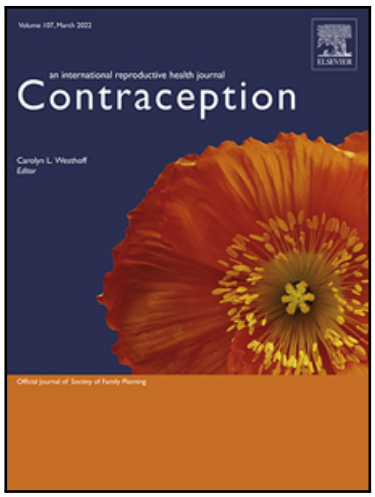

Now Is the Time to Safeguard Access to Emergency Contraception Before Abortion Restrictions Sweep the United States

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Commentary: Now Is the Time to Safeguard Access to Emergency Contraception Before Abortion Restrictions Sweep the United States

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Abstract

Abortion and contraception are essential components of reproductive healthcare. As 26 states are likely to severely restrict access to abortion following the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*, access to emergency contraception will be more important than ever. Existing barriers to emergency contraception – including cost, obstacles to over-the-counter purchase, low awareness and availability of the most effective options, myths about safety and mechanism of action – already substantially limit access. Proactive solutions include public information campaigns; healthcare provider education about all emergency contraceptive options, including IUDs and advance provision of emergency contraceptive pills; innovative service delivery options such as vending machines and community distribution programs; and policy initiatives to ensure insurance coverage, eliminate pharmacy refusals, and support all service delivery options. In addition, we urge the U.S. Food and Drug Administration to approve updated labeling to align with the best available evidence that oral contraceptive pills work before ovulation and do not prevent implantation of a fertilized egg, as this language contributes to public confusion and access barriers. In the face of extreme limits on reproductive healthcare, now is the time to expand and protect access to emergency contraception so that everyone has the possibility of preventing pregnancy after unprotected sex or sexual assault.

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1. Introduction

Individuals can only fully participate as equals in society if they have access to all strategies along the reproductive health continuum to determine when and if to give birth. Developed by Black feminist activists and scholars, the reproductive justice framework is defined by SisterSong as “the human right to maintain personal bodily autonomy, have children, not have children, and parent the children we have in safe and sustainable communities” [1]. Abortion is an essential component of reproductive justice, yet it is inaccessible for so many throughout the country – especially in the South and Midwest – due to numerous, harmful restrictions. Abortion will likely be even more severely restricted in 26 states after the Supreme Court rules in *Dobbs v. Jackson Women’s Health Organization*, with a decision expected in June or July 2022 [2]. The stark reality is that by prioritizing abortion restrictions, state lawmakers demonstrate they do not value people who can get pregnant, including most cisgender women as well as many nonbinary, gender noncomforming, and transgender people. It is seen in the refusal to expand Medicaid coverage (including postpartum coverage), unwillingness to invest in healthcare infrastructure, lack of support for family leave, and resistance to comprehensive sex education. The result is poorer health outcomes; especially in maternal mortality, and especially for Black birthing people who are 3 times more likely to die from a pregnancy-related cause [3].

Contraception and abortion are both necessary aspects of reproductive healthcare; contraception will never eliminate the need for abortion. However, contraception –especially emergency contraception (EC)– will be increasingly important for individuals as the stakes for preventing pregnancy become devastatingly high. Emergency contraception is unique in its

potential to prevent pregnancy after unprotected sex, contraceptive failure, and sexual assault. It will be more crucial than ever.

2. Barriers

Access to EC, available as pills and IUDs, is limited by substantial barriers. Time is of the essence when it comes to EC pills; the sooner they are taken, the more likely they are to interrupt ovulation and prevent pregnancy. Levonorgestrel EC, sold in the United States as Plan B One-Step® and value brands including Take Action® and EContra One-Step®, has been approved for over-the-counter (OTC) sale since 2013, yet myriad regulatory shifts over the years, including swiftly changing age restrictions for non-prescription sale, contribute to significant confusion about how levonorgestrel EC can be sold. It is not uncommon for pharmacy staff to request identification, imposing long-removed age limits. One study found that, among stores that imposed an age limit the required age ranged from 13 to 18, with several pharmacy staff indicating that were not sure what the age limit was despite having asked for ID [4]. The retail cost of EC in pharmacies—$40 to $50—is out of reach for many. This high price, already a barrier in itself, contributes to additional obstacles, such as pharmacies stocking EC behind the counter and locking the product in a fixed case or security box [4]. These stocking decisions force an encounter with pharmacy staff that may be unwelcome and eliminates one of the benefits of OTC status: the ability to maintain privacy, autonomy, and convenience. Such privacy concerns can be particularly prohibitive for people living in smaller and/or rural communities. In addition to these structural obstacles, an important limitation of levonorgestrel EC lies within the product itself; levonorgestrel EC does not appear to work after the luteinizing hormone surge has begun and it may be ineffective for those who weigh more than 165 pounds [5]. According to a metanalysis, levonorgestrel EC has an overall failure rate of 2.6% [6]. Myths about the safety of EC, including negative effects on future fertility, extreme side

effects, and harm to the reproductive system if taken multiple times, add to the stigma of EC and may limit individuals' willingness to use this product when they need it.

Ulipristal acetate EC, sold in the United States as ella®, was approved in 2010 and remains available by prescription only, although European authorities removed the prescription requirement in 2014 [7]. Ulipristal acetate EC works closer to the time of ovulation (a critical point in the cycle for preventing pregnancy) than levonorgestrel EC [8] and is therefore more effective for any user. It appears to be particularly more effective for individuals with higher body weight, although it too seems to have a limit of efficacy, at 196 pounds [6]. According to the same metanalysis referenced earlier, ulipristal acetate EC has a failure rate of 1.8% [6]. Ulipristal acetate EC is a promising alternative to levonorgestrel EC, but its use has been severely limited by intersecting barriers. Individuals who need ulipristal acetate EC must find a healthcare provider to provide a prescription, and then identify a pharmacy that will fill it. Despite more than 10 years on the US market, healthcare providers are unlikely to know about or prescribe ulipristal acetate EC [9,10], and pharmacies are unlikely to have it in stock [11]. While most pharmacies will order ulipristal acetate EC upon request, the additional wait for this time-sensitive product increases the risk of pregnancy.

IUDs are by far the most effective EC option and provide years of ongoing contraception if the IUD is left in place. The copper IUD is 99.9% effective when provided after unprotected sex [12,13] and emerging evidence demonstrates that the levonorgestrel 52 mg IUD is also a highly effective option [14]. The ability to nearly eliminate pregnancy risk with an IUD (rather than substantially reduce the risk with oral agents) could be extremely important in settings with severely restricted abortion access. However, to receive an IUD as EC, an individual must know that this is an option or present to a trained healthcare professional who does, be willing to undergo a procedure, and have the ability to pay. For those who do not have insurance, IUDs

can cost more than $1,000 [15]. Providers may not be aware of the use of IUDs as EC. Others may have biases surrounding IUDs that inhibit their willingness to offer them (particularly to certain patient populations such as adolescents or nulliparous patients)[16], or protocols that require two visits for patients to receive IUDs.[17] Therefore, the availability of trained providers and timely access to them is also severely limited in many places. States such as Texas have excluded qualified providers of IUDs including Planned Parenthood from their Medicaid program, again uniquely harming low-income people.

Pharmacy and provider-level barriers create an onerous gauntlet for many people who need EC. At the policy level, speculative language on the FDA-approved labels about how EC pills may work is used to justify far-reaching restrictions on EC access. It is highly unusual for labels to hypothesize about how a product might work, or for OTC labels to include mechanism of action language at all [18]. Nine words on the EC labels - (may also prevent) “attachment of a fertilized egg to the uterus (implantation)” [19] - have provided false scientific cover for anti-abortion groups that oppose EC. These include the families that own Hobby Lobby and Conestoga Wood, who took their opposition to covering EC as required by the Affordable Care Act all the way to the Supreme Court. This language has no basis in evidence, as the best available evidence demonstrates that EC pills work by preventing or delaying ovulation [8,20]. The label enables so-called “conscientious objectors” to refuse to provide EC based on religious concerns about abortion. These refusals disproportionately burden people of color, particularly those of lower socio-economic status and/or living in rural areas [21].

3. Solutions

In the face of worsening access to abortion, it is imperative that we proactively improve access and eliminate barriers to EC.

Accurate, evidence-based information for healthcare professionals and the general public is essential. We need funding and infrastructure for public information campaigns that educate people about all EC options. Myths and outdated information about safety, mechanism of action, and regulatory status must be countered with evidence and audience-appropriate messages.

Individuals can and should obtain EC before it is needed, to reduce costs and the stress of finding EC when it is urgent and to increase the possibility of obtaining ulipristal acetate, the most effective EC pill. Healthcare providers can help patients prepare in advance to prevent pregnancy after unprotected sex by offering an advance prescription for ulipristal acetate EC at each clinical encounter, calling pharmacies to ensure that ulipristal acetate EC is in stock, reminding patients that levonorgestrel EC is available OTC, and offering a prescription for levonorgestrel EC if required for insurance coverage.

Because levonorgestrel EC is approved for OTC status, it can be provided through innovative delivery systems such as vending machines. Provision of EC in vending machines can offer privacy, convenience, and extended access hours. At least 25 college campuses currently offer EC in vending machines, and a nation-wide effort is underway to expand to additional campuses [22]. EC access in vending machines can easily extend beyond college campuses to other public spaces such as mass transportation stations, laundromats, public parks, and other strategic access points. EC can be included in existing vending machines and new vending machines can be added to any safe public space with electricity (some vending machines also require internet access).

OTC status also allows the possibility of peer-to-peer and community distribution of EC. Mutual aid groups, abortion funds, and college activist groups are already developing distribution networks in which individuals contact a hotline and receive a delivery of EC, pregnancy tests,

condoms, and other reproductive wellness products. These groups are well-positioned to understand and meet the need for EC in their communities. They need logistical support, reassurance from legal professionals, product donations, and funding. These distribution networks could also expand beyond the traditional groups that have been at the frontlines of this work, including and not limited to church or other religious groups, private companies, government assistance programs, and carceral systems.

A change to the mechanism of action language on EC products is long overdue [18]. In the face of increasingly urgent need for expanded EC access, it is well past time for FDA to approve a change that updates language to align with the evidence that EC pills work before ovulation, and not after. Pregnancy prevention will be more urgent than ever, and it is unconscionable to continue to allow inaccurate language that is manipulated to limit access and public understanding of EC to remain on these labels.

Policymakers should take action to make sure EC is available at a wide variety of locations, at any time of day, without prohibitive cost barriers. Policymakers can increase EC access points by requiring emergency rooms to provide information about EC and access to it to survivors of sexual assault; supporting the use of vending machines as an EC access point; expanding pharmacist provision of EC pills (through extending prescription authority or collaborative practice agreements); removing regulatory barriers to EC provision via telehealth, including the use of all modalities and ensuring sufficient reimbursement; and increased funding to educate and train providers in the use of IUDs as EC. These access points are further enhanced when cost barriers to EC are reduced or, ideally, removed entirely. Cost barriers to contraception particularly impact communities of color - recent polling finds that one in three Latina women and four in ten Black women could not afford more than $10 for contraception [23,24]. To make certain that insurance actually covers OTC EC when people need it, more states should prohibit

insurers from requiring a prescription for coverage of OTC EC and make sure no such requirement exists in their state Medicaid program. Those states that already prohibit prescriptions for OTC EC coverage should enforce against non-compliant insurance companies.

At the federal level, there are multiple actions the Biden-Harris Administration can take to make certain that everyone has coverage of EC without cost-sharing, including OTC EC without requiring a prescription. Because the regulation of insurance markets is segmented among different agencies, this will require a multi-pronged set of actions. The Administration must rescind the Trump-era contraceptive coverage rules, which enabled virtually any employer or university to exclude EC from coverage entirely. The Administration should update guidance on the ACA's contraceptive coverage requirement to prohibit plans from requiring a prescription for OTC EC, thereby guaranteeing access without cost-sharing for most people with commercial health coverage. The Biden-Harris Administration can apply this requirement to issuers participating in the Federal Employee Health Benefits Program as well. Currently there is no independent requirement for Medicare coverage to include contraception. This should be rectified for all Medicare beneficiaries, including coverage of all forms of EC (including IUDs) with or without a prescription, and coverage should not have cost-sharing.

Policymakers must ensure that when someone needs EC, an individual healthcare provider's opposition to it does not prevent anyone from accessing the care they need. In the context of EC, these refusals of care often happen in pharmacies. Only eight states explicitly require pharmacists or pharmacies to provide medication to patients, while pharmacy boards in seven states allow refusals but prohibit pharmacists from obstructing patients' access to medication [19]. More states must ensure that people who need EC are not refused at the pharmacy. And at the federal level, Congress should pass the Access to Birth Control Act which ensures that any person who goes to a pharmacy for contraception is not limited by a pharmacy employee's

personal beliefs, and that they leave the pharmacy with their contraception in hand or can easily obtain it nearby [25]. Moreover, states and advocates should leverage existing antidiscrimination laws to prevent EC refusals at the pharmacy.

4. Conclusions

We need to act now to remove barriers and strengthen access to EC. Those who seek to limit access to EC rely on arguments grounded in personal ideology, not scientific evidence or concern for the well-being of others. Personal views should guide individual decisions, not limit the right to self-determination of others. Donors, policy makers, and activists must pay attention and take immediate action to preserve and expand access to EC. As accessing abortion becomes increasingly onerous, precarious, or impossible in some parts of the United States, we must make sure that everyone has a last chance to prevent pregnancy.

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