]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK500655/
- 29. https://rhntc.org/
- 30. https://www.reproductiveaccess.org/

## **APPENDICES**

#### **Appendix 1: Additional resources**

#### Starting hormonal contraception after oral EC

American Society for Emergency Contraception. Providing Ongoing Hormonal Contraception After Use of Emergency Contraceptive Pills 2016. <u>http://americansocietyforec.org/uploads/3/4/5/6/34568220/asec\_fact\_sheet-\_hormonal\_</u> contraception\_after\_ec.pdf

#### Providing the copper IUD as EC

New York State: Center of Excellence for Family Planning. Plan C: Copper IUD as Emergency Contraception. Implementation Toolkit for Administrators and Clinicians. March 2016. <u>https://caiglobal.org/index.php?option=com\_wrapper&view=wrapper&ltemid=1621/</u>

#### **Appendix 2: PICCK resources**

Telephone Triage Protocol for Emergency Contraception: We have two different sample nurse telephone triage guidelines for when a patient calls needing emergency contraception – a complete and a simplified version. The information is the same, though, the first protocol is more complete and contains considerations for patients with a BMI over 35. https://picck.org/resource/telephone-triage-protocol-for-emergency-contraception/

Emergency Contraception Information Sheet <a href="https://picck.org/resource/emergency-contraception-information-sheet/">https://picck.org/resource/emergency-contraception-information-sheet/</a>

Phone Room Guidance on Emergency Contraception https://picck.org/resource/ec-talking-points-for-training-of-phone-staff/

Emergency Contraception Checklist https://picck.org/resource/picck-checklist-for-champion-emergency-contraception/

# SAMPLE TELEPHONE TRIAGE PROTOCOL FOR EMERGENCY CONTRACEPTION (EC)

## Procedure:

Patient calls, "Can I have a prescription for the morning after pill called in to my pharmacy?" Or "The condom broke and I don't want to get pregnant, what should I do?"

If the call comes to a clerk or other non-medical staff person, it should be immediately transferred to a nurse or sent as a high priority phone note to the Nurse Triage Desktop.

#### The nurse asks the following questions:

Q1: Was your last period within the past 30 days?

- If yes go on to Q2
- If no encourage patient to come in for a pregnancy test. If not interested, screen for oral EC (skip to Q3, copper or levonorgestrel 52 mg IUD is not an option)

Q2: Since your last period, have you <u>only</u> had unprotected sex in the past 5 days (or 120 hours)?

- If yes counsel that IUD is an option, continue on to Q3 to determine oral EC options
- If no go on to Q3 (IUD is not an option)
- If unclear (missed oral contraceptive pills, etc.), route to provider for consultation

Q3: What is your height and weight (or check their BMI in the EMR)?

- If BMI is less than 26 go on to Q4
- If BMI is between 26 and 35 candidate for Ella and IUD (if counseled on IUD in Q2)
- If BMI is more than 35 counsel that oral EC may be less effective (Ella better option) and IUD may be best option *(if counseled on IUD in Q2)*, or route to a provider

Q4: Since your past period, have you only had unprotected sex in the past 72 hours?

- If yes candidate for Plan B, Ella, and IUD (if counseled on IUD in Q2)
- If no candidate for Ella and IUD *(if counseled on IUD in Q2)*

## **Patient Counseling:**

ORAL EC ONLY: They're eligible for two kinds of EC pills, Plan B and Ella, and you can call their pharmacy to see which one is in stock. Ella is at least as effective (or more effective) than Plan B. Efficacy can be affected by BMI (see above or below). Both pills are effective up to 120 hours after sex, but Plan B becomes less effective in hours 72-120. Offer to have a provider send a prescription to their pharmacy. Plan B is available over the counter, but it is cheaper with a prescription and insurance. Ella requires a prescription. Plan B comes in generic forms.

Consistent with the recommendation of the InfantRisk Center, PICCK recommends that all forms of emergency contraception are compatible with breastfeeding and breastmilk does not need to be discarded after taking Ella. This recommendation is based on the limited infant safety data available. Out of caution with the limited evidence base, the CDC recommends that breastfeeding persons discard pumped milk for 24 hours after taking Ella. ORAL EC or IUD: They are eligible for two kinds of EC, a pill form or an IUD. Both the copper and levonorgestrel 52 mg IUDs (Mirena or Liletta) work for EC with the same efficacy and timeframe. The IUD is more effective than the oral EC, but requires them to come in for an IUD insertion today/in the first 5 days after unprotected intercourse. They can only get an IUD if their only unprotected sex was in the past 5 days; if they have had other episodes of unprotected intercourse since their LMP, they are not eligible for an IUD. The IUD efficacy is not affected by BMI. The IUD can stay in—to provide ongoing contraception—or can be removed at the time of their next period.

### **Patient Instructions for Oral EC:**

- Fill the prescription immediately and take the tablet as soon as you can.
- The box may say to take it within 3 days of sex (if it's a Plan B product), but you can take it up to 5 days after sex.
- Your next period may be a few days early or late, and you may have spotting before then.
- Other side effects include nausea and headache, but these shouldn't last more than a day or two.
- If your next period is not normal, or is more than a week late, you should call for a pregnancy test appointment or take a pregnancy test at home.
- If you want an ongoing method of contraception, you can be given an appointment in Family Planning as soon as possible.

## **Procedures and Documentation:**

Documentation should be done as for all other telephone encounters.

For an IUD visit that same day, nurses should first call the scheduling coordinator to assess the appointment availability in the clinic.

<u>For a prescription</u>, nurses should first approach the on-call or clinic provider (depending on clinic protocol) and discuss the patient.

Prescription should be called into pharmacy as soon as possible after the conversation with the patient and after it has been ordered and documented in the patient's chart by a provider. Send the prescription with 11 refills.

For Ella, the nurse should call the patient's pharmacy to ensure that the medication is in stock, or can be procured within 24 hours. Reassure the patient that as long as Ella is taken within 5 days of unprotected intercourse, it remains effective.

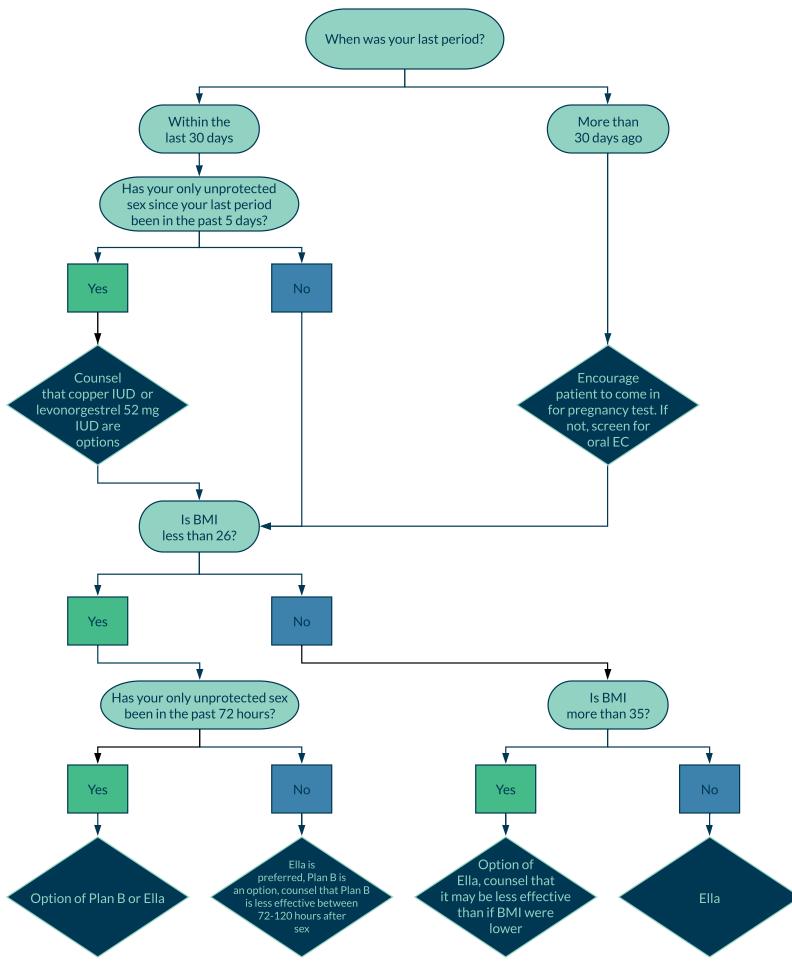
It is also permitted to call in a prescription for EC if requested by a patient because they want to have it on hand in case of an emergency, i.e. an "advance prescription." The same instructions for when to use it should be given to them, as written above.





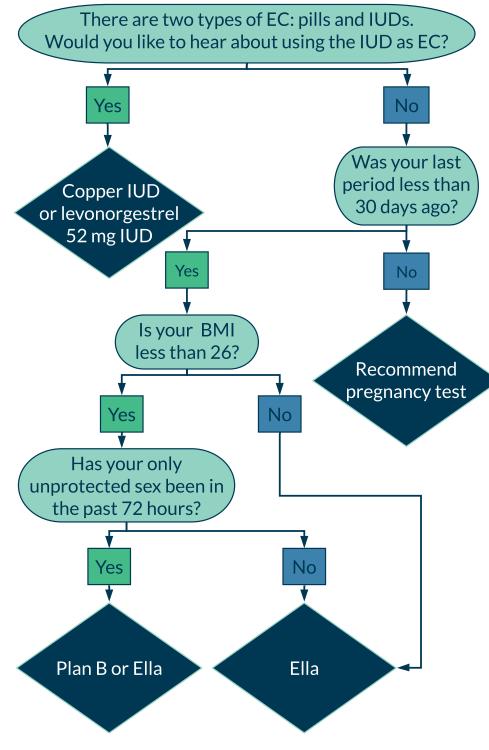


# CONSIDERATIONS WHEN SELECTING A METHOD OF EMERGENCY CONTRACEPTION



#### PICCK PATHERS IN CONTRACEPTINE CHOILE AND KNOWLEDGE

## **CONSIDERATIONS WHEN SELECTING A METHOD OF EMERGENCY CONTRACEPTION (EC)**



#### **Patient Counseling:**

ORAL EC: Ella is the most effective oral EC.

- BMI affects the efficacy of Ella and Plan B (see flow sheet).
- Both pills are effective up to 120 hours/5 days after sex, but Ella works better than Plan B after 72 hours/3 days.
- Plan B (and generic versions) are over the counter but are cheaper with a prescription and insurance. Ella requires a prescription.
- Both methods may cause nausea or headaches for a day or two.
- Your next period may be early or late and you may have spotting first.

IUD: The IUD is more effective than oral EC but requires a clinic visit.

- Both the copper and levonorgestrel 52 mg IUDs (Mirena/Liletta) can be EC when placed within 5 days of sex.
- IUD efficacy is not affected by BMI.
- The IUD can be used for ongoing contraception or can be removed at the time of your next period.

#### Patient Instructions for Oral EC:

- Fill the prescription right away and take the tablet as soon as you can.
- Plan B box may say take within 3 days but it can be taken within 5 days.
- If your next period is not normal, or is more than a week late, you should take a pregnancy test.

**Procedures and Documentation:** 

Documentation should be done as for all other telephone encounters.

For an IUD visit that same day, call the scheduling coordinator to assess the appointment availability in the clinic.

<u>For a prescription</u>, contact the on-call/clinic provider (per your clinic protocol).

Prescription with 11 refills should be called into pharmacy as soon as possible after the conversation with the patient.

For Ella, call the patient's pharmacy to ensure that the medication is in stock, or can be procured within 24 hours. Reassure that Ella remains effective if taken within 5 days of unprotected sex.



## WHAT IS EC?

EC is contraception that prevents pregnancy after intercourse. EC makes it less likely that a person will get pregnant from a specific instance of intercourse. EC works by delaying ovulation – it does not interrupt an established pregnancy or cause abortion.

## WHEN TO PROVIDE EC

- Unprotected intercourse in past 5 days
- Intercourse with method failure, including:
  - Condoms: Rips or slips so that semen could be in vagina
- Pulling out: Some semen could be in vagina
- Combined hormonal pills: 2+ missed active pills in a row
- Progestin-only pills: Active pill missed or taken too late according to directions (late pill directions vary by brand)
  - Spermicide, Sponge, Phexxi, Diaphragm, or Cervical Cap: Concern about proper placement before sex
  - Fertility awareness: Difficulty or concerns about tracking body changes or irregular periods
  - Ring: Left out 3+ hours or late replacing it according to directions (changing ring directions vary by brand)
  - Patch: Off for 24+ hours, 2+ days late changing patch, or late putting patch on after patch-free week
  - Shot: 14+ weeks since last shot
  - TIUD: Expelled

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- May be appropriate as primary contraception for those not frequently having intercourse
- Can be used as a bridge method until another form of contraception can be provided
- Provide oral EC prescription in advance of need for patient to have on hand in case of need
- Prescribe postpartum if patient does not receive another contraceptive method prior to discharge
- Prescribe EC with maximum refills

# **EMERGENCY CONTRACEPTION (EC) INFORMATION SHEET**

## **EMERGENCY CONTRACEPTION OPTIONS**

## Levonorgestrel pill



Brand: Plan B One-Step (1.5 mg) and several generic forms Active Drug: Levonorgestrel Time: Can be taken up to 5 days after unprotected intercourse, most effective up to 3 days BMI Efficacy: Less than 26 (less effective if larger BMI) Effectiveness when used as described: 89% Breastfeeding: No effect Access: Can be purchased over the counter. Can give prescription so \$0 to patient Post-EC Contraception: Can begin immediately Contraindications: None

## Ulipristal acetate pill

- Brand: Ella
- Active Drug: Ulipristal acetate
- Time: Can be taken up to 5 days after unprotected intercourse
- BMI Efficacy: Less than 35 (less effective if larger BMI)
- Effectiveness when used as described: 94%

**Breastfeeding:** No effect. Consistent with the InfantRisk Center, PICCK's recommendation for Ella is based on the limited infant safety data available.



Access: Requires prescription

Post-EC Contraception: Recommended to start hormonal contraception no sooner than 5 days after using Ella and to use back-up protection for 7 days after starting contraception. However, for methods requiring a provider visit, consider starting the method at the same time as taking Ella. Can counsel about the risk that the method may make Ella less effective. If starting hormonal method at the same time as Ella, patient should abstain from sex or use a barrier method for the next 12 days.

Contraindications: None

## Copper IUD and Levonorgestrel 52 mg IUD

Brand: Paragard (copper); Mirena and Liletta (levonorgestrel)

- Active Drug: None (copper); Levonorgestrel
  - Time: Can be inserted up to 5 days after first unprotected intercourse since last menstruation
- **BMI Efficacy:** No restrictions

Effectiveness when used as described: 99%

- Breastfeeding: No effect
- Access: Provider insertion
- **Post-EC Contraception:** Can be used as ongoing contraception for up to 12 (copper) or 7

(levonorgestrel 52 mg) years

Contraindications: Same as IUDs for contraception use

www.PICCK.org Provider Toolkit: <u>https://picck.org/resource/emergency-contraception-toolkit/</u>

Phone Triage and Method Considertations Aid: https://picck.org/resource/telephone-triage-protocol-for-emergency-contraception/

# PHONE ROOM GUIDANCE ON EMERGENCY CONTRACEPTION

## Did a patient call saying something along these lines?



- "I'd like a prescription for the morning after pill <u>OR</u> Plan B <u>OR</u> emergency contraception."
- "I had sex and didn't use birth control, can I do anything to prevent pregnancy?"
- "The condom broke and I don't want to get pregnant."
- "I was sexually assaulted and I need something to prevent pregnancy." \*

Consider offering an urgent visit or referral to the ED

The patient you're talking with may be eligible for emergency contraception, which can help prevent an unintended pregnancy.



- The medicine works best the sooner they take it, so these calls are <u>URGENT</u>
- Please send the call as <u>HIGH PRIORITY</u> to the RN

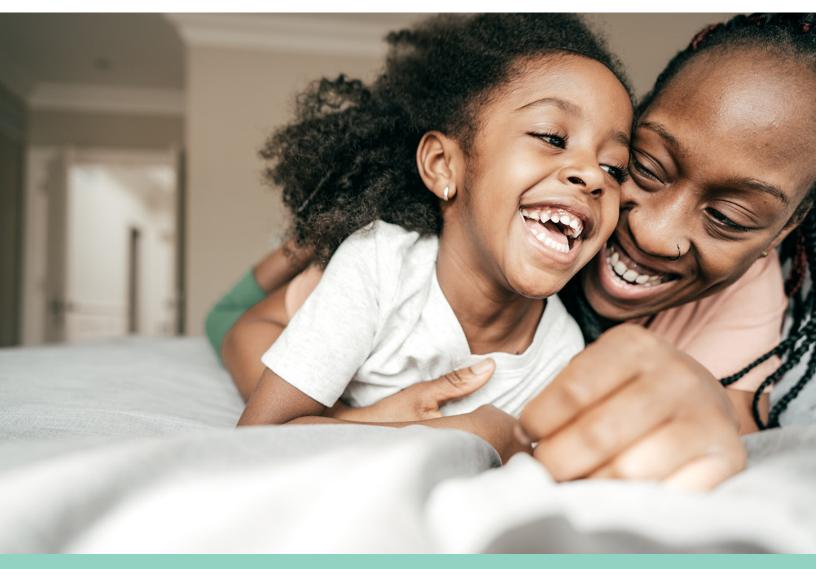


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Emergency Contraception	
Goals/Tasks	PICCK Contribution
<ul> <li>Providers:</li> <li>Learn about all methods, including indications</li> <li>Become comfortable with when to prescribe and when to offer IUD for EC</li> </ul>	<ul> <li>Grand rounds</li> <li>Webinar</li> <li>One-pager for providers on EC</li> <li>Resident presentation</li> </ul>
<ul> <li>Nurses:</li> <li>Understand urgency of calls</li> <li>Gain knowledge of all methods</li> <li>Be able to screen for EC eligibility</li> <li>Be able to counsel about EC options</li> <li>Learn where a patient can get ella</li> </ul>	<ul> <li>Presentation to nurses (includes training on the triage script)</li> <li>Phone triage script (includes screening and counseling)</li> <li>Infographic (counseling flow)</li> </ul>
Phone Room: Understand urgency of calls	<ul> <li>Talking points for presentation to phone room</li> </ul>
<ul> <li>Practice Leadership Decisions:</li> <li>Take up of nurse triage protocol</li> <li>Post of protocol</li> <li>Determine possibility of stocking ella in the practice</li> <li>Develop protocol for determining how ella availability at the pharmacy will be ascertained (RN vs patient)</li> <li>Establish standing orders for RN to call in script vs. getting provider prescription</li> </ul>	<ul> <li>Toolkit</li> <li>Sample protocol</li> <li>Sample email to launch change in protocol</li> </ul>
<ul> <li>Champion:         <ul> <li>Train phone room, explain the urgency of these calls</li> <li>Coordinate meeting for phone team and nursing leaders to launch implementation</li> <li>Determine how to ensure all staff members trained</li> <li>Communicate with hospital outpatient pharmacy to see if ella can be stocked</li> <li>Work with MD/admin leadership around same-day IUD as EC (scheduling, workflow, stocking of devices)</li> <li>Communicate with other departments re: best practices, referrals (ED, pedi, PC), PICCK training opportunities</li> <li>Decide on patient-facing resources to make available</li> </ul> </li> </ul>	<ul> <li>Trainings for other departments, as desired</li> <li>Patient-facing resources (curated)</li> </ul>
<ul> <li>Sustainability:</li> <li>Train new staff in phone room</li> <li>Train new nurses</li> <li>Check-in annually with other departments about referrals</li> </ul>	Best practices overview







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