

The conscientious objection: debate on emergency contraception

G. Montanari Vergallo¹, S. Zaami¹, N.M. di Luca¹, E. Marinelli¹

¹Department of Anatomical, Histological, Forensic and Orthopaedic Sciences, Sapienza University of Rome, Rome, Italy

Abstract

The authors discuss the emergency contraception (EC) topic, assessing scientific and ethical aspects. The almost totality of the studies carried out tends to report on the use of drugs as an emergency measure to prevent pregnancy. However, it is not yet completely excluded that emergency contraceptives can induce medical abortion.

The debate on side effects of EC continues to be a highly emotional and controversial issue both for advocates who believe they will lower considerably the number of unintended pregnancies and abortions, and for opponents who believe that using emergency contraception amounts to an abortion. This latter hypothesis highlights the conflicting aspect of the conscientious objection to abortion of physicians and pharmacists. This research work is aimed at investigating the emergency contraception issue, paying particular attention to the medico-legal and regulatory aspects of this subject. Particularly, the authors focus on the conscientious objection in order to assess, if any, legal protection for physicians and pharmacists who claim a right to conscientious objection.

Inappropriate use of EC could be resolved through a registry of user. This registry, of course, would not have the intention of persecution, but would only serve to detect possible cases of subjugation, exploitation and harassment. *Clin Ter 2017; 168(2):e113-119. doi: 10.7417/CT.2017.1991*

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Introduction

Post-coital or Emergency Contraception (EC) is considered as a valid method used to reduce the risk of unwanted pregnancy when a contraceptive method fails, or is incorrectly used or it has not been used at all. Unwanted pregnancies, especially during adolescence, culminate in the majority of cases with the abortion. The use of EC methods reduces this possibility and it does not expose women to eventual risk of adverse effects. However, if women or the couple continue to have sex without a scheduled contraception, there is a high probability of an unexpected pregnancy even after the use of EC(1). Indeed, it shows a lower efficiency than modern

oral contraceptives and its effectiveness depends on two main factors: 1. the earliness of the assumption (the term EC stresses the importance of time factor) (2); 2. The phase of the menstrual cycle when EC is assumed. The EC can occur with drugs orally administered or through the use of mechanical methods such as the insertion of a copper based intrauterine device (IUD).

The first use of the EC goes back to the sixties with the use of high-dose estrogen (1g ethinyl estradiol, 5 times a day for 5 consecutive days). In 1974, the Canadian gynecologist Yuzpe experienced a new CE method based on the association between ethinyl estradiol and levonorgestrel (200 mg of ethinyl estradiol in combination with 1 mg levonorgestrel, divided into two doses, the first within 72 hours after unprotected intercourse and the second 12 hours later) (3).

The sale of EC drugs dates back to the eighties. United Kingdom has been recognized as the first seller in 1984(4), followed by Finland in 1987 (5) and many other European and non-European states. Some of these countries, such as Belgium, Holland and Denmark were under an anti-abortion legislation when these drugs started to be commercialized (6). In 1995, the World Health Organization (WHO) and the International Planned Parenthood Federation established the Consortium for Emergency Contraception (7) they classified the EC as contraceptives and non abortifacient drugs and included them in the "WHO Essential Medicines List "(8). According to WHO, EC does not expose women to significant clinical risks. For this reason, in 2002 the European Parliament adopted the Resolution n. 2001/2128 (INI) on health and sexual and reproductive rights, recommending the governments of Member States to facilitate the access to EC primarily to minors and victims of violence, classified as at risk categories. Moreover, the requirement of non-repeatable prescription has been eliminated and the costs lowered (9).

In fact, since June 2nd, 1999 France liberalized the drug for all women regardless their age (10), followed by Norway (11), the UK, Sweden and Switzerland (12-14). In 2001, Sweden, Belgium, Denmark, Finland, Lithuania, Albania, Spain, Germany and Ireland established that drugs for EC can be sold *over the counter* (OTC) (13-14). Italy has been the last country to liberalize the use and selling of EC for

Corrispondenza: Simona Zaami, Via Bolzano 14 00198 Roma. E-mail: simona.zaami@tiscali.it.

women older than 18 years old, in February 11th, 2016. For women under the age of 18, however, the recipe had to be renewed every time (15). In most Member States, the transition to the sale of the EC without a prescription occurred following a modification of existing law regulating the sale of single drugs. Only France and Portugal issued a special law. France with the “Loi n° 2000-1209 relative à la contraception d’urgence” of December 13th, 2000 (16) established that drugs for EC could be sold *over the counter* (OTC) because they are not dangerous for women’s health, if used following the medical prescription. The law gives special attention to girls under the age of 18 who may get for free the “morning after pill” at pharmacy, without the consent of any parents or the legal representative. In exceptional cases, when the underage cannot immediately contact a doctor or a clinic, the law gives the opportunity to get the drug in high schools by school nurses. Even the “Loi n° 2001-588 relative à l’interruption volontaire de grossesse et à la contraception” of July 4th, 2001 art. 24 reiterates that dispensing contraceptive drugs to minor for emergency contraception do not need the consent of a parent or legal representative (17). In January 9th, 2002 the Décret n° 2002-39 “relatif à la délivrance aux mineures des médicaments ayant pour but la contraception d’urgence” (18) was approved. It established the obligation for the pharmacist to provide the “day after pill” for free, even in case of under 18 years girls, after an interview to ascertain the reasons and the psycho-physical state. The pharmacist should also explain which are the normal methods of contraception and prevention of sexually transmitted diseases.

Moreover, the decree established an anonymous control system that tracks the drugs distributed to minors by sending a receipt to the National Bank for the insurance against work-related illnesses. On December 1st of each year, the National Bank shall forward to the Social Security Ministry all the relating data to the period from September 1st of the previous year and August 31st of the current year.

On May 29th, 2001 Portugal issued the “Lei n° 12/2001 Contraceção de emergência” in order to reinforce the methods to prevent an unwanted pregnancy, especially in the adolescents (19). The law provides that emergency contraceptives are available for free in health centers, family planning clinics, such as gynecology and obstetrics hospitals, centers for young people, but also in pharmacies with or without a prescription. The law also requires that the distribution of the drug should be on advice of a health professional, after an initial counseling. The law states that women who need these drugs, if desired, should be seen in family-planning clinics. Portuguese law obliges the State to promote information campaigns on contraception, on sexually transmitted diseases and to their prevention methods. Such information should be available in health facilities and pharmacies. Training course on emergency contraception are also provided.

EC drugs available in Italy

In Italy two main molecules for EC are available: Levonorgestrel (LNG marketed under the name of NorLevo® or

Levonelle®) and Ulipristal acetate (marketed under the name ellaOne®). Both drugs had the obligation of non-repeatable prescription when they got into the market (in 2000 and in 2011 respectively) (20). Later, scientific studies showed the high safety index of both drugs due to very low toxicity, none overdose risk, no abuse liability and no requirement for medical exams (21). Thus, in 2016 the Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA) changed the prescriptive regulation of such drugs: Currently, they are free from medical prescription for patients over 18 years. Patients under 18 years old have to show to the pharmacist a medical prescription, which has to be renewed every time. When the age of the customer is not clear, the pharmacist has to request an identity document. In addition, it is no longer necessary to show a negative beta HCG urine test to obtain the so called “pill of the five days later” as it was requested in the previous laws (art. 3 of the Italian Medicines Agency’s Determination on November 8, 2011, which was reiterated by art. 1 of Determination on April 21, 2015).

LNG is available in formulations from 1.5 mg (single administration) and 0.75 mg (the first tablet to be taken immediately and the second after twelve hours). The two regimens are equally effective (22,23). International scientific sources such as International Federation of Gynecology & Obstetrics (FIGO) and International Consortium for Emergency Contraception (ICEC) (24) believe that Levonorgestrel action is based on the contraceptive action of the drug and its prevention and delay on the ovulation (25). Moreover, the excellent efficacy of this drug has been demonstrated: no pregnancy was recorded when it was administered in the pre-ovulatory phase through the hormonal analysis, as it turned out ineffective when it was taken after ovulation. This confirms that the drug cannot prevent implantation of the embryo (26). It was also proved that the drug does not produce changes in histological and biochemical features of the endometrium whereas there is no conclusive knowledge on the action of the drug on sperm. Nevertheless, an uncertainty about the drug mechanism of action exists, which depends on the unpredictable time of the ovarian cycle in which it is taken. LNG has no effect after the implantation process is started. Studies have clearly shown how the effectiveness of LNG in EC depends on the precocity of administration (27). In fact, the administration within 12 hours after unprotected sexual intercourse presents a 0.5% risk of pregnancy which increases to 4.1% when the administration occurs around the 72 hours. This underlines that EC effectiveness is crucially dependent on administration time. Furthermore, some investigations have shown that the drug is not effective in women with a body mass index greater than 25 (28). Concerning the prescription of LNG as CE drug in Italy, there has been an increase in the amount of sold packages: from 40,000 packages sold in 2000 to 380,000 in 2008 reaching 355,000 in 2016 (29).

In Italy the use of the so-called “pill of the day after” is among the lowest in Europe, higher only than the German (2.1%)²⁹. Indeed, in our country, the prevalence of EC use in women of childbearing age (aged between 15 and 45 years) is around 2.7%: a much lower percentage than the 15% found in Norway (where the EC drugs are all sold as OTC) or the 12% in the UK.

Ulipristal acetate (UPA) is a selective modulator of the progesterone receptor: in absence of progesterone it plays as an agonist, whereas in presence of progesterone, it plays as an antagonist, blocking the pick of lutein hormone (LH) (30,31). Thus, the use of UPA acetate can alternatively bring to the inhibition of the ovulation or prevent the implantation of the egg in the uterus that has been fertilized. Indeed, it is also effective if taken immediately before the time at which the ovulation is expected and LH concentration starts to increase. This is in contrast with the action of LNG, which blocks ovulation only if LH concentration has not yet increased. When the preovulatory LH reaches its peak, the efficacy of UPA fails. The UPA effect is achieved in a single administration and its efficacy lasts up to 120 hours after an “unprotected” relationship (for this reason the common name of UPA is “the pill five days later”). However, it is advisable to it as soon as possible. The previous law providing the mandatory requirement for pregnancy test limited drug use in the past. Indeed, from the past April 2nd, 2016 when drug was commercialized just 4,500 packs were sold. In the same time period, in Germany, where legislation is similar to the Italian one, but without the obligation for pregnancy test nearly 13,000 UPA packages have been sold. From a survey by the Italian Society for Medical Contraception (ISMC) conducted on 200 specialists across the country: 7 out of 10 gynecologists did not prescribed UPA because of the mandatory pregnancy test (32). It will be interesting to monitor sales of the drug after the new recent legislation. UPA has been included in the register of intensive monitoring drugs at European level. A web-based registry was also set up to gather information about any undiagnosed pregnancy before the first UPA or subsequent to treatment failure (33).

Before comparing the effectiveness of the above described drugs in preventing an unwanted pregnancy, the probability of observing a clinically proven pregnancy after a single sexual act should be firstly calculated. This probability of a clinically detected pregnancy based on the timing of the sexual act may vary according to the phase of the ovarian cycle.

It is well established that the fertile period of a woman lasts about six days (5 days preceding ovulation and the day of ovulation itself). The highest conception probability is reached when the sexual act is done the day before ovulation (from 30 to 45%). However the day of ovulation is not certainly identifiable, especially when the menstrual cycle is irregular. Indeed, a conception occurred the day after ovulation has never been demonstrated.

A study conducted by Glasier and colleagues compared the efficacy of UPA (30 mg) and LNG (1.5 mg) on a sample of 2221 women with regular ovarian cycle, who requested EC within 5 days of unprotected intercourse (34). The primary end point was the rate of pregnancy among women, who took the drug in the first 72 hours. Among these latter women 5 pregnancies among the 844 women (1.8%) in the UPA group were reported and 22 in the 852 women in the LNG group (2.6%). In comparison, the expected pregnancy rate, in the absence of EC, was 5.5%. Results demonstrated that UPA was also more effective than LNG also in the group of women who received emergency contraception between 72 and 120 hours following the sexual act.

Taking into consideration data from a meta-analysis including results of similar studies, the same authors confirmed the statistically significant superiority of UPA group at 72 hours.

In fact, compared to the EC with LNG, the use of UPA provides three main advantages. First, UPA offers an immediate efficiency, followed by a decrease of the risk of unwanted pregnancy from 75% in the first 24 hours from the sexual intercourse and to about 50% in the first 72 hours. Furthermore, UPA displays the possibility to block ovulation even in phases of the menstrual cycle in which LNG does not appear to be active. Finally, a further advantage of UPA if compared to LNG is represented by a more elevated and prolonged capacity to block ovulation.

It is necessary to inform the user that there are some drugs which may interact with EC medications; among them, drugs used to treat epilepsy (eg. phenobarbital, phenytoin, primidone, carbamazepine), those for the treatment of HIV infections (ritonavir) and some antibiotics (rifabutin, rifampicin, griseofulvin).

Drug side effects were observed in 54% women in the UPA group and in 56% of those in the LNG group. In the most cases, these effects were transient and from mild to moderate in intensity. The most frequent side effects included nausea, vomiting, menorrhagia, pelvic pain, headache, breast tenderness and dizziness. It is important to inform the consumers that, in the event of vomiting within three hours after intake, they have to take the drug again. In case of recurrent vomiting, the use IUD (“intrauterine device”) has to be taken into consideration. The emergency contraception (when not repeated) is not currently considered as a prothrombotic risk factor. In a case study of 73,000 women without cardiovascular risk factors, no thrombotic event has been recorded (35). However, the literature described a case of retinal thrombosis rouse in the first 24 hours after drug intake (36).

The debate on Emergency Contraception.

The marketing of these drugs has developed an intense debate regarding both medical and health aspects, that the ethical and legal issues (37). The central issue concerns the beginning of pregnancy. In the scientific world the beginning of pregnancy coincides with the time of implantation of the fertilized egg in the womb. In fact, only with the implantation in the uterus it would occur in the woman’s body histologic and hormonal changes that characterize the state of pregnancy. In this perspective the abortive action of the emergency medication can be excluded, since it acts at a time prior to the implantation of the embryo to the uterus. The opposite result is reached if the beginning of pregnancy is considered at the moment of fertilization: from this point of view such drugs should be recognized as abortive. This possibility has convinced some people to believe that the drug dispensing cannot be free, but should be regulated as with the voluntary interruption of pregnancy. For this reason, the French church and the Society for the Protection of Unborn Children have appealed to ask for limitation in the use and prescription of such drugs. The judges, however, referring to the scientific studies, have rejected both appeals. In fact,

they demonstrated that it was not possible to classify it as an abortion drug that was not able to cause the detachment of an embryo already implanted in the womb. Even in the Italian Movement for Life and the Forum of Family Associations proposed a legal way against the marketing of NorLevo®. They believed that the information provided on the sheets of contraceptive drug were not correct, because the drug can act on the embryo and cause abortion. The judges highlighted the need to better explain the mechanism action of the drug (38). Following the decision of the court package insert of the medicine was changed and was put on the market a second drug for emergency contraception called Levonelle (39).

In Argentina, however, the judges declared unconstitutional the “píldora del día después” (equivalent of NorLevo®) and welcomed the abortion argument, holding that methods which block egg implantation should be in any case considered abortifacient (because it would put an end to an already begun pregnancy) (40).

In Italy, the debate focused precisely on the mechanisms of action of the drug and, in particular, whether it is acting prior or not to the implantation of the fertilized egg. The biological processes that determine a still has to be clarified. Both the two manufacturers of this drug explain this mechanism in two different way. The pharmaceutical company Shering, which trades levonorgestrel under the name of Levonelle®, explain that the “mechanism is not precisely known” and that “at the given doses it is believed that the drug work mainly by preventing ovulation and fertilization, when sexual intercourse has occurred in the pre-ovulatory phase, when the probability of fertilization is the highest. It can also cause changes in the endometrium that make it unsuitable for implantation of a fertilized egg. It is not effective if the implant has already occurred.” In the package leaflet of NorLevo® it is written: “... with the purpose of preventing pregnancy by blocking ovulation or preventing implantation of the fertilized egg eventually, if the sexual intercourse took place in the hours or days preceding ovulation, that is, in the period of highest probability of fertilization.” In conclusion, there are two mechanisms of action: 1) the drug would act with a contraceptive effect primarily by inhibiting ovulation, but this can only happen if the drug was assumed in the days before ovulation. In this case it does not interrupt an established pregnancy; It cannot therefore be considered a form of abortion. For this reason the drug is out of guarantees going by the legislature with Law no. 194 of 1978, which applies only to the interruption of pregnancy after implantation of the fertilized egg, according to the most accepted interpretation; 2) in the event that ovulation had already occurred, or is not being blocked by the drug, are not described effects of the LNG on the oocyte nor on the sperm. The target becomes, from this moment onwards the fertilized oocyte, probably through the alteration of the endometrium, with subsequent plant impediment. The National Bioethics Committee believes that at this stage it is obvious and undeniable an abortive action, because “the effect, in this case, is to suppress the embryo” considered “human life in its own right “ able to develop without solutions of continuity until the birth, according to a well-defined” program “ (41,42).

Conscientious objection of the physician and the pharmacist

The right to conscientious objection in “reproduction science” is recognized by the Italian law in two cases: the interruption of pregnancy (Law of May 22nd, 1978, no. 194 and the assisted reproductive technology (Law of 19th February 2004, no. 40). There are no written rules authorizing conscientious objection in the prescription and in the supply of the “morning-after pill” (43).

Conscientious objection can be applied in situations which may potentially infringe the right to life that our legal system recognizes and guarantees to the unborn too. In a report of the Minister of Health on the implementation of Law 194 of 26 October 2015 it is clearly stated that conscientious objection is a right (44). This right is recognized by the Universal Declaration of Human Rights of 1948 (article 18), the International Covenant on Civil and Political Rights (article 18), the Convention on the Rights of the Child (article 14), the American Convention on the Human Rights (article 12), in the European Convention on human rights and fundamental freedoms (article 9), in the Charter of fundamental rights of the European Union (article 10); the African Charter on Human and Peoples’ Rights (art. 8). With specific reference to bioethics, the Council of Europe (resolution of October 7, 2010 on the right to conscientious objection in health care that condemns all forms of discrimination against objectors) states that: no person or hospital or institution can be obliged or considered responsible or discriminated if he/it refuses for any reason to perform or assist an abortion, or an euthanasia intervention or other acts that may cause the death of a fetus or of an embryo. As for our Constitution, freedom of conscience is implicitly contemplated in article 2 (fundamental human rights), in the articles which govern and protect freedom and equality in matters of religion (articles 3, 7, 8, 19, and 20) and in art. 21, which protects freedom of expression. The Ministry of Health and National Federation of Physicians and Dentists (FNOMCeO), as well as the National Bioethics Committee confirmed the doctor right to appeal to the so-called “conscience clause” in case of prescription and administration of the “morning-after pill” (45). However, they stated that it is always necessary to find a balance between the rights of the health professionals and those of the patients, because the doctor right to conscientious objection cannot, in any way, affect the right to the woman health (46). Indeed, woman health is considered not only related to the bio-physiological aspects, but also to the psychological ones that may be relevant in case of prescription denial. Therefore, if the conscientious objector doctor is required to prescribe “the morning-after pill”, he has the right to refuse, expressing its objection, but at the same time he has to ensure that the patient will receives the prescription at the appropriate time. For example, he could address the woman to a public health service (eg. Hospital or a clinic) where the prescription can be performed. In this way, the objector doctor respects the right of the woman to obtain the drug (47). In fact, in EC, conscientious objection occurs in a relationship between the woman and the doctor and in a situation of urgency that can cause problems if the doctor as objector, refuse drug prescription (48). In Italy, the matter is regulated by the Law no. 194 of 1978: “Rules for

the social protection of maternity and on the voluntary interruption of pregnancy". Substantially, discipline distinguishes between individual choices and public responsibility, since conscientious objection is a human individual right, which does not involve health facilities as a whole. Indeed, while the doctor or nurse are guaranteed to appeal to conscientious objection, the health structure has an obligation to ensure the provision of health services (law article n. 9). However, the conflict still remains and it is of not easy management between the woman right to access certain services provided by the national health service, the hospital duty to ensure those services and that of the doctor to claim its own moral and religious freedom (49,50). The available data on national territory demonstrate the organizational difficulties of health facilities because the mean percentage of doctors and nurses who are conscientious objectors amounts to 70%, reaching 80% in some regions of the South Italy. This evidence underlines a situation very different from that in other European countries. France, for example, requires all hospitals to guarantee the availability of abortion services. In England objectors are only 10% doctors and in the whole country there are booking centers open without time break every day of the week. In addition, health professionals who decide to work in the family planning facilities cannot declare themselves as objectors. In Sweden, however, the right to conscientious objection does not exist (51).

To assess whether there is a criminal responsibility for the physician or pharmacist who declare to be conscientious objector, it has to be established if there is a legal duty of the physician to prescribe the "morning-after pill", and in this case, the omission may be penalized.

The legal obligation for the health professional to prescribe (or to administer) EC drugs may be in conflict with the moral duty not to destroy a "human being". It worth of notice to remember that the conflict of conscience arises if it is believed that the drug operates not as anticonceptive but "against gestation" attributing abortifacient effects to the drug if pregnancy is considered to begin from fertilization.

Can it be assumed for the doctor an obligation to prescribe and /or administer EC drugs? Decisive appears the first point of the new "Professional Oath", which claims the freedom to be recognized to the doctor in the exercise of his profession. This concept is also reiterated in article n. 4 of the Code of Medical Ethics of 2014, while the article 22 of the same code allows the physician, if required performance are in contrast with his conscience, to refuse their work, unless this behavior does not constitute a serious and immediate damage to the health of the patient (52).

These concepts are fully sharable that it would be unthinkable a profession that, instead of responding to the principles of science and conscience, were subject to external influences, or reduced to a mere compliance with rules.

The conflict of conscience may also exist for the pharmacist who is obliged to sell these drugs. The Royal Decree of September 30th 1938, n. 1706, still in force in Italy, attributes specific obligations and responsibilities to the pharmacist. The pharmacist is in fact required to dispense available drugs, to send to whomever concerned the prescriptions regularly filled and to provide as quickly as possible missing preparations. If he does not comply with these rules, he may

incur the interruption of public service, punished by article 340 of penal code. In this concern, two objections may be raised: 1) it is hard to think how a simple administrative authorization has to make available (in absence of the conditions referred in the Law no. 194/1978) a drug which is able to interrupt the existential process of the embryo, especially since the law states that embryo has all citizen rights and it is criminally protected 2) the conscientious objection is recognized to the all health care professionals (article 9, paragraph 1, Law no. 194 of 1978) thus the denial of this right to the pharmacists, who also are part of "health professionals" would be an infringement of the principle of equality of all citizens as reported in the article n.3 of the Italian Constitution). The Code of Ethics of the pharmacist, in the version of 2007, invokes the principle of freedom of conscience in the respect for human life (article n.3). Any limitations to that freedom of conscience is likely to transform the pharmacist in a simple trader or executor of the doctor orders, distorting in this way the essence of the profession (53).

It can be argued that the refusal to supply a "rescue medication", could results in a lesion of the citizens right to have access to the drug. These concerns can be overcome with proper organization. Indeed, if the state guarantees the citizen with the medication prescribed by the doctor, the obstacle to recognize the right to conscientious objection for the pharmacist is automatically eliminated (54). Furthermore, recent legislation established that these drugs can also be sold in drugstores, so the pharmacist who refuses to supply these drugs does not affect the right of women to get them. In conclusion, it is possible to affirm that the right of conscientious objection can be legitimately exercised by the doctor and pharmacist, especially when a law governing the use of EC drugs does not exist (55).

Conclusions

The conscientious objection is a consolidated right and, as a consequence, in case of EC physicians, health-care professionals and also pharmacists, can legitimately deny the patient medical care if they believe that it is intended to kill a human being, unborn, without risking to be punished for such refusal as neglect of an official duty. The authors point out the socio-cultural importance of this phenomenon which has considerable, social and moral implications especially for young women under 18 years of age, who need urgently adequate tools of medical assistance, prevention and health education. Indeed, the data seem to confirm that they represent the group with the largest use of EC. It should be appropriate, as previously stated, to reinforce the educational commitment of adolescents to increase the use of more effective hormonal contraception and increase ethical awareness on their behaviors and their consequences. These are issues that should be tackled at the National Government level, possibly implementing a legislative act. More generally, in Italy, there is the need to achieve higher levels of education for a more responsible contraception, since our Country continues to show the lowest figures concerning the use of EC drugs: around 17% against, a 70% in Germany and France.

On the other hand, EC drugs cannot in any case substitute normal contraception since this can be a dangerous occurrence for the health of the woman. Inappropriate use of EC could be resolved through a registry of users. This registry, of course, would not be meant as a means of persecution, but would only serve to detect possible cases of subjugation, exploitation and harassment.

Authors' contributions

All the authors have made substantial contributions to conception and design of the manuscript. G.M.V. wrote the manuscript, but all Authors have been involved in drafting the manuscript and revising it critically for important intellectual content and all of them have given final approval of the version to be published.

Competing interests

The authors declare that they have no competing interests.

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