Key Facts about Emergency Contraception (EC):

for Emergency Department Staff
that Provide Care to Sexual Assault and Rape Survivors

Massachusetts General Law c. 111, § 70E codifies the rights of female rape victims of childbearing age to receive timely access to EC in the Emergency Department (ED). To comply with this law, acute care hospitals must provide this legislatively-mandated fact sheet prepared by the Commissioner of Public Health to all ED staff that provide care to female rape victims of childbearing age who present to the ED (survivors) and fulfill all of the requirements described herein.

Under the law, all acute care hospital EDs must ensure that staff providing care to survivors:

- **Are provided with this** legislatively-mandated, medically and factually accurate MDPH Commissioner approved **EC provider fact sheet** titled *Key Facts About Emergency Contraception: For Emergency Department Staff that Provide Care to Sexual Assault and Rape Survivors,* available online at **www.mass.gov/emergencycontraception**.
- **Promptly provide the** legislatively-mandated, medically and factually accurate MDPH Commissioner-approved **EC patient fact sheet** titled *Five Key Facts about Emergency Contraception: For Survivors of Sexual Assault* to every survivor who presents to the ED after a rape. This EC patient fact sheet is available in the Massachusetts Sexual Assault Evidence Collection Kit (MSAECK) in English, and online in English, Spanish, Portuguese, and Haitian-Creole at **www.mass.gov/emergencycontraception**. If this fact sheet is unavailable in the patient's preferred language, use a competent medical interpreter to translate it instead.
- **Promptly offer EC to each survivor** and initiate a full course of EC medication (and not only a written prescription) in the ED upon her request.
- **Understand that they are prohibited from requiring** any survivor to complete any part of a sexual assault evidence collection kit or a police report as a condition of receiving any of the above.
- **Document the offer of EC information and EC medication** in the patient's medical record and ensure that any contraindications to EC resulting in the denial of EC access to a survivor who presents for care in the ED are documented in her medical record and based on best clinical practice.
- **Complete the MSAECK Form 2A: Provider Sexual Crime Report (PSCR) 'Emergency Contraception Report' (checkbox)** located in the mandatory reporting section of the anonymous PSCR for each assault case reported in the ED:

  70E Emerg. Contraception Administered: ☐ Yes ☐ Not indicated ☐ Declined ☐ Not offered

  - The anonymous Emergency Contraception Report must be completed for each assault case reported in the ED, whether or not EC was indicated or administered. A copy of the PSCR may also be found at **www.mass.gov/emergencycontraception**.
- **Ensure that the fully completed mandatory, anonymous PSCR is promptly faxed** to the Executive Office of Public Safety at 617-725-0260, and to the local public safety authority in the town where the assault occurred.
- Provide a notice of patient rights as required by M.G.L. c. 111, § 70E, as amended by Chapter 91A.
- Do not interfere with hospital compliance with the law, regardless of their personal values or beliefs, by instituting systems to ensure that 24 hours a day, 7 days a week all survivors are promptly provided full rights under M.G.L. c. 111, § 70E.

! After reviewing this fact sheet, please address any questions to a supervisor, or contact the MDPH Family Planning Program for additional information, support, or technical assistance at: www.mass.gov/emergencycontraception or 617-624-6060.

Medically and factually accurate information on Emergency Contraception (EC) pills:

EC is a safe and effective way to prevent pregnancy after sexual assault or rape.[1-8]

Taking EC as soon as possible significantly decreases a woman's chances of becoming pregnant from the assault. It is an important part of your role as an ED provider to provide medically accurate information about and prompt access to EC in the ED post-sexual assault, to ensure that the standard of care is met for all survivors.

What is EC?

EC regimens were first described in 1974 by doctors prescribing special doses of birth control pills to prevent pregnancy after rape. A dedicated product became available in 1998. Although EC has been safely and widely used by women seeking to prevent unintended pregnancy for over thirty years, public awareness remains low.[1,2] Therefore, it is especially important to inform survivors about EC.[2,6]

How do EC pills work?

- As with regular daily birth control pills, **EC pills prevent pregnancy by delaying or inhibiting ovulation**.[1,2,5,6,9-11]
- Recent reports state that **EC pills do not interfere with the development or implantation of a fertilized egg**.[6,12] No direct clinical evidence supports the theory that EC pills inhibit fertilization and prevent implantation of the fertilized egg.[1,2,5,6]
- EC will only work to prevent pregnancy if a woman is not already pregnant. **EC will not interfere with an established pregnancy and will not cause spontaneous abortion or miscarriage**.[1,2,5,6]

EC pill contraindications and side effects

Contraindications:

- Known or suspected pregnancy reported by the patient.[1,2,9,10]

Side Effects:

- Side effects are mild and few adverse events have been reported.[1,5]
- Some women may experience nausea and vomiting, and may be given anti-emetic medication preventively.[1,2] These symptoms are more common with combined oral contraception pills (OCPs) than with FDA-approved EC products.
- Other side effects may include short-term fatigue, headache, dizziness, lower abdominal pain, or a change in the timing or flow of the next menstrual cycle.[9,10]

Note: *Use of EC pills is* ***not*** *contraindicated in women whose pregnancy status is unknown. A pregnancy test is not required before EC can be administered,[1,2,6,13,14] although it is recommended prior to choosing ella® (refer to the product's package insert for details).[9,10]*

If a patient does not consent to a pregnancy test, she should still be offered information on EC, as there are no restrictions for use in cases of rape[3,4] and Massachusetts law requires hospitals to offer and initiate EC upon request for all survivors.[13,14]

! Potential Impact of BMI/Weight on EC Efficacy

A recent study suggests that more research is needed to determine the potential impact of BMI/weight on EC efficacy.[6,8] For women with a BMI of 26 or over who used progestin-only EC, pregnancy rates were no different than if they had not used EC at all. Ulipristal acetate (ella®) appeared to decline in efficacy at a higher BMI threshold of 35, suggesting that the most highly effective method for obese women is the copper IUD. Increasing the dose of EC pills for overweight or obese women has not been studied and is not currently recommended.[6,8] Helpful FAQs on weight and EC efficacy have been prepared by **www.rhtp.org** and **www.not-2-late.com**.

Women who are overweight or obese should not be denied their right to access EC pill regimens in the ED today, although they may also wish to consider emergency copper IUD insertion as soon as possible to maximize pregnancy prevention after sexual assault or rape (see page 3).

The most effective type of EC is emergency copper IUD insertion within 5 days after sexual assault or rape.[1, 2, 6]

Emergency copper IUD insertion may be clinically indicated as EC for women with a high BMI.[6,8]

ED staff are mandated to provide information about and acess to EC in the ED so that rape survivors have timely acess to the most highly effective pregnancy prevention methods. As emerging data now suggest that both ulipristal acetate and progestin-only pills rapidly decline in efficacy with increasing body mass index (BMI),[6,8] it is important for EDs to provide, at a minimum, information about and access to more highly effective EC methods, including emergency copper IUD insertion.

Emergency copper IUD insertion may not be:

- currently or consistently available in all ED settings, or
- clinically indicated at time of visit (due to active trauma or STI infection), or
- immediately appealing to many recent survivors of sexual assault or rape.

However, as the average American woman weighs 166 pounds, ED staff should be able to provide supportive referrals for emergency IUD insertion to facilitate access (see box below).

Intra-uterine contraceptive device (IUD): The copper IUD is **99.9% effective at preventing pregnancy for up to 5 days after sexual assault or rape**, and provides a highly efficacious, immediate, and cost-effective ongoing birth control method for up to 10 years post-insertion.[1,2,6]

- Pregnancy rates following copper IUD insertion are extremely low in comparison to any EC pill regimen, and remain at 0.1% since having been introduced in 1976. Hormonal IUDs have not been studied and are not recommended for use as EC.[6]
  - **Preliminary data suggests** that when clinically indicated, emergency insertion of the **copper IUD is probably the best EC choice for obese women.**[6,8]
- Like EC pills, the copper-bearing IUD works primarily by inhibiting fertilization, however post-coital insertion also may prevent the implantation of a fertilized egg.[2,15]
  - Use of a copper IUD is not associated with an increased risk of tubal infertility.[6,15]
- Clinical guidelines for emergency IUD insertion,[1, 2] including in the context of sexual assault[7,15] are available at **www.mass.gov/emergencycontraception.**
  - Research indicates that the presence of STI infection, not the placement of an IUD, increases PID risk.[15] Therefore, current ACOG guidelines[2] allow STI screening and IUD insertion on the same day, even for women presenting after rape,[7,15] as an asymptomatic chlamydia or gonorrhea infection may be treated with the IUD in place.[2,15]

! Helping survivors access emergency copper IUD insertion

- Women who are interested in scheduling an emergency IUD insertion should not be denied the right to receive EC pills in the ED and should be offered or referred for emergency IUD insertion as soon as possible.
- A supportive referral for IUD insertion may be provided to a nearby **MDPH Family Planning Program** by contacting 617-624-6060.
- **Rape Crisis Centers** can also provide medical advocacy for survivors in need of timely medical appointments and other ongoing services. Call 1-800-841-8371 or visit **www.surviverape.com**.

Two types of EC pills have been approved by the U.S. Food and Drug Administration (FDA):

1. **Ulipristal Acetate pills:** ella® is an EC pill that contains ulipristal acetate, a medicine that was FDA-approved in 2010 after being available in Europe for several years. It is available by prescription.

- The FDA has approved ulipristal acetate EC pills to be **initiated up to 120 hours (5 days) after unprotected sex (or sexual assault)**.[10]
- Ulipristal acetate is considered the **most effective medication available for preventing pregnancy after unprotected sex because it is statistically more effective than progestin-only pills throughout all 120 hours (5 days)**.[6,11]
  - Use of ulipristal acetate has been shown to result in up to 65% lower pregnancy rates following the use of progestin-only pills when administered in the first 24 hours, and up to 42% lower rates up to 72 hours after unprotected sex.[6]
  - Ulipristal acetate can prevent more pregnancies once the leading follicle has reached a larger size and ovulation is about to occur.[6,11]
- Unlike progestin-only EC, **the efficacy of ulipristal acetate does not decline throughout the 5 days following unprotected sex**. In part, this is because ulipristal acetate is able to prevent follicular rupture at a later stage of follicular development than progestin-only pills.[11,16]
- A recent study suggests that **the efficacy of ulipristal acetate may rapidly decline with increasing body mass index (BMI), beginning at a BMI of 35, or roughly 194 pounds.**[6,8] Until further evidence becomes available:
  - Women who weigh over 165 pounds, or who are likely to ovulate soon may be advised that ella® is the most effective pill regimen available, and that emergency IUD insertion may also be considered.[6,8]
  - Women who weigh over 194 pounds or have a BMI of 35 or over may be advised that when clinically appropriate, emergency IUD insertion is recommended as the most effective type of EC available.[6,8]
- It is not known whether use of ulipristal acetate, a progesterone agonist/antagonist, may briefly decrease the effectiveness of a woman's regular progestin-containing hormonal birth control method (like the pill, ring, or patch). **Therefore, women who choose ulipristal acetate for EC should be advised to abstain from sex or to use a barrier birth control method (such as a condom) until the start of their next menstrual cycle regardless of whether or not an ongoing hormonal method of birth control is used.**[10]

Dosing: 30 mg ulipristal acetate by mouth within 120 hours (5 days) after sexual assault or rape.[6,10,11,16]

Note: *More research is needed to learn if pregnant and breastfeeding women can safely use ella®. Patients who are unsure of their pregnancy status prior to the assault should be advised to take a pregnancy test before choosing ella®.*[10]

Two types of EC pills that have been approved by the U.S. Food and Drug Administration (FDA):

2. **Progestin-only pills:** Plan B One-Step®, and generic equivalents such as Next Choice™, MyWay™, and Levonorgestrel are FDA-approved EC pills that contain progestin, a hormone found in many daily birth control pills. **Plan B One-Step® is currently the only non-prescription EC product available for purchase by anyone (without age restrictions) at pharmacy shelves or counters**, although generic versions may soon be available without age restrictions.

   - The FDA has approved progestin-only EC pills to be initiated up to 72 hours (3 days) after unprotected sex (or sexual assault); however, research has shown progestin-only EC pills to be **effective when initiated up to 120 hours (5 days) after sex**.[17,18]
   - About **seven of eight pregnancies (88%) can be prevented** with timely use of progestin-only EC pills.[9]
     - Progestin-only pills reduce pregnancy risk by 87–90% if taken within 72 hours of unprotected sex. If taken between 72–120 hours, they reduce pregnancy risk by 72–87%.[18]
   - Patients should be informed that **progestin-only EC pills are more effective the sooner they are taken**.
     - For every 12 hours that a woman delays initiation, her chances of becoming pregnant increase by almost 50%.[19]
   - A recent study suggests that progestin-only pills may not be effective in women weighing over 175 pounds, as **the efficacy of progestin-only pills appears to rapidly decline with increasing body mass index (BMI), beginning at a BMI of 26 (or roughly 165 pounds).**[6,8] Until further evidence becomes available:
     - Women who weigh over 165 pounds, or who are likely to ovulate soon may be advised that ella® is the most effective pill regimen available, and that emergency IUD insertion may also be considered.[6,8]
     - Women who weigh over 194 pounds or have a BMI of 35 or over may be advised that when clinically appropriate, emergency IUD insertion is recommended as the most effective type of EC available.[6,8]
   - Using progestin-only EC pills **will not affect a woman's ability to become pregnant in the future**.[5] If progestin-only EC pills are taken when a woman is pregnant, or if pregnancy occurs despite use, they **will not cause an abortion or harm the developing fetus**.[3,5,9,10,20,21]

Dosing: 1.5 mg levonorgestrel by mouth as soon as possible within 120 hours (5 days) after sexual assault or rape. (If a two-dose regimen is used, both pills may be taken at once).[1,2,5,9,11]

Several daily combined estrogen/progestin oral contraceptive pills (OCPs) have been determined by the FDA to be safe and effective for off-label use as EC when taken in higher doses.[22] While some women may benefit from learning how to use OCPs for EC in the future when other options are not available, this method is not only less effective, but also increases the likelihood of experiencing side effects (like nausea and vomiting), making OCPs the least desirable option for most women following sexual assault. Dosing varies by type of OCP.[1,6,22] More information on these regimens is available at **www.not-2-late.com**.

Medical follow-up after taking EC pills for sexual assault or rape survivors

- Patient should be instructed to contact a medical provider immediately if she vomits within 2-3 hours of EC administration. A repeat dose may be advised.[9,10]
- If patient experiences severe lower abdominal pain 3-5 weeks after EC administration, she should be evaluated for ectopic pregnancy.[9,10]
- If menstruation does not occur within 4 weeks of EC administration, a pregnancy test is indicated.[13]
- If patient declined EC, she should be advised to have a pregnancy test 10 days after the ED visit.[13]
- Patients should be advised to use a back-up birth control method if possible, such as a condom until the start of the next menses.
- A regular hormonal contraception method can be initiated or resumed immediately after taking progestin-only EC or combined OCPs, or at the start of the next menses after taking ulipristal acetate.[10]
- EC does not prevent transmission of sexually transmitted infections (STI) or HIV.[9,10] Concerned patients should be counseled about the risks and benefits of STI and HIV prophylaxis.

Additional Support Services

- **Rape Crisis Centers** can refer survivors in need of ongoing services: Contact 1-800-841-8371 (English) or 1-800-233-5001 (Spanish) or **www.surviverape.org**.
- **MDPH Family Planning Programs** provide confidential, low-cost reproductive health care services sensitive to the needs of survivors. Contact 617-624-6060.
- **Massachusetts Department of Public Health Division of Health Care Quality** can assist survivors (or hospital staff) in lodging a formal complaint if the reason EC was not provided in the ED was not medically accurate or based on best clinical practice. Contact 1-800-462-5540.
- In the future, survivors can access EC at a clinic, pharmacy or search online. Massachusetts pharmacists trained to dispense EC without a prescription to all **individuals**, including those **under the age of 17** or who lack a valid ID, can be located at **www.massgov.com/emergencycontraception**.
- **National Clinician's Post Exposure Prophylaxis Hotline** can assist providers in urgent decision-making following exposures to HIV and hepatitis B and C at 1-888-448-4911 from 9am-2am EST (daily).

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This legislatively-mandated, medically, and factually accurate fact sheet prepared by Massachusetts Department of Public Health (pursuant to M.G.L. c. 111, § 70E) reflects current medical research and standard of practice (revised March, 2014). See **www.mass.gov/emergencycontraception** for a full text version of the law and other related resources.