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Emergency Contraception: unresolved clinical, ethical and legal quandaries still linger

Simona Zaami[1], Fabrizio Signore[2], Alberto Baffa[2], Raffaella Votino[2], Enrico Marinelli[1*], Alessandro Del Rio[1*]

[1]Department of Anatomical, Histological, Forensic and Orthopedic Sciences Departmental Section of Legal Medicine, "Sapienza" University of Rome, Italy

[2]Department of Obstetrics and Gynecology, Misericordia Hospital, Grosseto, Italy

***: Equal contribution**

Corresponding Author: Simona Zaami. E-mail: simona.zaami@uniroma1.it

Abstract

Emergency contraception (EC) has been prescribed for decades, in order to lessen the risk of unplanned and unwanted pregnancy following unprotected intercourse, ordinary contraceptive failure, or rape. EC and the linked aspect of unintended pregnancy undoubtedly constitute highly relevant public health issues, in that they involve women's self-determination, reproductive freedom and family planning. Most European countries regulate EC access quite effectively, with solid information campaigns and supply mechanisms, based on various recommendations from international institutions herein examined. However, there is still disagreement on whether EC drugs should be available without a physician's prescription and on the reimbursement policies that should be implemented. In addition, the rights of health care professionals who object to EC on conscience grounds have been subject to considerable legal and ethical scrutiny, in light of their potential to damage patients who need EC drugs in a timely fashion. Ultimately, reproductive health, freedom and conscience-based refusal on the part of operators are elements that have proven extremely hard to reconcile; hence, it is essential to strike a reasonable balance for the sake of everyone's rights and well-being.

Key Words: Emergency contraception; guidelines; ethics; medicolegal issues

Introduction

For over 50 years, emergency contraception (EC) has been prescribed for women to reduce the risk of pregnancy after unprotected intercourse, including cases of unanticipated sexual activity, contraceptive failure, or sexual assault[1, 2]. Even though EC has become increasingly widespread over the past two decades, unwanted pregnancy, on account of contraceptive failure or unprotected (or inadequately protected) sexual intercourse still constitutes an issue. EC and the linked aspect of unintended pregnancy undoubtedly constitute highly relevant public health issues, which are liable to impact women's self-determination, reproductive freedom and family planning. However, there is a highly-charged ongoing debate on EC drugs, their availability without a physician's prescription, and the reimbursement policies that should be implemented. Oral emergency contraception has first appeared in medical literature in the 1960s, although the U.S. Food and Drug Administration

(FDA) approved the first dedicated product for emergency contraception only in 1998. Since then, several new products have been introduced. The review's Authors have aimed to investigate and expound upon the ethical and legal ramifications of EC use, in light of relevant guidelines, recommendations and positions from national and supranational bodies and institutions (United Nations, World Health Organization, International Federation of Gynaecology and Obstetrics, European Courts of Human Rights, Council of Europe, European Medicines Agency). An analysis has been conducted based on relevant findings in order to find out what European countries have issued national EC-specific guidelines for health care institutions, doctors and pharmacists. EC undoubtedly has repercussions that go far beyond the scientific and medical realms; The rift between the rights of those who object to it, whether on moral, philosophical or religious grounds, and the rights of patients who wish to exercise their self-determination or reproductive rights cannot be overlooked. It is essential to outline and properly eviscerate the reasons behind those apparently irreconcilable positions; only by finding common ground can the rights of all parties be effectively upheld by legislators, for the sake of strengthening our cohesion as a pluralistic community.

EC Methods

Four different EC methods are currently available in Europe[3, 4]:

•Levonorgestrel pills (LNG ECPs)

•EC pills containing ulipristal acetate (UPA ECPs)

•EC pills containing mifepristone

•Copper intrauterine devices (IUDs), to be applied within five days following unprotected sexual activity.

It has been shown that ulipristal acetate and the levonorgestrel-only regimen have the ability to prevent or procrastinate ovulation. Levonorgestrel delays follicular development when administered before the level of luteinizing hormone increases. Ulipristal acetate inhibits follicular rupture even after the level of luteinizing hormone has started to increase[5, 6]. Emergency contraception should not be conflated with medical and medicational abortion (i.e. abortion inducing medicines), whose ultimate purpose is to terminate an existing, already established pregnancy. EC is in fact effective only prior to the establishment of a pregnancy, in that it can prevent pregnancy following unprotected sexual intercourse, but is otherwise ineffective after implantation of the fertilized egg into the womb. Studies centered around high-dose oral contraceptives have found that hormonal EC is ineffective in affecting an established pregnancy or destroy, or even damage, a developing embryo[7]. Hence, EC medicines are not comparable to abortifacient drugs: levonorgestrel, EC pills, like Plan B One-Step , Next Choice One Dose and other generics contain the hormone progestin. They are available over the counter at drugstores without age restriction in most countries, whereas drugs containing lipristal acetate (UPA), and certain brands of oral contraception taken in increased doses for use as emergency contraception require a prescription at any age. On the other hand, abortifacient drugs contain

medication called mifepristone to induce abortion. Mifepristone can be taken under supervision up to 70 days after the first day of the last menstrual period. It is used in conjunction with misoprostol, which is taken later to complete the abortion. Mifepristone ends pregnancy by blocking the hormones necessary for maintaining a pregnancy. Misoprostol causes the uterus to contract and empty[8]. Furthermore, in countries or regions with no EC availability, the so-called "Yuzpe regimen" is frequently used, i.e. oral contraceptive medication made up of progestin and estrogen. EC can lower the risk of unwanted pregnancy resulting from unprotected sexual activity by 75 to 99%, based on the applied method of choice. The most effective EC method is the copper intra-uterine device, followed by EC pills containing ulipristal acetate and mifepristone. Levonorgestrel-only EC pills reduce the risk of pregnancy by at least half and possibly by as much as 80 to 90 percent following an act of unprotected intercourse[9]. As for the copper IUD, it primarily works through the inhibitory action of copper ions on sperm, thus preventing fertilization. Moreover, endometrial receptivity is adversely affected as well. This additional effect, which is not achieved via hormonal EC, apparently increases effectiveness[10]. Emergency contraception should not be confused with medical and medicational (i.e. abortion inducing medicines) abortion procedures, which are meant to terminate an existing pregnancy. EC is effective only before a pregnancy is established.

Recommendations and guidelines pave the way for more effective EC delivery mechanisms

In a February 2018 release, the World Health Organization asserted that "all women and girls at risk of an unintended pregnancy have a right to access emergency contraception and these methods should be routinely included within all national family planning programmes. Moreover, emergency contraception should be integrated into health care services for populations most at risk of exposure to unprotected sex, including post-sexual assault care and services for women and girls living in emergency and humanitarian settings". The WHO further underscores that "states should ensure that the commodities listed in national formularies are based on the WHO model list of essential medicines, which guides the procurement and supply of medicines in the public sector. A wide range of contraceptive methods, including emergency contraception, is included in the core list of essential medicines[11, 12]". According to the Committee on Economic, Social and Cultural Rights (United Nations Economic and Social Council in 2000) health-care facilities, commodities and services must be accessible to everyone without discrimination, and that includes EC services and drugs, as part of "the right to the highest attainable standard of health" (Article 12)[13]. Factors such as physical and economic accessibility and the opportunity to access all relevant information are key. Human rights bodies have long prompted states to make access to health care services easier to those who face considerable barriers in that regard, such as high fees, the requirement for preliminary permission by a spouse, parent/guardian or hospital authorities, hard to reach health-care facilities, and the lack or shortage of affordable and convenient public facilities. International human rights institutins and advocacy groups,such as the Committee on the Elimination of Discrimination Against Women (CEDAW), have often voiced their concerns over women's lack of access to contraceptive services and information in all regions of the world. The Committee has singled out

several obstacles affecting EC accessibility and has urged States to address them. Such obstacles include: high costs; lack of comprehensive medical insurance coverage; overly strict legal requirements; discrimination based on marital status; duress and coercion, with the potential to negatively affect women' s decision-making abilities and right to freely choose a given form of contraception[14].

EMA Paves the Way for Better Accessibility to EC

In January 2015, following a recommendation from the European Medicines Agency[15], the European Commission greenlit the marketing and distribution of ulipristal acetate EC pills in the European Union zone, which became purchasable from pharmacies over the counter. Although the decision from the European Commission is not legally binding, hence does not lead to mandates for EU Member States with respect to EC accessibility, most European national legislatures have adhered to the decision, making UPA ECPs are available directly in the pharmacies or are in the process of doing so[16].

What about accessibility? The European Parliamentary Forum on Population & Development (EPF) weighs in: checkered scenario in Europe

The diversity in national approaches and EC clinical guidelines may result in access inequalities in terms of reliable EC options for women in Europe.

In March 2018, a wide-ranging survey was released under the auspices of the European Parliamentary Forum on Population & Development (EPF), in partnership with Third-I and group of experts in sexual and reproductive health and rights who designed the survey questions and structures. The Atlas stratifies countries by color, in accordance with their respective performances in terms of making emergency contraception services well delivered and accessible: green, light green, yellow, orange, red, based on the decremental level of performance quality in EC delivery.

- 14 countries have been found to enforce restrictive policies in terms of EC accessibility (Andorra, Bosnia Herzegovina, Montenegro, Grecia, Bulgaria, Hungary, Slovakia, Poland, Lithuania, Belarus, Russia, Azerbaijan, Cyprus, Georgia) — more than any of the other groups. Such nations have apparently fallen short in terms of cost-effective reimbursement schemes and are also lacking in terms of online information provision
- Countries such as Iceland, Albania, Malta, Armenia, Czech Republic still present serious flaws in the delivery system, availability and reimbursement schemes for contraceptives.
- Luxembourg, Sweden, Estonia, Spain, Portugal, Moldova, Portugal, Austria, Ireland, Turkey, Slovenia have fairly effective delivery systems, ensuring EC to those who need it, but still lacking in terms of reimbursement mechanisms
- Green (Belgium, France, UK, Norway, Netherlands and Germany: only three among the countries surveyed manage to offer above-par or excellent general reimbursement schemes for contraception, which play a key role in opening up access to such services for citizens who need them. Belgium, France and the UK rank best of the 46 countries surveyed. A major factor setting these states apart is general reimbursement schemes which cover a range of contraceptive supplies[17].

At least 3 countries have chosen to enact age restrictions: Croatia and Italy (for women younger than 18) and Poland (for women younger than 15)[18].

The Hungarian government will continue to require prescriptions for all types of EC, basing such a decision, passed in January 2015, on patient safety concerns. in Malta, oral formulations of LNG and UPA EC were found to be available as of December 2016, without the need for medical prescription. In October the Maltese Medicines Authority announced the approval of EC pills over the counter, in an effort to safeguard quality, safety and efficacy levels. By December 2016, both UPA and LNG ECPs could already be bought at the local pharmacies. LNG ECPs still require a medical prescription in Hungary and Poland, whereas at least one brand of LNG ECPs has been registered in Croatia and Italy to be sold over the counter since October 2015[19]. Women in Croatia, Germany, Hungary, Italy, and Poland needed to visit a health care provider in order to obtain a prescription before purchasing levonorgestrel (LNG) ECPs. In 22 EU countries, women could purchase LNG ECPs in pharmacies, and in some countries, such as the Netherlands, Sweden, and Portugal, women could also purchase LNG ECPs from drugstores and other types of convenience stores. In Malta, LNG ECPs were not (and still are not) licensed and were therefore unavailable[20]. In 2012-2014, the European Consortium on Emergency Contraception undertook a survey about the availability of EC-targeted guidelines in European Union countries. It turned out that most EU countries had sets or recommendations or guidelines on EC, with the exceptions of Austria, Croatia, Ireland, Latvia, and Malta. Interestingly, the guidelines of eleven countries did not comprise UPA EC, and in only eleven out of 28 EU countries did they appear to be updated. Mostly, guidelines had been laid out and released by scientific and medical organizations, predominantly national societies of obstetricians and gynecologists. Moreover, although general practitioners and pharmacists undoubtedly play an important role in EC counselling and provision such profiles had rarely been directly involved in the devising and development of EC, or contraception in general, guidelines[21].

Table 1: How major European countries provide guidance for EC prescription and use

Country	Specific EC guidelines	Contraception guidelines comprising EC	Guidelines denomination and Issuing Organization
Austria	None	None	X
Belgium	None	2009	*Domus Medica*, released in 2009 by the scientific group of Belgian general practitioners; indications set forth therein mention LNG and UPA EC pills as well as IUD
Croatia	None	None	X
Cyprus	Officially adopted WHO guidelines (2008), renewed in 2015	WHO guidelines (2008, updated in 2015)	Department of Reproductive Health and Research World Health Organization. Medical eligibility criteria for contraceptive use, Fifth edition, 2015
Czech Republic	Yes	X	Moderní gynekologie a porodnictví, volum 16, číslo 1, published in 2007 exclusively devoted to EC
Denmark	Yes (2009)	X	Nødprævention, published in 2009 and exclusively devoted to EC
Estonia	Yes (2005)	Yes (2003)	Suukaudne hormonaalne kontratseptsioon, published in 2003, includes recommendations on LNG EC pills and IUD for EC; Ravimeetod – postkoitaalne kontratseptsioon, published in 2005, with recommendations on LNG EC pills
Finland	Yes (2010)	X	*Jälkiehkäisy*, updated on January 12, 2010, are exclusively devoted to EC.
France	Yes (2013)	Yes (2004)	*Contraception d'urgence Prescription et délivrance à l'avance*, released by the Haute Autorité de Santé (HAS) in 2013. In December 2013, HAS issued the factsheet *Fiche Mémo – Contraception d'urgence*
Germany	Yes (2015)	Yes (2008)	*Rezeptfreie Abgabe von Notfallkontrazeptiva („Pille danach"). Handlungsempfehlungen der Bundesapothekerkammer*, issued by the Federal Pharmacy Chamber (BAK), a set of recommendations for pharmacists
Greece	Yes (2013)	Yes (2012)	Sets of recommendations on LNG and UPA EC pills as well as on the use of IUD for EC were released in 2012-2013

Hungary	Yes (2012, 2015)	WHO guidelines (2008), renewed in 2015	Department of Reproductive Health and Research World Health Organization. Medical eligibility criteria for contraceptive use, Fifth edition, 2015; *SÜRGŐSSÉGI FOGAMZÁSGÁTLÓ TABLETTÁK Irányelvek orvosok és egészségügyI ellátó hálózatok számára* (Emergency Contraceptive Pills: Medical and Service Delivery Guidelines, 3rd edition, 2012)
Ireland	Yes (2015-2016)	None	Pharmaceutical Society of Ireland, guidance for pharmacists on the safe supply of hormonal EC
Italy	Yes (2015)	Yes (2004)	The Italian edition of Emergency Contraception: A guideline for service provision in Europe was published in February 2015, by the title *Contraccezione di emergenza: Una linea guida per la fornitura di servizi in Europa*, and was officially endorsed by the Societa' Italiana di Ginecologia e Ostetricia, Associazione Ostetrici Ginecologi Ospedalieri Italiani, Societa' Medica Italiana per la Contraccezione, Societa' Italiana della Contraccezione, and Associazione Ginecologi Territoriali.
Latvia	None	None	X
Lithuania			recommendations on hormonal EC and IUD were released in 2008 by the Lithuanian University of Health Sciences
Malta	None	None	X
Moldova	Yes (2015)	Yes (2015)	the 2004 World Health Organization's Medical Eligibility Criteria for Contraceptive Use, renewed in 2015
The Netherlands	None	Yes (2011)	Contraception Guidelines issued by the Dutch College of General Practitioners
Poland	Yes (2011)	Yes (2005)	Guidelines on contraception and EC are published in the monthly scientific journal *Ginekologia Polska*
Portugal	Yes (2015)	Yes (2011)	*Consenso sobre Contracepção* 2011, jointly outlined and published by the Sociedade Portuguesa de Ginecologia, Sociedade Portuguesa da Contracepção and Sociedade Portuguesa de Medicina da Reprodução. *Recomendações sobre Contraceção de Emergência*, *by* the Portuguese Society of Contraception published specifically for

			EC
Romania	Yes (2015)	Yes (2006-2008)	*Contraceptia si sanatatea reproducerii – ghid practic de utilizare a contraceptiei orale combinate si a dispozitivelor intrauterine*, published in 2006*; Ghid pentru managementul contraceptiei, published in 2006; and Planificarea familiala – ghid practic pentru furnizorii de servicii de planificare familiala*, published in 2008. In 2015, the Societatea de Educație Contraceptivă și Sexuală and the Asociația de Planificare Familială din România, published *Contracepția de urgență. Un ghid pentru furnizarea de ser- vicii în Europa*, with recommendations targeted to LNG, UPA and IUD
Serbia	None	Yes (2011)	*Kontracepcija, published in 2011*, the official book for students of the Medical Faculty
Slovakia	None	Yes (2009)	*Medical eligibility criteria for contraceptive use,* issued in 2009 by the Slovak OB/GYN Society
Slovenia	Yes (2011)	None	*Smernice za rabo nujne kontracepcije,* published in 2011 in Zdrav Vestn, Slovenia's guidelines dedicated exclusively to EC.
Spain	Yes (2015, 2019)	Yes (2008)	*In 2015* the Spanish Society of Contraception (Sociedad Española de Contracepción or SEC), published *Anticoncepción de Urgencia. Guía para la provisión de servicios en Europa,* with recommendations for LNG and UPA EC pills and the Cu-IUD. In addition, in 2019 this Society published the evidence-based clinical update *Protocolo Anticoncepción de Urgencia*
Sweden	Yes (2005)	None	Sweden has guidelines dedicated exclusively to EC: *Antikonception – Behandlingsrekommendation* (2005)
Switzerland	Yes (2008-2011)	None	*Sexuelle Gesundheit* are Switzerland's guidelines exclusively devoted to EC, published in 2008 by Sexual Health Switzerland: The Swiss Foundation for Sexual and Reproductive Health. Institutions also rely on the 2011 Emergency Contraception: Clinical Effectiveness Unit, by the UK Faculty of Sexual and Reproductive Healthcare
United Kingdom	Yes (2017)	None	*FSRH Guideline, Emergency Contraception,* published in March 2017 by the Faculty of Sexual and Reproductive Healthcare, is the United Kingdom's guidelines exclusively devoted to EC.

Devising better standards for EC accessibility: the Council of Europe lays the groundwork for more effective policies

The Council of Europe, the leading human rights organization in the continent, includes 47 member states, out of which 28 are also European Union members. All of the Council's members are signatories of the European Convention on Human Rights, which is charged with fostering and protecting human rights, sustainable democratic institutions and the rule of law. The European Court of Human Rights is tasked with overseeing the implementation of the Convention in each member state. Nils Muižnieks, the Council of Europe Commissioner for Human Rights, has released a set of recommendations for States to uphold and effectively safeguard the sexual and reproductive health and rights of European women. The recommendations unequivocally state that sexual and reproductive rights are human rights, hence all signatory States have the obligation to, enforce, protect, and uphold them. In that respect, initiatives aimed at pursuing better affordability, availability and accessibility of modern contraceptives is key to preserving reproductive rights, and that includes the removal of barriers that hinder timely access to emergency contraception; moreover, ensuring that all survivors of sexual violence, including women in war zones or detention facilities, victims of trafficking, asylum seekers, refugees and evacuees, can access comprehensive sexual and reproductive health services, including emergency contraception, should be prioritized. The Council of Europe report points out that "access to effective methods of modern contraception continues to be impeded by a range of affordability and availability deficits, information shortfalls and discriminatory policy barriers[22]". The Commissioner's remarks further highlight that exclusion is bound to lead to inevitable adverse outcomes and implications, particularly in certain segments of society, where women cannot afford modern contraceptive means autonomously. In addition, such barriers appear to be even more daunting in central and eastern European regions, where the contraceptive costs stay relatively high compared to average incomes. Still, it is worth noting that even in countries where contraceptives are relatively more affordable, many women, particularly adolescents and those living below the poverty line are still in no condition to buy them.

Ensuring timely access to EC for rape survivors is of utmost importance

As pointed out in the above mentioned Council of Europe report, policymakers should take action to ensure that EC is a consistent component of post-rape care. As many as 5% of rape victims become pregnant[23]. Many national legislatures have put in place provisions requiring the availability of EC drugs in health care institutions and other facilities where rape survivors are treated. Following the release by the World Health Organization of international guidelines on sexual violence in 2013[24], which laid out recommendations for the EC to be an integral part of thorough women-centered care for rape survivors, various countries with high rates of sexual assault, among which Bolivia[25], Brazil[26], Ecuador[27], Kenya[28], South Africa[29] have also issued guidelines aimed at the proper management of sexual assault cases; all such releases recommend that EC be made available in a timely fashion. In addition, the United States President's Emergency Plan for AIDS Relief (PEPFAR) has issued targeted instructions on EC for post-rape care of children and adolescents[30]. The U.S.

Department of Justice (DOJ) released in 2013, the second edition of "a National Protocol for Sexual Assault Medical Forensic Examinations"[31] aimed at providing guidance for the proper management of sexual assault incidents. Such a set of guidelines was meant to confirm earlier recommendations which called for emergency contraception to be made directly available to victims of sexual assault; for women who are treated in religiously-affiliated hospitals, prompt referral must be guaranteed for them to have timely access to EC. The DOJ has remarked that in cases of sexual assault, unwanted pregnancy is often an overwhelming and realistic fear; it becomes therefore essential for health care providers to discuss treatment options with patients, including emergency contraception. Nonetheless, only 17 US states have legal statutes which mandate that emergency contraception be made available to victims of sexual assault, and the enforcement of such provisions has also proven somewhat challenging[32].

Furthermore, another very relevant treaty was adopted by the Council of Europe Committee of Ministers on 7th April 2011: the Convention on preventing and combating violence against women and domestic violence, also known as the Istanbul Convention[33]. It was opened for signature on 11th May 2011, and came into force on 1st August 2014. Among the nations that signed and ratified the Convention, thus making it binding, Italy has since then decided to set in motion a process aimed at improving care and assistance for sexual assault victims, by devising and enforcing national guidelines for health care institutions and facilities; such directives explicitly mention EC as a necessary tool in such cases[34].

European Commission Parliamentary Assembly: access to contraception may be instrumental to reduce abortion rates

A 2008 set of Recommendations from the European Parliamentary Assembly has stressed how access to EC could contribute to reducing abortion rates[35]. Specifically, the report lays out that the availability of affordable contraception has gone a long way towards reducing abortion rates over the years, in particular in Central and Eastern Europe. It is worth noting that in some countries such as the former Soviet republics, abortion was used for decades as a substitute for contraception. There is no proof that abstinence may be an effective answer either: according to some studies, abstinence-based programs in the United States have often proven ineffective in preventing sexually transmissible diseases (STDs), unwanted pregnancies and even abortions. Guaranteeing access to affordable emergency contraception and easing up the restrictions on over the counter marketing maybe significant contributing factors in abortion prevention, albeit such a correlation is still somewhat controversial[36, 37].

Lingering ethical quandaries: when does pregnancy begin?

Conscientious objection is often grounded in the belief that fertilization marks the beginning of pregnancy, and human life has equal moral value irrespective of its form or development stage. Often, Catholic hospitals and facilities are not allowed to provide EC even to rape victims, if any possibility exists that a woman may have got pregnant as a result of the sexual assault[38]. Therefore, the ethical debate on this issue

centers on whether a pregnancy begins at fertilization or at a later stage of the reproductive timetable, with potentially serious implications. This problem does not occur in those cultures where abortion is viewed as a form of contraception to be used if other methods fail. According to the Guttmacher Institute, an organization and advocacy group for the advancement of sexual and reproductive health, any definition that conflates fertilization with pregnancy runs counter to the well-established and widely acknowledged view of the medical and scientific community[39]". In fact, medical and scientific authorities tend to consider a pregnancy to be established only after the implantation of a fertilized egg has taken place. The beliefs of many EC opponents in that regard are viewed by many as purely just faith-based opinion and/or moral theory. The assertion that EC drug use is tantamount to aborting a pregnancy is a merely subjective view: no medical data definitively support that.

How to reconcile reproductive rights and EC with conscientious objection of health care operators?

In a broader sense, scientific advancements have created a rift between sexuality and procreation, which no longer go hand in hand; the ensuing disconnect between sexuality and procreation has led to a biological and emotional separation between sex and reproduction, which was initiated by contraception. Sex without reproduction (achieved through contraception) is inevitably contentious, ethically and morally, and so is, for instance, in-vitro fertilization (IVF), i.e. reproduction without sex[40, 41]. Objecting professionals, doctors, nurses and pharmacists, may conscientiously refuse to dispense EC medicines because they consider emergency contraception to be equivalent to abortion or because they deem contraception itself as an immoral intervention. Coscientious objection to EC is controversial, with many analysts pointing out that it is extremely difficult to strike a respectful balance between the interests of objecting providers and patients in this case[42]. Some EC methods act following oocyte fertilization, yet before the establishment of the pregnancy itself. Some view that mechanism of action as leading to a sort of "early abortion", hence labeling such techniques as "abortifacient". People who object to all forms of abortion regard such contraceptive techniques as morally wrong (whether on ethical, moral or religious grounds). Many objectors consider the so-called "morning-after pill" (one of the most common EC methods) a potential form of abortion. Morning-after pills are high-dose birth control pills. They prevent pregnancy by acting in various ways: by keeping eggs from being released, by inhibiting sperm or by warding off the implantation of a fertilized egg. The last of these methods of operation is regarded as an abortion by some people. When a woman uses an emergency contraceptive, neither she nor the doctor can know whether the technique works as a contraceptive to prevent fertilization, or terminates the development of the fertilized egg. Thus, the possible risk of "abortion" leads opponents of abortion to object to these techniques. According to a bulletin from the American College of Obstetricians and Gynecologists EC users are mostly 25 or younger, have never been pregnant, and have used some form of contraception before[43]. Various studies have shown that making emergency contraception more available does not encourage risky sexual behavior or increase the risk of unintended pregnancy[44, 45]. Several published randomized trials have evaluated the policy of providing emergency contraception to women at the time of a routine gynecologic visit so that they will

have the medication immediately available if a contraceptive mishap occurs[46]. Apparently, scarce evidence supports the fears and concerns about reckless sexual behavior and overreliance on emergency contraception[47, 48]. It is as yet unknown whether over the counter EC availability could come at the expense of doctor-patient contact overall or what impact the purportedly fewer contacts might have on clinical outcomes and sexual behavior[49]. The American Academy of Pediatrics (AAP) has released a policy statement on conscience-based refusal to provide information or treatment. According to the policy position, pediatricians have a professional duty to inform their patients about any relevant, legally available treatment options to which they object; moreover, they are morally bound to refer patients to other physicians who are willing to provide, and educate about, such services. Hence, any failure to inform/educate about availability and access to EC services would breach the duty to their adolescent and young adult patients[50]. A significant AAP Policy Statement on Emergency Contraception argues that despite multiple studies that have found no increase in risky behaviors and no conclusive evidence that hormonal EC cannot disrupt an established pregnancy, public and medical discourse shows how the personal values of physicians and pharmacists continue to affect EC access, particularly for adolescents. Several randomized controlled trials have concluded that the advance provision of emergency contraceptive pills did not increase rates of sexually transmitted infections or sexual risk-taking, although one study noted that EC could increase higher sexual risk-taking, causing a higher tendency to substitute EC for more effective contraceptives such as condoms[51, 52]. A randomized controlled trial of 2000 women in China compared women with advance EC access to women with no access at all, and remarked that the pregnancy rate was the same between the two groups. According to the study, the advance provision of EC does increase its use; still, no direct evidence has been found that it may reduce unintended pregnancy rates, concluding that EC may not lower abortion rates[53].

Further argument by EC opponents: over-the-counter EC is harmful to patients

Opponents argue that over the counter EC drugs might potentially deprive users of the benefit of medical counseling sessions, through which the physician could assess possible exposure to STDs, prescribe ongoing contraceptive methods, and provide behavioral counseling. Patients would in fact be less likely to use emergency contraception correctly on their own than if properly instructed in an office visit. Furthermore, some opponents contend that unrestricted access to EC might encourage high-risk sexual behavior, which entails a high risk of being exposed to STDs, particularly in adolescents; also, relying on EC methods as substitutes of other contraceptive methods, they argue, could ultimately be harmful to users. Doctors or pharmacists who choose to deny to prescribe or provide EC to patients do so on account of ethical, religious and moral concerns. Yet, conscience clauses generally include safeguards for patients, meant to ensure that access to the best treatment option is not denied. Such clauses would theoretically bind doctors who invoke a conscientious objection to refer the patient to another non-objecting physician; granted that EC (or even abortion) is legal, then patients ought to be guaranteed access to it in a timely fashion. In cases where only one qualified doctor is available (in remote or rural regions, for instance), he or she should not be able to use conscience clauses to deny care to a patient. However, rarely are all such protections

explicitly in place within the norms. In fact, although most conscience clauses are interpreted to refer only to doctors who get directly engaged in a given procedure, others are more loosely defined and could be inferred to include other professionals with less direct involvement in the procedure itself. For example, there have been cases involving pharmacists refusing to fill emergency contraception prescriptions and health care institutions refusing to provide abortion services or emergency contraception, which led to patients being denied access to a legal abortion or necessary medication. Both the World Health Organization (WHO)[54] and the International Federation of Gynaecology and Obstetrics (FIGO)[55] have released guidelines on the thorny issue of conscience clauses. They state that medical professionals who refuse to perform any procedure have a duty of referral, in a timely fashion, to another professional willing to perform the procedure or fill any prescription.

Freedom of conscience can be exercised within certain boundaries: the ECHR sheds a light

The European Convention on Human Rights has outlined clear provisions both for freedom of conscience and for the appropriate limits on the exercise of that freedom in terms of others' rights. Article 9 states, "Everyone has the right to freedom of thought, conscience and religion…." This is further explained in Article 14, which states, "The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as religion, political or other opinion…." However, it is qualified by Article 9, "Freedom to manifest one's religion or beliefs shall be subject only to such limitations as are prescribed by law and are necessary in a democratic society in the interests of public safety, for the protection of public order, health or morals, or for the protection of the rights and freedoms of others[56]." That became apparent in 1999, with the French case, Pichon and Sajous v. France, which went all the way to the European Court of Human Rights. The two French applicants owned and ran a pharmacy. In 1995, they refused to sell prescribed contraceptives to three women, citing conscientious refusal. These three women then decided to file a complaint for this refusal, an offence provided for and punished by the French Consumer Code. The pharmacists argued before domestic courts that their refusal was justified as no statutory provision required pharmacists to supply contraceptives or abortifacients. After losing their initial case, and two appeals, the applicants complained to the European Court of Human Rights, asserting that their right to freedom of religion under Article 9 of the Convention had been disregarded by the domestic courts. Their refusal to sell contraceptives was, in their eyes, a manifestation of their freedom of religion. The court held that the applicants' conviction did not interfere with the rights guaranteed by Article 9, which does not always guarantee the right to behave in public in a manner governed by a person's belief or protects each and every act or form of behavior motivated or inspired by religion or belief. The Court declared the application inadmissible based on the reasoning that "the sale of contraceptives is legal and occurs on medical prescription nowhere other than in a pharmacy, the applicants cannot give precedence to their religious beliefs and impose them on others as justification for their refusal to sell such products[57]". It is worth highlighting that in terms of health care, within the framework of the ECHR, the use of conscience conscience clauses is limited by those articles that protect the right to life and the right to privacy, including Article 2(1),

"Everyone's right to life shall be protected by law" and Article 8(1), "Everyone has the right to respect for his private and family life…."[58]. It can be concluded that cases concerning conscientious objection in the implementation of medical procedures or the provision of medication have not been treated as 'exceptional cases' by the ECHR[59].

Italian statutes, on their part, uphold the right to conscientious objection in "reproduction science" in two cases: voluntary interruption of pregnancy (as set by law of May 22nd, 1978, no. 194) and assisted reproductive technology (law of 19th February 2004, no. 40)[60, 61]. Hence, no statutory norms exist to allow for conscientious objection in the prescription and in the supply of any EC method[62]. Nonetheless, article 22 of the 2014 Italian Code of Medical Ethics allows operators who are required performances or services that are in contrast with their beliefs to refuse their work, unless such a denial constitutes a serious and immediate damage to the health of the patient[63].

Conclusions

The issue of conscientious objection invoked by health professionals in the broad setting of reproductive and sexual health care undoubtedly has an impact on women's ability to access health services. The right to object and deny treatment or medication on grounds of conscience has already been recognized by many European and international analysts and scholars, who deem it to have stemmed from the right to freedom of thought, conscience and religion. Still, it should not be viewed as an absolute right. Undeniably, conscientious objection has the potential to impact large segments of the population; that scenario is even more complex due to the reliance on privately owned and run institutions for the provision of health care services, often with public funding as well. That undoubtedly results in a certain degree of ambiguity between the public space, in which people and corporate entities should have similar rights and responsibilities, and the private sector, in which there is more room for personal beliefs such as those on which conscientious refusal is usually based[64]. When conscientious objection and the exercise thereof conflict with patients' human rights and basic freedoms, a balance must be sought between the right to conscientious objection and the rights of others who may be negatively affected. The right to respect for private life, the right to equal treatment and opportunities and to be free from discrimination, and the right to receive and impart information are all basic, fundamental rights that cannot be impinged upon. In the broader context of reproductive care, nations that allow health care professionals to exercise their right to conscientious objection need to make sure that such an exercise does not compromise or deny the right of women to access health care services[65].

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