

## Medical advancements: emergency contraception (EC). Medico-legal implications of EC on adolescents

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### Abstract

The article's main focus is documenting what the best options are in order to make sure that minors are allowed to play a key role in the management of issues arising from the use of emergency contraception. In that regard, there is a lack of clean-cut legislative measures and, although there are several legal and ethical norms designed to get parents or legal guardians involved in such decisions, there seems to be an increasingly widespread tendency to give weight to the minor's will, thus acknowledging her decision-making capacity. Lastly, the paper's authors undertake a thorough examination as to what the duties of doctors are, and the measures that need to be put in place in order to safeguard the minor patients' conditions. They arrive at the conclusion that emergency contraception is suitable for minors even in absence of the stated consent from their parents or guardians, but it is of utmost importance to implement adequate measures aimed at the provision of proper care, prevention and education. *Clin Ter 2018; 169(1):e34-37. doi: 10.7417/CT.2018.2051*

**Key words:** emergency contraception, minors, counseling facilities, information, gynecologist

### Introduction

Over the past century, changes in medical science have been characterized by an indisputable primacy of specializations and a progressive fracturing of medical knowledge into multiple subspecialties (1) which have, on the one hand, made it possible to intervene with greater effectiveness on individual diseased organs, but on the other hand, have all but nullified a direct and human doctor-patient relationship (2). Yet, 21<sup>st</sup> century medicine presents a great deal of contradictions; hospital-acquired infections are still rife (3) and giving birth may still result in tragedy (4-6). In spite of all that, there has been growing momentum towards the development of innovative diagnostic and preventive measures (7), resuscitation and transplant techniques have been greatly improved (8-10) and the number of transplantable organs, even if they are still experimental interventions (11)". Stem-cell research is set to make the regeneration of almost any kind of human

tissue feasible (12); preimplantation genetic diagnosis on embryos is expected to identify congenital abnormalities (13-17). The development of new molecules is likely to improve cognitive processes (18) and will guarantee an ever wider array of treatments. Reproductive medicine has greatly evolved, as well as emergency contraceptive methods.

### Morning after pill: mechanism of action

Before delving into emergency contraception (abbreviated in EC)-related issues with minor patients, it is worth dwelling on a few technical aspects. Over the past 50 years, giant strides have been made in the field of EC, which have brought to the discovery of safe and well-tolerated molecules. CE is resorted to limited to cases of unprotected sexual intercourse or of failure of other contraceptive methods (19). In such cases, the timely administration of said molecules can lower the likelihood of pregnancy by inhibiting ovulation or putting it off for a few days, so that spermatozoa in the female genital tract cannot fertilize any egg throughout their life cycle (20, 21). The definition of "emergency" hints to the need for the timely administration of such drugs in order to harness their full potential, which is limited to a fairly short time-frame during which they can intervene on ovulation (22, 23). Nonetheless, EC cannot replace conventional contraceptive methods, since it has lower effectiveness compared to modern oral contraceptives.

There are two EC drugs currently marketed in Italy: Levonorgestrel, sold under the name "Norlevo" or "Levonelle" (24-25) and 30 mg Ulipristal acetate, under the name "ellaOne" (26). Levonorgestrel has proved effective when administered within 72 hours from potentially reproductive sexual intercourse (effectiveness rate of 95% within 24 hours, 85% within 24-48 hours, 58% within 48-72 hours); two pills should be taken 12 to 16 hours apart. Ulipristal acetate has longer lasting action, spanning as long as 120 hours after unprotected intercourse; for that reason, it is informally known as "five days later pill" Both drugs inhibit the fertilization of eggs, since they are designed to delay ovulation by a few days before the process itself begins

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(72-hour pill), or even after it has already begun (120-hour pill); if ovulation has already occurred and an egg has been fertilized though, such drugs are ineffective (27).

Both drugs used to require a medical prescription (valid for a single purchase) to be dispensed. The Italian Medicines Agency, through a directive on 21<sup>st</sup> April 2015, (28, 30), has modified the prescription requirements of EllaOne contraceptive medicine as follows: “for patients aged 18 or older: no prescription required. For underage patients, medical prescription is still needed, valid for a single purchase”. Furthermore, in order to come by the “five days after pill” a negative beta hcg test is no longer necessary, as it was already the case in the rest of Europe. Since the medical prescription requirement was repealed, sales have been significantly rising: between May 2014 and April 2015, EllaOne accounted for just 6.8% of the emergency contraception market, reaching 53.8% in the following year, with peaks of over 70% in certain regions, a huge 686.7% growth nationwide. Therefore, sales of Ulipristal acetate have greatly soared: 7,796 packs in 2012, 11,915 in 2013, 16,796 in 2014 and 83,346 in 2015; minors between 15 and 17 accounted for most of the increase (31).

#### **The administration of contraceptives to minors. Can emergency contraceptives be prescribed without parental consent?**

In Italy, statistical data reflect how emergency contraceptives are in high demand among adolescent girls, which often do not use any birth control, or do so only occasionally. Can underage girls legally come by emergency contraceptives without parental consent?

Italian legislation do not comprise any specific law regulating underage girls' access to contraceptives. Law n. 405, 1975 (32) established family counseling centers, within which law, article 2 explicitly extended to minors all rights that adults enjoy with regards to contraception.

Article 2 of Law 194/78 states that the “access to all means available and medically prescribed in order to pursue responsible procreation goals shall be granted to all citizens, including minors”. It is not specified in the article's wording whether or not consent from parents or legal guardians is a requisite condition, but their involvement is not ruled out either. Art.12, 2<sup>nd</sup> subsection expressly states that minors are entitled - once documented the existence of “serious circumstances making it impossible or not advisable to get involved parents or legal guardians” - to appeal directly to the courts in order to exercise their right to have an abortion (33). If such a rationale is legally sound for abortion requests, it holds valid for access to the “morning after pill”, by virtue of its being deemed an emergency contraceptive measure. Moreover, Italian legislation on sexual abuse acknowledges individuals over the age of 13 as entitled to engage in sexual acts (with other minors, not older than 3 years their senior) (34). Obviously, no legal restriction exists in cases of minors who have their parents' consent. An issue does arise in cases of underage girls who do not want their parents involved. In such instances, no regulation exists. It is therefore necessary to take into account the minor's age: 1) in cases of individuals under 14, the parents' or legal guardian's opinion must be

probed; if there is a discrepancy between the minor's decision and her parents' (or guardian's), doctors must call for a decision from a family law judge; 2) For minors between 14 and 18 years of age, consent to undergo emergency contraception may be acquired irrespective of the parents' presence.

The Italian legislative framework entails the fulfillment of legal requirements related to certain age-brackets or possible wrongdoing that doctors may learn of upon receiving a request for the prescription of contraceptives. In particular, as for cases of consensual intercourse, doctors are mandated to report to the authorities any instance of 1) sexual acts involving children under the age of 10; 2) sexual relations between a child under the age of 14 and a partner over 3 years his or her senior 3) sexual acts occurred between a minor between the age of 14 and 16 and an adult in a position of being the minor's guardian or in exchange for money (art. 609-*quater* c.p.). Doctors must report to a juvenile court if they find out that the underage girl engages in prostitution (Law n. 269/98).

The 2014 Italian Code of Medical Ethics, article 34, mandates that doctors “provide minors with informational support in order for them to be able to understand his or her health conditions and the diagnostic or therapeutic pathways to be undertaken, for the purpose of getting them involved in the decision-making process”.

Doctors are required to take into proper consideration opinions expressed by minor patients about every decision-making process liable to affect their well-being (art.35) (35-38).

In light of all the above mentioned directives, it might seem inconsistent to concede that an underage girl may engage in sexual acts while at the same time, she may not legally opt for contraceptive pharmaceutical treatment.

The suitability of prescribing contraceptive drugs is also identifiable within the United Nations Convention on the Rights of the Child, which codifies the right of children to freely express their opinions any issue or prospect which may affect them, and to receive adequate medical care, including family planning education and services (art.24) (39, 40). The European Parliament, via Resolution 2001/2128, has also acknowledged that sexual education should be provided starting at an early age, and to that end, it “recommends the governments of the Member States to provide comprehensive information concerning effective and responsible methods of family planning, ensuring equal access to a range of high quality contraceptive methods as well as fertility awareness methods” (41). On the basis of such recommendations and considering how minors' decision-making capacity is universally acknowledged, it can be undoubtedly stated that underage girls are entitled to have access to emergency contraceptives, though in absence of parental consent or permission from their legal guardians, with utmost respect for their right to privacy (42, 43).

Hence, prescription of emergency contraceptives for minors poses a privacy-related issue as well. How should a doctor act when asked for a contraception prescription by an underage girl who is unwilling to inform her parents? The 2014 Italian Code of Medical Ethics, art.10, asserts: “Doctors have a confidentiality duty with respect to any information that they learn of by virtue of the exercise of

their professional activity...disclosure is only acceptable when motivated by solid reasons under current codes, or in order to fulfill a legal obligation, as mandated by law” (38). According to this paper’s authors, if doctors face a mentally capable underage girl who deliberately decided to conceal from their parents her decision to take birth control drugs, her decision should be complied with. In fact, if a doctor fails to respect his or her patient’s will, their trust-based relation may well be undermined, resulting in the patient feeling estranged and giving up on the treatment or care that she needs. Rather, doctors should welcome any chance to advise their patients on the best available contraceptive methods.

Article 2 of Law n.194/1978, in acknowledging the appropriateness of prescribing contraceptives to minors, identifies health care facilities and counseling centers as ideal places for the provision of sexual and reproductive health care aimed at adolescents. The reason appears to be clear: prescription of contraceptives for that age bracket must come hand in hand with solid counseling and education which need the support of disparate professional figures: gynecologists, psychologists, social workers, etc... Such professionals may be found in public facilities. For that reason, the law identifies counseling centers as the most suitable places for the prescription of EC to adolescent patients. Certainly, family doctors and general practitioners should provide girls with all the relevant information in order to enable them to make a sensible decision. Whether counseling takes place in public facilities or in private institutions, it is pivotal in the patient’s decision-making process, because she needs all the information which may assuage her anxiety and dispel her worries. It is therefore essential that doctors adopt the right approach with the patient, aimed at starting effective communication, with as high a degree of empathy as possible.

First and foremost, doctors should make sure that their patients possess solid psychological maturity, based on interviews and all available elements. Secondly, they should mention the possibility to get their legal guardians involved. If the patient objects, the doctor should ensure that she is not being swayed by her partner, and that there is no element of abuse on the part of her parents or guardians (44). In such instances, doctors are legally bound to report any possible wrongdoing to the authorities. Thus, physicians should assess their minor patients’ health conditions, the motivations behind their choices, their ability to fully understand the information and to evaluate the consequences of their decisions, in addition to appreciating possible negative repercussions. In those cases in which doctors detect an overly high degree of emotionality or if they realize the presence of external pressures from third parties, they should recommend psychological counseling. If the right conditions to prescribe EC are found to exist, doctors ought to inform the patient thoroughly, not just on the methodology and times of administration of the medicine, but on possible side-effects and contraindications such as: precedents of thrombosis; major liver disease or acute active porphyria; the administration of other medication liable to conflict with the contraceptive drug’s effectiveness. Doctors should also make it clear that, in case of ongoing pregnancy, administration of emergency contraceptive medicine cannot bring about a termination of pregnancy. At any rate, physicians must explain that emergency contraception should not be viewed and used as an

ordinary contraceptive method, since it is far preferable to resort to safer, long-lasting contraception, because pregnancy may be harmful to an adolescent’s health (41) regardless of the fact that she decides to terminate her pregnancy or to go forward with it. Having done that, doctors should grant the patient’s request and work towards fostering a better, more functional relationship with those who requests such drugs on account of a perceived sense of “urgency” (45).

#### **Conclusions: from emergency to conscious choice**

Scientific studies have proven that a great deal of adolescent girls have received extremely lacking sexual education. In particular, an American survey has shown that they have an average degree of knowledge as to the existence of contraceptive methods, but an insufficient knowledge about its ultimate goals, its mechanisms of action and ways of use (46). From such findings, it can be inferred that there is a pressing need for social policies geared to provide solid sexual education to adolescents, with regards to contraceptive methods as well. Mandatory prescription for underage girls, who may purchase such drugs freely if they were sold over the counter, without consulting with a gynecologist who can provide all necessary information as to the drug’s potential harmfulness, appears to be sensible.

Sexual education ought to be left up to the school system, because often times doctors do not have enough time to engage in proper counseling in health care facilities and centers. Regrettably, the Italian public school system presents blatant shortcomings. It would be valuable to include in school curricula elements of reproductive biology and analysis of the psychological implications of relationships between the sexes. It is also crucial to promote campaigns designed to spread information and enhance awareness in youngsters, as well as projects aimed at the creation of facilities in which adolescents, whether native or foreign, can come into contact with psychologists and doctors who can provide answers to their questions in a competent and professional fashion, thus turning the sense of urgency into sensible decision-making.

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