Medical vs Surgical Abortion. Overview of European Legislation and Health Care Practice

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Abstract

Introduction: Abortifacient drugs, such as RU-486 or mifepristone, used in combination with a prostaglandin analogue (misoprostol) for the purpose of achieving medical abortion, have given rise to major legal, ethical and moral quandaries, which legislators all over Europe have striven to overcome by reconciling the reproductive rights of women with those of dissenting medical personnel.

Materials and Methods: We have conducted a comparison between international legislative approaches from the 1970s to 2020 upon the subject of voluntary abortion, with an eye on their applicability as well as other ethical concerns, supported by the analysis of the scientific debate on medical vs surgical abortion.

Results: The unresolved rift between the reproductive will of women and medical professionals’ claim to conscientious refusal to treat, i.e., refusal to perform abortions or to prescribe abortifacient medicine, in such overwhelming numbers in Italy and elsewhere, has given rise to the impossibility of many women to terminate their pregnancies as they choose to. As a matter of fact, in 2018, only 64.9% of Italian public hospitals were able to guarantee access to abortion services. Hence, 35% of Italian facilities fail to meet the standards set by Law 194/78.

Conclusion: The authors have aimed to shed light on how medical abortion is to be preferred over a surgical one, and how major European countries have dealt with such an extremely thorny issue that has polarised the public opinion and scientific community members alike.

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Introduction

RU-486 (mifepristone) is an active antiprogesterone and antiglucocorticosteroid agent, generally used in combination with a prostaglandin analogue (misoprostol) in order to bring about a medical abortion during pregnancy. Except for Poland, Ireland, and Malta, where abortion is banned, access to the medication is regulated throughout the European Union, albeit through varying, rather than uniform protocols, as reflected in Table 1 (1, 2). Much like in the EU, in the United States and several Eastern European countries, as well as in India, China, and all countries where abortion is legal, mifepristone combined with misoprostol is the most widespread means to induce an abortion. The World Health Organization itself has deemed the drugs safe and effective (3, 4).

Table 1. Comparison between voluntary termination of pregnancy vs medical abortion in different European countries

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>Voluntary Termination of Pregnancy</th>
<th>Medical Abortion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Legal within the first 3 months of pregnancy (20).</td>
<td>Legal and accessible. The regulation for mifepristone allows the drug to be administered only in medical facilities; medical abortion can therefore only be performed in hospitals (21).</td>
</tr>
<tr>
<td>Belgium</td>
<td>Legal within the twelfth week of pregnancy.</td>
<td>Available in Belgium and given until up to 49 days of amenorrhea (22).</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>Legal within the twelfth week of pregnancy (23).</td>
<td>Abortifacient drugs are not registered, thus illegal.</td>
</tr>
<tr>
<td>Croatia</td>
<td>Legal within the tenth week of pregnancy (24).</td>
<td>Medical abortion has been available since 2015. Only recently has the Croatian Agency for Medicinal Products and Medical Devices (HALMED) approved the drug combination used in medical abortion. Yet, their administration is only allowed in hospitals accredited to perform abortions, with professional supervision.</td>
</tr>
<tr>
<td>Cyprus</td>
<td>Legal within the tenth week of pregnancy since 2018 (25).</td>
<td>Misoprostol is legally usable for termination of pregnancy.</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Legal within the first 3 months of pregnancy (26).</td>
<td>Legal upon demand since 2013.</td>
</tr>
<tr>
<td>Denmark</td>
<td>Legal within the twelfth week of pregnancy since 1973 (27).</td>
<td>Medical abortion is used until end of 8th week. Surgical abortion may be chosen until end of 12th week. Until 8th week, most abortions are medical. Overall, approx. 40% of all the abortions are medical and approx. 60% of all the abortions are surgical (28).</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Country</th>
<th>Legal Abortion Periods</th>
<th>Medical vs Surgical Abortion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estonia</td>
<td>Legal within the eleventh week of pregnancy (29).</td>
<td>Mifepristone in combination with misoprostol (Arthrotec) for the purpose of medical abortion was registered in 2003. Medical abortion can be used up to the 63rd day of pregnancy (30).</td>
</tr>
<tr>
<td>Finland</td>
<td>Legal within the twelfth week of pregnancy. Up to 20 weeks if there is a risk to physical health of woman or if the woman is younger than 17. Up to 24 weeks in case of major fetal malformation; no limit if there is the woman’s life is in danger (31).</td>
<td>Legal and free of charge, on outpatient basis.</td>
</tr>
<tr>
<td>France</td>
<td>The ten-week limit was extended to the twelfth week in 2001 (32).</td>
<td>France was the first country to legalize the use of RU-486 as an abortifacient in 1988, allowing its use up to seven weeks of pregnancy under medical supervision. According to a United Nations Population Division estimate, 19% of all French abortions used RU-486 as of 2002. Medical abortion represents almost 50% of all performed abortions. In response to the Covid-19 pandemic, France has extended access to medical abortions to nine weeks of pregnancy (33).</td>
</tr>
<tr>
<td>Germany</td>
<td>Legal within the first 3 months of pregnancy; mandatory counseling is required; abortion is also legal later in pregnancy in cases of medical necessity (34).</td>
<td>Legal within 9 weeks (63 days) since last menstruation, requires medical prescription (35).</td>
</tr>
<tr>
<td>Greece</td>
<td>Legal within the first 3 months of pregnancy (36).</td>
<td>Mifepristone and misoprostol are registered, available and affordable. However, medical prescription and hospitalization are required (37).</td>
</tr>
<tr>
<td>Hungary</td>
<td>Legal during the first twelve weeks of pregnancy (38).</td>
<td>Banned</td>
</tr>
<tr>
<td>Country</td>
<td>Abortion Status</td>
<td>Medical Abortion Requirements</td>
</tr>
<tr>
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<tr>
<td>Ireland</td>
<td>Legal since 2018 (following a constitutional amendment approved by a referendum in May 2018) within the twelfth gestational week and later in cases where the pregnant woman’s life or health is at risk, or in the cases of a fatal fetal abnormality.</td>
<td>Abortifacient drugs are illegal (39).</td>
</tr>
<tr>
<td>Latvia</td>
<td>Legal during the first twelve weeks of pregnancy (40).</td>
<td>Legal and available since September 2008. Prescription and gynecological assistance are required. Medical abortion can also be carried out in certified in-patient facilities.</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Legal during the first twelve weeks of pregnancy (41).</td>
<td>Banned.</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>Legal during the first twelve weeks of pregnancy, following two consultations with a medical doctor and a psychologist, and a waiting period of at least three days (42).</td>
<td>Legal within 7 weeks (49 days) of pregnancy.</td>
</tr>
<tr>
<td>Malta</td>
<td>Banned under all circumstances. Malta is the only country in the European Union to ban abortion altogether (43).</td>
<td>Banned.</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>Legal during the first 24 weeks of pregnancy (i.e., when it is believed that the fetus has develop vital functions enabling it to live outside of the womb) (44).</td>
<td>Legal (45).</td>
</tr>
<tr>
<td>Poland</td>
<td>Only legal in cases where the mother’s life or health is at risk, in cases of major fetal malformations or pregnancy as a result of rape.</td>
<td>Banned (46).</td>
</tr>
<tr>
<td>Portugal</td>
<td>Legal during the first ten weeks of pregnancy.</td>
<td>Legal since 2007 (47).</td>
</tr>
<tr>
<td>Romania</td>
<td>Legal during the first fourteen weeks of pregnancy.</td>
<td>Legal with prescription (48).</td>
</tr>
<tr>
<td>Slovakia</td>
<td>Legal during the first twelve weeks of pregnancy.</td>
<td>Not available (49).</td>
</tr>
</tbody>
</table>
Slovenia  | Legal during the first ten weeks of pregnancy. | Mifepristone available (50).
Spain    | Legal within the 14th week of pregnancy, and at later stages in cases of serious risk to the health of the mother or fetal abnormalities. | Legal within the first trimester of pregnancy. Not easily accessible and costly. Surgical abortions account for most termination of pregnancy procedures (51).
Sweden   | Legal within the twelfth week of pregnancy (52). | Medical abortion up to 63 days of pregnancy was approved in Sweden in 1992. Medical abortions accounted for 93% of all abortions in 2018 (53).
United Kingdom | Legal within 24 weeks of pregnancy (54). | Mifepristone, approved for use in Britain in 1991, and Misoprostol are legally accessible up to the ninth week (55).

In Italy, the legislation enacted to regulate access to voluntary termination of pregnancy (Law 194/1978, titled “Norme per la tutela sociale della maternità e sull’interruzione volontaria della gravidanza”, or “Norms on the Social Protection of Motherhood and the Voluntary Termination of Pregnancy”), has effectively repealed Articles 545 to 555, which used to criminalise the termination of pregnancy in any way or form (5).

As a continuation of this legislative development, following the completion of the experimentation process, RU-486 has been marketed in Italy since 10 December 2009. Nonetheless, it is worth noting that, unlike other European countries, where it was already legal to medically terminate a pregnancy up to 63 days of amenorrhea, Italy has lowered that time limit to 49 gestational days.

The impact that the “procreative revolution” has had on the awareness of the population, however, has pushed the Italian Supreme Court to issue rulings that have helped to overcome several legal and practical hurdles over the years (6, 7).

Materials and Methods

Materials and study design

A large and qualitative review of the literature between the seventies and 2020 has been conducted to analyse the scientific background on medical and surgical abortion. The aim was to clarify the differences among the current laws and guidelines governing voluntary termination of pregnancy in different European countries, with an eye on the Italian situation, where the applicability of these laws is faced with ethical concerns. The study was conducted between 2019 and 2020 at the Sapienza University of Rome, Department of Anatomical, Histological, Forensic and Orthopedic Sciences, in collaboration with the Department of Medical and Surgical Sciences, University of Foggia.

Methods

The authors have examined the main medical databases, e.g. Pubmed, Google Scholar, Scopus and Cochrane Library, as well as legal databases (Lexis, Justia, Kleagle) by applying effective combinations of terms, i.e. surgical abortion; conscientious refusal to treat; mifepristone; medical abortion; voluntary
termination of pregnancy; abortion guidelines; health standards; emergency contraception; conscientious objection; contraception; RU-486; WHO guidelines on medical abortion procedures.

Discussion

The development and availability of new procedures and treatments undoubtedly entail novel ethical quandaries, at least theoretically. The issue of procreative freedom has unfolded along two distinct and irreconcilable lines of reasoning: if, on the one hand, medically assisted procreation has made it possible for women of relatively advanced age to achieve motherhood (8, 9), voluntary termination of pregnancy is in keeping with the woman’s will not to become a mother (10). Nowadays, access to abortion services, as codified in Italian statutes, presents considerable difficulties, even more so in cases of unplanned pregnancies, when contraceptive methods fail or when sexual abuse results in pregnancy. In fact, access to emergency contraception, which has positively contributed to lowering abortion rates, may not be easily available in a timely fashion (11-13).

Contraceptive use rising as abortion falls: differences between Italy and European countries

In 2018, more than 64.9% of Italian public hospitals guaranteed access to abortion services. Hence, 35% of Italian facilities fail to meet the standards set by Law 194/78 (11).

One of the most relevant factors that led to such a situation is certainly conscientious refusal to treat by medical personnel, which is codified as a right in Law 194/78, under Article 9. According to said provisions, objectors may opt out of “performing procedures and activities specifically and necessarily aimed at achieving a termination of pregnancy” (14). Conscientious refusal to treat does not however exempt professionals from providing care before and after an abortion procedure or intervening in cases of emergency or imminent danger to the patient’s life. After all, the Italian healthcare system is bound to uphold the free exercise of women’s right to sexual and reproductive freedom by guaranteeing access to abortion procedures through the services and professionals set in the provisions of Law 194/78, by minimising the detrimental effects of conscientious refusal to treat under such a right, and possibly even ordering transfers of objecting physicians if no one else agrees to perform the procedure.

The practical execution of such measures is undeniably complicated in a country such as Italy, where conscientious objectors account for roughly 70% of health care professionals (15), which is an extremely high share compared to the European average – 10% in the United Kingdom, 7% in France, and none in Sweden (16-21). In most European countries, the law allows surgical abortion upon a woman’s request in the first weeks of pregnancy or in an advanced gestational period under certain circumstances (16-51) (Table 1).

France was the first European country to legalise abortion by virtue of Law 75-17 of 17 January 1975 (Law on the Termination of Pregnancy). According to the French law, every pregnant woman has the right to an abortion until the twelfth week of pregnancy. After this time limit, the French law consents to abortion only if the continuation of pregnancy proves to pose a real and serious danger to the woman’s health or life (16). In France, RU-486 has been legal since 1988. The pill is administered within the first seven weeks of pregnancy and under medical supervision. In this country, medical abortions represent approximately 50% of all abortions performed. In particular, according to an estimate from the United Nations Population Division, 19% of all abortions in France registered since 2002 have occurred by taking RU-486. Moreover, in response to the COVID-19 pandemic, France has extended access to medical abortion until the ninth week of pregnancy (17).

In contrast, the Republic of Ireland has an extremely restrictive approach to abortion,
unless there are circumstances that put a woman’s health and life at risk. In Ireland, the constitution recognises the right to life for unborn children. Should such conditions arise that endanger the health of the woman and/or the child, however, the law does not set time limits for terminating pregnancy, though a surgical abortion is the only possible option (47).

Regarding drugs used for medical abortion, there are only a few European countries where abortifacient drugs are not registered (45), or they are illegal or banned (46-51) (see Table 1). In the European Union, Malta is the only state that has banned both surgical and medical abortion (49). These differences between various European countries, from the north to the south of Europe, have historical, political and religious origins. Medical abortion in Spain, for example, is not easily accessible and it is very expensive. For these reasons, surgical abortions account for the majority of pregnancy termination procedures (44). Conversely, in Sweden, medical abortions accounted for 93% of all abortions in 2018 (19).

Any woman who turns to a healthcare professional has the right to thorough and comprehensive consultations on abortion practices (also, and above all, in relation to the clinical condition of a pregnant woman) as well as on the risks and benefits of one method compared to the other. Consultation is advised, but not mandatory for adult women, while it is required for minors. The “contraceptive revolution”, or rather the introduction of the abortion pill, in fact, started in the 1960s and 1970s in Western European countries, which were the first to legalise abortion and where, therefore, it is perceived as a fundamental right of all women.

Italy: government legislation and abortion plan

The high degree of sensitivity in Italy towards ethically and religiously contentious issues has most likely played a role in stymieing and delaying scientific progress in terms of access to abortion and medically assisted procreation (MAP) procedures.

Based on Law 194 (“Norms on the Social Protection of Motherhood and the Voluntary Termination of Pregnancy”), women may legally resort to voluntary termination of pregnancy at national public facilities within the first 90 days of gestation, after which pregnancies may only be terminated for therapeutic purposes (5).

Nevertheless, the share of conscientious objectors has grown by 12% over the past 10 years, reaching as much as 90% in regions such as Molise, Trentino-Alto Adige and Basilicata. Significantly, in the whole region of Molise, there is currently only one registered physician who has not expressed a refusal to treat (11).

In 2014, the European Committee of Social Rights of the Council of Europe formally reprimanded three hospitals in the central Marche region, Jesi, Fano and Fermo, where all medical personnel had expressed a refusal to treat. The Committee claimed that such a situation constituted a violation of women’s right to health, which is enshrined in the European Social Charter (52).

Another element negatively affects medical abortion: in compliance with the recommendations issued by the High Council of Health, most Italian regions require women seeking abortifacient drugs, such as RU-486, to be hospitalised to terminate a pregnancy (53). Due to that requirement and the organisational and ethical challenges which it engenders, many facilities have mostly opted for surgical abortion instead, to the extent that in 2018, fewer than 25% of Italian women could resort to medical abortion (11).

In December 2015, the Association of Italian Physicians for Contraception and Abortion (AMICA), counting on the support of various organisations and high-profile backers, sent an open letter to the Italian Ministry of Health, in which it asked to make medical abortion procedures less restrictive, on a day hospital basis and, where possible, accessible even in family counselling centres and ambulatory care facilities, for the sake of ensuring health care services availability and adequacy. On 8 August 2020, the Ministry of Health updated the set of guidelines regulating access to the abortifacient drug RU-486, allowing for its administration on an outpatient basis, i.e. with no need for
hospitalisation, and even extending the ultimate time limit for abortion from the seventh to the ninth gestational week. Such a development, based on scientific evidence, undoubtedly constitutes a meaningful step forward for Italy in terms of fully enforcing Law 194/78. Nevertheless, such a consequential decision has occurred within an uneven socio-political context. As a matter of fact, the ministerial decision has been made on the heels of an opinion which was asked from the High Institute of Health, following a regulatory decision made by the regional government of Umbria. That opinion was meant to discourage the tendency on the part of regions to perform medical abortion on a day hospital basis. The Umbria legislative initiative followed the 2010 set of ministerial recommendations (53), after the Italian Medicines Agency (AIFA) had authorised the marketing and distribution of the drug in compliance with European standards, albeit with restrictions in place that do not apply in other countries, such as the three-day hospitalisation requirement and the seven-week gestational limit.

The newly introduced ministerial directive has raised widespread controversy. The Legal Affairs Department of the regional government of Piedmont, in agreement with the Italian Episcopal Conference, has opposed the directive, arguing that it may run counter to Law 194/78 and stressing that outpatient administration of RU-486 could lead to serious complications for women.

**Conclusion**

It is obviously essential that the new guidelines do not conflict with the original primary purpose of Law 194/78 in terms of providing sound healthcare and psychological consultations for women in order to “try to remove the underlying reasons that induce women to seek an abortion” (5). Furthermore, it is essential to guarantee access to follow-up support activities for those women who ultimately decide to terminate their pregnancies, for the purpose of ensuring the fetus is expelled in a complete and safe fashion in the interest of the patient’s well-being.

Furthermore, the WHO itself has been advocating for medical abortion (4) over surgical abortion in light of the many advantages in terms of financial benefits for healthcare providers (as a result of fewer hospitalisations, reduced use of anaesthesia and fewer surgical procedures) and a higher degree of safety, given the lower rates of complications arising from surgical interventions, such as suction aspiration and curettage. Moreover, in cases where medical abortion is not carried out in a timely fashion, resorting to surgical abortion is inevitable, often as an emergency procedure, which increases the risk for patients to contract infections or haemorrhages during surgery (54, 55).

The Italian ministerial directive is ultimately and consistently aimed at guaranteeing and upholding the “right to responsible and conscious procreation” by removing some of the barriers hindering access to termination of pregnancy and extending the period in which such procedures can be accessed, in an effort to discourage illegal abortions and reduce the need for late surgical abortions, often performed under emergency circumstances.

The nationwide application of said ministerial decree, released on 8 August 2020, will make it possible to gather more consistent and reliable data as to the rates of adverse events associated with medical abortion, which will provide scientifically reliable analytical elements for assessing its impact compared to surgical abortion procedures.

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**Disclosure**

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**Competing interests.** None to declare.
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16. Loi n° 82-1172 du 31 décembre 1982 Relative a la couverture des frais afferents à l’interruption volontaire de grossesse non therapeutique et aux modalites de financement de cette mesure.


37. “Sexual and Reproductive Health Law”, enacted by the Parliament on 31st January 2002, entered into force on 1 July 2002, which also lays out the grounds for the termination of pregnancy.

38. Law “on sexual information, illegal abortion and termination of pregnancies”, enacted on 15th November 1978, which amended Penal Code Act 348-353.


43. Law on medical measures to implement the right to a free decision regarding the birth of children, 1977.

44. Ley Orgánica 2/2010 de salud sexual y reproductiva y de la interrupción voluntaria del embarazo, Articles 13 and 14.

45. Decree No. 2 of 1 February 1990 on the conditions and procedures for the artificial termination of pregnancy.

47. The Health (Regulation of Termination of Pregnancy) Act 2018 (Act No. 31 of 2018; previously Bill No. 105 of 2018.

48. Abortion has been regulated since 1994 by a decree of the Lithuanian Minister of Health which replaced the former Soviet law and restricted again the grounds for abortion beyond 12 weeks of pregnancy.


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Conception and design: Negro F; Varone MC, Cotoia A; Beck R
Critical revision of the article for important intellectual content: Negro F; Varone MC, Cotoia A; Beck R
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Final approval of the article: Negro F; Varone MC, Cotoia A; Beck R