Ten years of emergency contraception in Italy (2012-21) in the context of the second contraceptive revolution

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1. Introduction

Emergency Contraception Pills (ECPs) first appeared in the early 1990s (Trussell et al. 1992), with the first ECP being approved by the US Food and Drug Administration in 1999 for use by prescription (Metha *et al.* 2022). Over the last several decades, new ECPs have emerged and become increasingly widespread in both developed and developing countries (for Europe, see ECEC 2022; for the US, see Haeger *et al.* 2018 and Trussell *et al.* 2019; for Sub-Saharan Africa, see Ahinkorah *et al*. 2021 and Kwame *et al.* 2022).

The most diffused ECPs are based on two different active ingredients. The first ECP is levonorgestrel (LNG), a synthetic progestogen commonly known as the morning-after pill, meant to prevent pregnancy if taken within 48 hours of sexual intercourse. The second is ulipristal acetate (UPA), which can inhibit conception if taken within 120 hours (5 days) of unprotected sex. Another method of post-coital control – less diffused and not discussed in this paper – is the immediate insertion of the copper IUD, necessitating the intervention of a health professional. The use of ECPs is recommended in case of contraceptive error (condom breakage, forgetting the daily pill) or after unprotected sex.

The side effects of ECPs are modest, and they have few contraindications (Haeger 2018; ASEC 2022). They can also be taken by women unable to use contraceptive pills for medical reasons and by breastfeeding women. If a pregnancy begins despite having taken an ECP, there is no additional risk of either miscarriage or malformation for the newborn. There is consensus in the scientific literature that both LNG and UPA prevent fertilization by inhibiting or delaying ovulation (Rosato *et al.* 2016).

Pharmacy sales of two ECPs were introduced in Italy in 2006 (LNG) and 2012 (UPA). During 2012-21, the diffusion of ECPs in Italy increased considerably, from 340 thousand single doses sold in 2012 to more than 650 thousand in 2021. As the number of women of childbearing age resident in Italy decreased over the same period, the diffusion of ECPs more than doubled: from 2.2 per 100 women aged 15-49 in 2012 to 5.5 in 2021. However, the increase was not linear over time: if sales were constant at around 340 thousand single doses per year in the three years 2012-14, there was a continuous increase over the following five years, reaching more than 588 thousand in 2019. Sales then fall in 2020, only to rise again the fol-

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lowing year. Since May 2015 (UPA) and June 2016 (LNG), ECPs can be purchased without prescription by adults.

These first data suggest that the diffusion of ECPs is strongly linked to liberalizations. Moreover, given that 2020 was the year COVID-19 exploded, it is reasonable to assume that sales of ECPs were somehow affected by the restrictive measures imposed on the population due to the pandemic.

Throughout 2012-21, the numbers of conceptions, births and induced abortions (hereon abortions) in Italy decreased each year (Ministry of Health 2022). Part of this decline was due to a parallel diminution in women of childbearing age, as the very large cohorts of Italian women born in 1955-74 concluded their reproductive lives and were replaced by much smaller cohorts born in the following thirty years. Yet, the reduction in potential mothers does not alone explain this decrease, given that in the same period, birth, abortion and conception rates, as well as the abortion ratio (the probability of a conception ending with an abortion) also decreased significantly. This decline in legal abortion rates and ratios has not been due to a parallel increase in illegal abortions (Ministry of Health 2022, p. 19), and has continued a decades-long trend linked to the gradual abandonment of coitus interruptus and the spread of modern contraception (see the next two sections). Nonetheless – as underlined by official reports (Ministry of Health 2016) – the drop in the abortion ratio between 2014-15 and 2015-16 is striking – more marked than the pattern observed in previous years and larger than the decreases in later years. It also coincides with the period when the sale of ECPs was liberalized for adult women.

The Italian case is interesting for two reasons. First, the possibility of access to emergency contraception emerged in a very specific contraceptive and reproductive context, different from that of countries such as the US, the UK and France: In comparison with those countries, Italy on the one hand is "backward" (for example, due to the slow spread of the daily pill and the absence of sterilization), and on the other hand has some of the lowest abortion and adolescent fertility rates in the world. Second, few studies examine emergency contraception in Italy, mainly at how public policy on access affects sales and women's reproductive health.

Starting from these considerations, this article focuses on the two key points of the spread of ECPs in Italy during the 2012-21 decade: the liberalization of non-prescription sales in 2015-16 and the contraction in sales induced by the 2020 pandemic. First, we assess the effect of the 2015-16 liberalization on the sale of ECPs and the reproductive behavior of Italian women, proposing a simple formula to estimate an upper limit of the number of pregnancies avoided through ECPs. Second, we look at changes in sales during 2020-21, and particularly during the strict COVID-19 lockdown of March-May 2020, when it was possible to leave one's home only to go to the supermarket, the pharmacy or to walk the dog. These empirical analyses are preceded by a section summarizing the history of the second Italian contraceptive revolution in order to better define the place of ECPs in Italian reproductive behavior.

The paper is organized as follows. Section 2 describes the second contraceptive revolution in Italy; Section 3 provides background on ECPs, largely related to the developed countries; Section 4 describes data and methods; Section 5 shows the results and Section 6 concludes.

2. The second contraceptive revolution in Italy

The first contraceptive revolution unfolded in a fairly similar way throughout Western Europe. Between the 19th and the first half of the 20th century, couples abandoned natural fertility: they were normally fertile and tried to control their fertility only during sexual intercourse, when they did not want the woman to become pregnant. They they used coitus interruptus and, to a lesser extent, natural methods and voluntary abortion. Moreover, until the mid-20th century, sexual relations among unmarried women were usually sporadic, except for sex-workers.

This homogeneity between countries disappears with the second contraceptive revolution (Leridon 1987), when technology also enters this field. Let's just consider the most common contraceptive methods in Western countries and Japan. The condom – known for centuries – is widely used, cheap and increasingly comfortable; the IUD (intrauterine device) is widely used; the pill has been on the market since the early 1960s and is gradually becoming less invasive from a pharmacological point of view; female and male sterilization techniques are becoming less invasive and safer. Except for the condom, these methods are not coitus-related methods, which means that their users are usually infertile: if they want to have a(nother) child, they have to stop using them, which is also difficult in the case of voluntary sterilization.

The second contraceptive revolution is not only technological, but also a social and cultural revolution. It differs profoundly from the first, because it is not achieved solely by couple's agreement, made in the privacy of the bedroom, but requires intense interaction with other subjects, in particular health professionals (primarily doctors and pharmacists, but also counsellors) and the market. Moreover, since we are dealing with drugs, devices and medical-health procedures, their availability and cost are conditioned by regulatory systems that involve health policy, or politics tout court.

The second contraceptive revolution in Western countries is linked to two major changes in reproductive behaviors. The first is the legalization of abortion, which is medically much safer than illegal abortion. Medically assisted legal abortion is used as a method of birth control for a small group of women, and in different ways in different Western countries, as shown by the trend in repeat abortions (Mazuy *et al.* 2014). For a much larger proportion of women, however, legal abortion is used after a contraceptive failure, and it becomes an opportunity for contacts with health workers, who can encourage the subsequent use of modern contraception.

The second change is the increase in extra-marital and extra-couple sexual activity, also among women. The eruption of sexuality outside the life of a married couple opens up an enormous "market" for contraception that simply did not exist when female sexuality was mainly confined to marriage.

Given the characteristics of the second contraceptive revolution, it is hardly surprising that, unlike the first, its nature and diffusion varied greatly according to each country's social, cultural and health context. A detailed description is beyond the scope of this article (see, for example, UN Population Division 2011): let's briefly consider some specific features of Italy, summarizing the results of some studies (Castiglioni and Dalla Zuanna 2010; Castiglioni 2013; Loghi *et al.* 2013; ONM 2021, 193-197; ISTAT 2017, chapter 2; ISTAT 2019; Ministry of Health 2022, p. 19).

Firstly, although contraceptive use is not too low in Italy – in 2019, 77% of sexually active women aged 18-49 used at least one method – the use of coitus-related methods is much higher than in most of the Western countries: 18% said they had used coitus interruptus, 35% the condom, and only 21% the daily pill (ISTAT 2019). Second, in Italy there is a strong polarization between the contraceptive methods used by cohabiting couples and those used by singles: the former are increasingly using the pill, the latter the condom. Third, the use of the daily pill is growing steadily, as we will see when we look at the sales data. Fourth, the IUD, which enjoyed a certain popularity in the last decades of the 20th century, is now used less and less. Fifth, female sterilization has never taken off in Italy, much less male sterilization, probably due to cultural factors and partially ambiguous legislation. Sixth, in Italy, all contraceptives are paid for: they are not distributed free of charge in health centers or clinics, as is the case in other countries; they must be purchased in pharmacies, except for condoms, which are also sold in supermarkets and other shops. However, only in the 80's, under the menace of HIV, advertising on the use of condoms started to spread in Italy. Before that period, purchasing condoms was something people did very discreetly. This remarks that the historical discontinuity happened more or less in the last 25 years of the last century.

The Italian contraceptive vector, unbalanced in favor of coitus-related methods, may seem ineffective in guaranteeing low fertility and low voluntary abortion in a context of increasing frequency of sexual intercourse, especially among young people (Caltabiano et al. 2020; Dalla Zuanna and Vignoli 2021). On the contrary, in Italy one of the lowest fertility rates in the world (TFR=1.20 in 2023) coexists with one of the lowest voluntary abortion rates in Europe – a third lower than forty years ago – and adolescent conception rates among the lowest in Europe. This spectacular reduction in legal voluntary abortions – which as we have seen cannot be explained by a parallel increase in illegal abortions – still awaits an adequate interpretation, which goes beyond the objectives of this article. Several factors should be adequately considered as the pharma-market, the health-system, the socio-economic context, the institutional issues (at both national and regional level, as the organization of health-system in Italy is organized by the twenty Regions), the political choices (support to pro- or anti-abortionist), and so on. The reduction could be also linked to the type of Italian abortion law 194/78, which conditions access to legal free-of charge abortion on prior contact with the public or private health system (family doctors, clinics, family and couples counseling centers, etc.), which can lead women to consider alternatives to abortion, and in any case to implement – after the interruption of pregnancy – safe contraception, avoiding repeated abortions (see the e-book: https://www.neodemos.info/2018/12/21/i-suoi-primi-quarantanni-2/ and the podcast https://www.neodemos.info/2024/03/12/abortion-voluntarily-in-italia/).

This surprising characteristic of Italy could be connected to the careful use of contraception, because the failure rate of birth control methods also depends on the mode of use (Schneider and Schneider 1996; Moreau *et al.* 2014). As far as we know, however, there are no in-depth and complete studies on this topic. Below we will try to understand how – in the context just described – the ECPs contributed to limiting unwanted conceptions during 2012-21. However, the empirical analysis

must be preceded by an examination of the mechanisms of diffusion and use of ECPs in developed countries and in Italy.

3. Availability and diffusion of ECPs in developed countries and in Italy

The diffusion of ECPs depends on several factors: type of ordinary contraceptive use, awareness among women and couples, availability (in pharmacies, other shops, or health centers), cost, and ease of access (with or without a medical prescription). These different factors can vary according to economic, social, and cultural contexts and the two different ECPs. For example, in the US in 2018, "seven states explicitly allow either pharmacies or pharmacists to refuse emergency contraception" (Heager 2018). The cost of a single-dose ECP in the US is not small, at $25 for LNG and $67 for UPA in online pharmacies (Heager 2018), while they are somewhat less expensive in Europe. In early 2020, the cheapest available brand of LNG-UPA (in euros) in France was 7-19; in Germany, 17-30; the UK, 15-57; Spain, 15-25; Sweden, 17-28; Poland, 10-30; Bulgaria, 15-22; and Serbia, 9-24 (ECEC 2022). Since per capita income is comparable in the first five countries, ECPs are arguably more accessible than in the US. In the latter three countries, where per capita income is significantly lower, the low price does not directly translate into greater accessibility.

Cost and scarce availability, especially in rural areas, are important factors in the low diffusion of ECPs in both developed and developing countries (Milkowski *et al.* 2021; Ahinkorah *et al.* 2021). Up to 2022, UPA could only be purchased with a prescription in the US. In contrast, no prescription has been required for LNG since 2006, with complete liberalization of sales in 2014 (Mehta *et al.* 2022).

A different path has been followed in Europe. In November 2014, the European Medicines Agency (EMA) amended its marketing authorization (centralized for all EU countries) and recommended a change in classification status for UPA from prescription to no prescription. In January 2015, the European Commission issued an implementing decision, the last step in allowing the sale of UPA without a prescription across the EU. While the Commission's decision was not legally binding, most (but not all) countries automatically implemented it, and UPA has since been available directly in pharmacies without prescription. Though the timing of the liberalization of LNG was different, by the end of 2010s, LNG drugs were sold without prescription practically everywhere in Europe, even if in some countries – such as Italy – restrictions persist for minors (ECEC 2022).

After the liberalization of sales, the prevalence of ever use of ECPs among sexually active young women aged 15-24 in the US strongly augmented, rising from 18% in 2008-10 to 32% in 2015-17. During the same period, the proportion of ECPs purchased in pharmacies by women aged 15-24 grew from 32% in 2008-10 to 70% in 2015-17, whereas the proportion purchased in community health or family planning clinics dropped from 46% to 18% (Mehta *et al.* 2022). In the US, given their lower cost and greater freedom of purchase, drugs based on LNG are much better known and much more frequently purchased than those based on UPA (Batur *et al.* 2016), although the latter are more effective at preventing pregnancy (Rosato *et al.* 2016).

In European countries as well, the switch from prescription to non-prescription ECPs has generally led to significant growth in the use of these drugs (Italia and Brand 2016), even though greater availability and freer access has not everywhere led to an increased use of emergency contraception. In France, the liberalization of LNG in 1999 saw a marked rise in ECP use. Young French women aged 15-24 who declared that they had used emergency contraception at least once more than doubled from 15% in 1999 to 32% in 2004 (Moreau *et al.* 2006). However, no significant increase in use has been observed since the liberalization of UPA in 2015 (Rahib *et al.* 2018). Moreover, a time comparison between surveys shows that neither availability in pharmacies nor removal of a charge for emergency contraception increased use among women having an abortion in Scotland (Cameron *et al.* 2012).

We now turn our attention to the usage of ECPs in Italy more specifically. At the time of writing (December 2024), in Italy, the LNG morning-after pill can be purchased in pharmacies by people aged 18 and over without a medical prescription while minors must present a prescription, necessarily renewed for each purchase. LNG was authorized in 2006, and ten years later, an Italian Medicines Agency (AIFA) decree liberalized its sale to adults. In Italy, like in many European countries such as France, Germany, Spain and UK, LNG is a behind-the-counter drug for those aged 18 and over, meaning that the buyer must explicitly ask the pharmacist. In a few countries, such as Sweden and Norway, LNG pills are available over the counter (without needing to ask the pharmacist explicitly), and in certain stores and supermarkets.

The situation is less restrictive in Italy for the five-day-after pill: UPA was authorized in 2012, liberalized for adults in May 2015, and then for minors in October 2020. UPA as also a behind-the-counter drug, obtainable upon request to the pharmacist, who is required by AIFA to also give the buyer an information brochure on contraceptive practices emphasizing that ECPs should not be used as a substitute for ordinary forms of contraception.

The liberalization of the two drugs in Italy (largely echoing the European approach) has thus largely been the opposite of that in the USA, where the sale of LNG was liberalized in 2006 for those over 18 and in 2014 for minors while, as of early 2023, a medical prescription is still required to obtain UPA, even for adults. As mentioned, UPA liberalization in Italy, even for minors, occurred under the strong recommendation of the European Medicines Agency, supported by its remarkable effectiveness, even though taken a few days after risky sexual intercourse. As elsewhere, the cost of the UPA pill is higher than that of the LNG pill. Both prices are near the European mean, close to Germany, Spain, and Sweden. The prices (in euros) in January 2024 of the most diffused trade names are 21.5 for LNG and 28.9 for UPA (five euros less if bought online on the cheapest websites). As for most medicines in Italy, a 19% refund of the ECP purchase can be claimed upon tax return filing, though the buyer must provide his/her tax code to the pharmacist.

4. Data and Methods

We use two types of data. The first consists of a complete monthly series of sales in Italy of single doses of LNG and UPA in 2012-21, provided directly to the

authors by AIFA. The second is individual data on live births (registered in the local Municipal Registry Office, called "Anagrafe" in Italy) and voluntary abortions (registered in the hospitals), recorded by the Italian National Institute of Statistics (ISTAT) between 2012 and 2022. These data allow us to estimate the conceptions that occurred two months earlier (abortions) and nine months before (births). The information on women aged 15-49 legally resident in Italy also comes from ISTAT which collects population data (by age, sex and civil status) annually from the Municipal Registry Offices. We employ four different methodologies.

First, using the monthly sales series, we examine whether there are discontinuities in the months immediately following the legislative changes.

Second, we estimate the maximum number of conceptions avoided through use of post-coital contraception, following a simple two-step procedure, not far from that proposed by Moreau *et al.* (2014) for estimating contraceptive failure rates. In the first step we estimated the average probability of conception following unprotected sexual intercourse as equal to 5%. This value is obtained by averaging the probability of conception for each of the days of the menstrual cycle, calculated on Caucasian European women not using contraceptives (Colombo and Masarotto 2000). This 5% is close to the value of 5.4% calculated by Trussell *et al.* (2003).

According to Glasier *et al.* (2010), the mean probability of conception for a single sexual inter-course for women who do not use other hormonal drugs is 2.15% if LNG is used and 1.36% if UPA is used. Thus, in the second step, under the assumption that the ECP was purchased because inter-course occurred, the maximum number of conceptions avoided by the two drugs are estimated as follows: for LNG, the number of packs sold is multiplied by (0.05 – 0.0215 = 0.0285), and for UPA the number of packs sold is multiplied by (0.05 – 0.0136 = 0.0364). This estimate is only indicative, as the capacity of ECPs to protect against unintended pregnancy may depend on several factors (Krassovics and Virágh 2016). For example, the distribution of users by age can influence the average "natural" risk of conception, since the probability of conceiving is lower at the beginning and end of reproductive life. The probability of conceiving after taking ECPs also varies depending on the type of usual contraceptive: the risk of conceiving could be lower if the ECP is taken by a woman who forgot to take the daily pill for a day, as opposed to one who does not adopt any contraception, who uses coitus interruptus, or after a condom breaks. The probabilities of conception for a single intercourse covered by ECPs proposed by Glaser *et al.* (2010) therefore do not capture all possible contextual differences, as they are derived from randomized samples that exclude women using hormonal contraception. In contrast, the use of ECPs after forgetting the daily pill could be common. However, in a sample of Italian women surveyed by Nappi *et al.* (2014, Tab. 2), among women at-risk of pregnancy who used ECPs at least once (20% of the population at-risk), only 22% said they did so after forgetting the daily pill, while 41% said they had resorted to it after the condom failure, and 37% after unprotected intercourse. In light of these considerations, our estimate can be considered an upper limit (i.e. the number of conceptions that would have been avoided if the sexual relations of all users had been at "natural" risk of conception) although not too far from the actual number of conceptions averted.

Third, conceptions avoided through the use of ECPs would otherwise have been unintended pregnancies, of which a significant proportion would have ended in abortion (Jones *et al.* 2002; Trussell *et al.* 2004). Using the individual ISTAT data set on births registered in the Municipal Registry Office and on abortions recorded in hospitals allows us to measure, through a logistic regression analysis, the net effect on the abortion ratio (abortion/conceptions) of the switch to ECP behind-the-counter availability, controlling for other variables observable in both data sets. Starting from births and abortions recorded in 2014-17, we built three databases on conceptions that occurred during the six-month period of February-July, in the years 2014, 2015, and 2016. Again, conceptions ending in births are calculated anticipating by nine months the monthly births registered in the Municipal Registry Office, while conceptions ending in an abortion are calculated anticipating by two months the monthly abortions recorded by hospitals in the ISTAT source. We do not consider either miscarriages (approximately 4-5 per thousand women aged 15-49 over the course of the decade, with a growing trend linked especially to the progressive aging of women of childbearing age, ISTAT 2017, 90-96) or illegal abortions (estimated to be around 10-13 thousand a year in 2016, Ministry of Health 2022, p. 19). For each of the three years (starting February 1st and ending July 31st), we model the dichotomous response variable outcome of the conception (abortion vs. birth) with a logistic regression, the independent variable being the period of the year February-April vs. May-July. We focus on the period of the year because, as we show in the following part, the months of May-July 2015 were those in which the sales of ECPs jumped, just after the UPA liberalization. If liberalization affects the abortion ratio, the odds ratio for May-July vs. February-April should be lower in 2015 than in 2014 and 2016. We control for the following covariates: age (in five-year intervals), citizenship (Italian, foreign), place of residence (North, Centre, South), marital status (married, single, other), and number of children ever born.

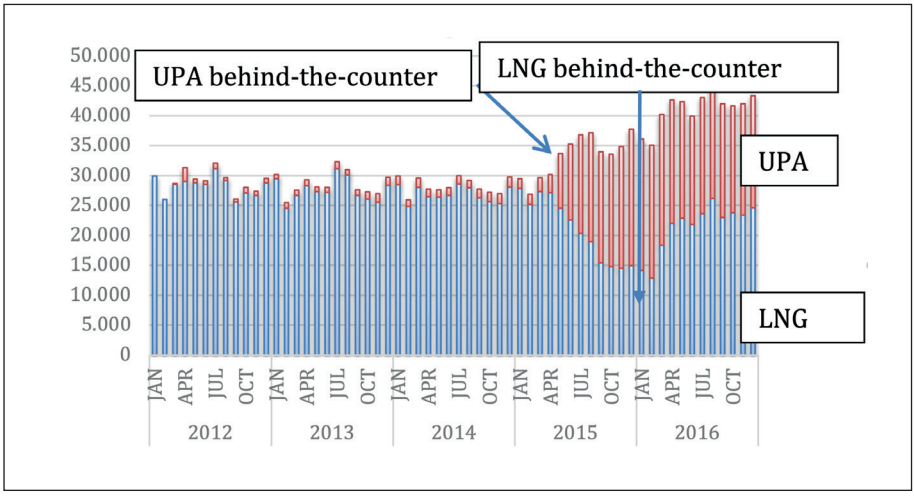
Fourth, to estimate the effect of the March-May 2020 COVID-19 lockdown on ECP sales and reproductive behaviors, we compare the monthly series of ECP sales in the three years 2019-21 with the number of conceptions that occurred during the months around the lockdown, ending with a birth or voluntary abortion, distinguishing by the age of the woman.

5. Results

5.1. Sales trends in Italy of ECPs before and after their liberalization

Between January 2012 and April 2015, before the liberalization, the monthly sales of LNG and UPA in Italy were almost constant, around 25 thousand for LNG and one thousand for UPA (Fig. 1), or 2.5 for every 100 women aged 15-49. From a European perspective, this is a low level, lower than 4.5% in France (2010), 3.5% in Spain (2013), and 3.9% in Germany (2015) – see section 2. With the liberalization of sales to people aged 18 and over in April 2015, UPA sales boomed in Italy, exceeding 18,000 packages sold in August 2015 and oscillating in the following months between 18,000 and 22,000 packs. In 2016, the first full year of UPA sale liberalization, 237,837 packs were sold in Italy, fourteen times more than the 16,793

Fig. 1. *Monthly sales of LNG and UPA pills in Italy between Jan 2012 and Dec 2016*



Source: Our elaborations of data provided by the Italian Medicines Agency (AIFA).

in 2014. In contrast, from May 2015 to February 2016, the sale of LNG continued to decline, descending below 13,000 packs in February 2016, less than half the level of February 2015, likely due to the non-liberalization of LNG sales. When LNG also became a behind-the-counter drug without prescription, in March 2016, sales began to recover rapidly in Italy and by the end of the year had returned to the levels of late 2014. UPA sales did not decrease after LNG was liberalized, even though the cost of LNG has always been lower, perhaps as a result of pharmacists recommending UPA for its greater effectiveness. The total sale of these two ECPs went from 340,000 packs a year in the three years of 2012-14 to almost half a million in 2016, i.e., 3.8 for every 100 women aged 15-49.

Overall, the effect of the shift from ECPs as a prescription to a behind-the-counter drug for adults led to a sudden growth in sales in Italy: +46% between 2014 and 2016. When only UPA had been liberalized in the beginning, there was a substitution effect from LNG to UPA. However, in the months that followed, LNG was also deregulated, UPA sales stabilized, and LNG sales returned to pre-deregulation levels. This similarly occurred in Germany, where the sale of UPA was liberalized a few months before that of LNG, the effect being that UPA replaced LNG in an initial phase, and then there was an overall growth in ECPs. In a sample of German pharmacies, the sale of ECPs grew by 38% from May-October 2014 to May-October 2015 (Italia and Brand 2016).

5.2. The effect of ECPs on conceptions

Applying the probability estimated in section 3 to monthly sales data (Fig. 1) we obtain the upper limit of the numbers of conceptions avoided monthly and annually in Italy during 2012-16 (Tab. 1) through the use of LNG and UPA.

For example, the upper limit of the number of pregnancies avoided thanks to LNG in 2012 is calculated by multiplying the number of LNG sold in 2012 by the difference between the probability of pregnancy without any control and the mean probability of conception for a single sexual intercourse for people using LNG: 339,405 x (0.05 – 0.0215) = 9,673, first row of Table 1.

Following the liberalization of sales, the upper limit of pregnancies avoided annually due to ECPs increased by 6,000 units, rising from 9,957 in 2014 to 15,975 in 2016 (last row of Tab. 1), more than 60% in just two years. This surge was due to the general increase in the use of ECPs, and to the partial replacement of LNG with UPA, which has greater efficacy (Glasier *et al.* 2010).

Tab. 1. *Estimation of the upper limit of the number of pregnancies avoided through the use of LNG and UPA in Italy, 2012-16*

	2012	2013	2014	2015	2016
LNG	9,673	9,449	9,201	7,229	7,317
UPA	284	434	611	5,298	8,657
Total	*9,957*	9,883	9,812	12,527	15,975

Source: Our elaborations of data provided by the Italian Medicines Agency (AIFA).

To understand the effect of the increase in post-coital contraception on the decline in conceptions in the 2013-16 period, we compare the results in Table 1 with the data in Table 2. From 2013-14 (twelve months centered on 1 December 2013) to 2015-16 (twelve months centered on 1 December 2015), conceptions resulting in births and abortions decreased by 40.3 thousand (595.6 – 555.3 thousand, third and fifth rows of Table 2). This decline partly mirrors the decrease in women of childbearing age. If, in 2015-16, women had had the same conception rate as in 2013-14 (44.3 per thousand, third row of Tab. 2), the number of conceptions would have been 576.9 thousand (13,022,773 x 0.0443), thus 18.7 thousand fewer than in 2013-14. As the number of actual conceptions in 2015-16 was 555.3 thousand (fifth row of Tab. 2), there were 21.6 thousand fewer conceptions not due to the decline in the number of women of childbearing age. According to our estimates, a maximum of 6 thousand of these 21.6 thousand avoided conceptions (i.e. 27.8%) are due to the increased use of ECPs (15,975 – 9,883 = 6,092; see columns 2013 and 2016 in Tab. 1). An additional of at least 15.6 thousand conceptions were prevented by other means, mainly an increased use of modern ordinary contraception, a decline in sexual intercourse, and a change in the age distribution of women of childbearing age, although this last factor, while certainly important in the medium to long term, should not greatly affect comparisons in close years. The decline in the number of induced abortions could also be linked to other factors, such as changes in healthcare organization (Minerva 2015). However, these factors should not be overestimated. Today in Italy it is easily possible to have a safe and confidential abortion: the number of non-objecting gynecologists is around the same as in 1983, but the number of operations is only a third of what

it was then. Furthermore, the waiting times between the issuing of the certification and the operation have been continuously decreasing for years (Ministry of Health 2016, 2022, podcast https://www.neodemos.info/2024/03/12/aborto-volontario-in-italia/).

Tab. 2. *Conceptions and outcomes of conception in Italy in 2011-21. Absolute values and indicators.*

June-May	Women	Outcomes			Rates x 1.000 women 15-49			Abortion
	15-49	Conceptions	Births	Abortions	Conceptions	Births	Abortions	Ratio (*)
2011-12	13,684,631	640,931	532,954	107,977	46.8	38.9	7.9	16.8
2012-13	13,582,795	610,865	510,571	100,294	45	37.6	7.4	16.4
2013-14	13,439,542	595,620	498,533	97,087	44.3	37.1	7.2	16.3
2014-15	13,230,365	575,512	483,535	91,977	43.5	36.5	7	16
2015-16	13,022,773	555,347	470,924	84,423	42.6	36.2	6.5	15.2
2016-17	12,809,558	540,466	458,112	82,354	42.2	35.8	6.4	15.2
2017-18	12,602,357	511,232	433,106	78,126	40.6	34.4	6.2	15.3
2018-19	12,407,796	493,866	420,956	72,910	39.8	33.9	5.9	14.8
2019-20	12,209,642	498,490	431,430	67,060	40.8	35.3	5.5	13.5
2020-21	11,965,446	430,915	367,218	63,697	36	30.7	5.3	14.8

Note. For estimations of pregnancies ending in birth and abortion, and of female population (at first of January of the second year of the indicated two-year period), see section 3. We do not consider either miscarriages (approximately 4-5 per thousand women aged 15-49 per year, ISTAT 2017, 90-96) or illegal abortions (estimated to be around 10-13 thousand a year in 2016, Ministry of Health 2022, p. 19). So as to better highlight the possible effect of the sale liberalization for adult women, which took place in May 2015 (UPA) and in June 2016 (LNG), we consider the conceptions that occurred in the twelve months starting 1 June and ending 31 May of the following year.
(*) 100 x Ratio between voluntary abortions and conceptions
Sources: For population and births: https://demo.istat.it/. For abortions: ISTAT, Individual hospitals' data.

5.3. Liberalization of ECPs and the abortion ratio

As specified in part 4, for the three individual databases of conceptions that occurred during the six-month period of February-July in the years 2014, 2015, and 2016, we model the outcome of the conception (abortion vs. birth), the independent variable being the period of the year February-April vs. May-July. If the liberalization of May 2015 affects the probability of abortion, the odds ratio for May-July vs. February-April should be lower in 2015 than in 2014 and 2016. Indeed, this is precisely what we observe in Table 3. Though the odds ratios are less than one for the three years – as the abortion ratio in Italy follows a seasonal trend, that of 2015 is lower compared to the other two years.

Tab. 3. *Odds ratios for abortions vs. births. Conceptions of May-July compared to those of February-April (baseline). Three logistic models were applied to conceptions in Italy in 2014, 2015 and 2016*

	Odds Ratio	SE	P
2014	0.918	0.010	0.000
2015	0.852	0.010	0.000
2016	0.972	0.012	0.016

Note: for each model, the control variables are age, citizenship, place of residence, marital status, and number of children ever born. Complete models are available on request.

5.4. ECPs sales and conceptions during the COVID-19 pandemic

The analysis of the monthly sales data highlights the connections between the COVID-19 epidemic and sales of ECPs (Fig. 2A). Sales collapsed during the strict lockdown of spring 2020. In April 2020 – the month entirely covered by the rigid lockdown – only 18.5 thousand monodose ECPs were sold, compared to 48 thousand in April 2019 and 60 thousand in April 2021. They also decreased, albeit more slightly, in the autumn of 2020 and the first two months of 2021 when, with a new wave of COVID-19 in Italy, new less severe restrictions on the movement of people were introduced. In the following months of 2021, when these restrictions were lifted, sales greatly exceeded those of 2019.

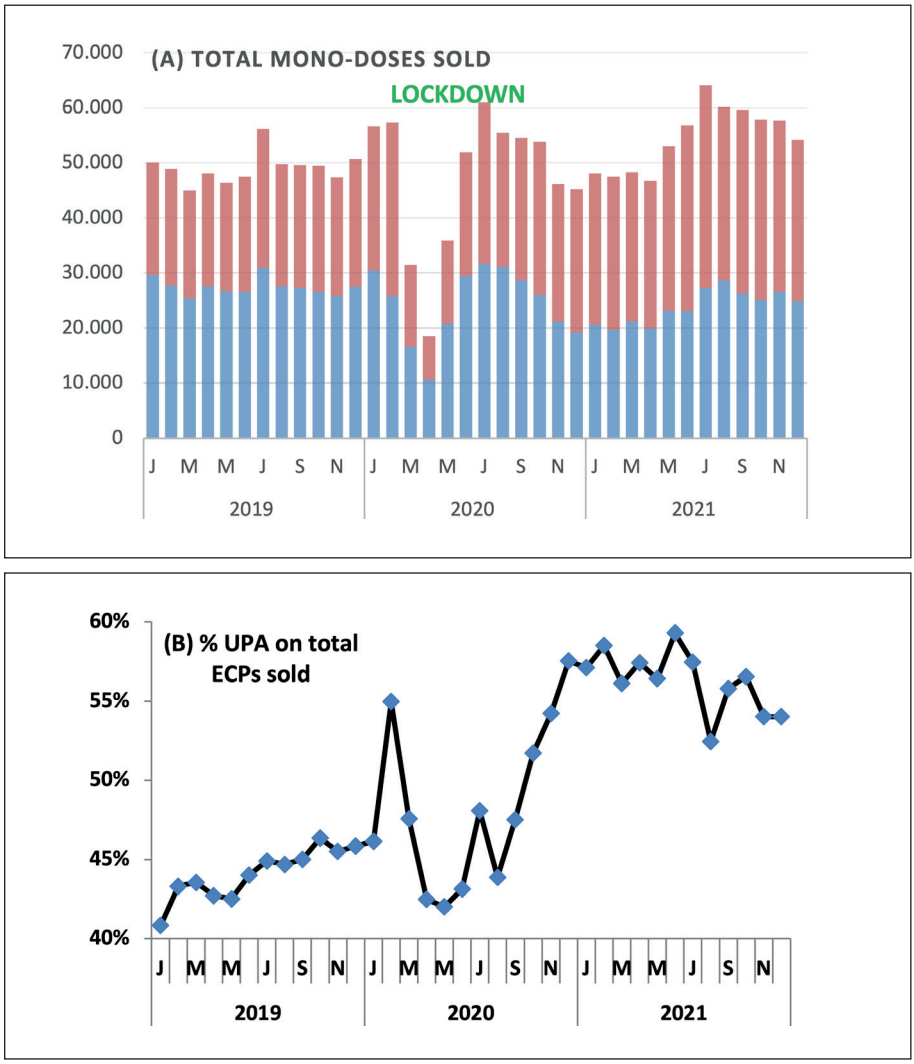
The increase in sales of ECPs mirrored the increase in sales of UPA, while sales of LNG remained almost constant. Figure 2B shows that the proportion of UPA on ECPs rose sharply after October 2020. It could be linked to the fact that in October UPA became available behind-the-counter even for minors, whereas a medical prescription continued to be required for LNG for those under 18.

Despite the almost halving of sales of ECPs during the strict lockdown of 2020, births and abortions resulting from conceptions during the same period notably decreased, especially – but not only – among the youngest women (Table 4), as also shown by other authors (for births: Aassve *et al.* 2021, Castagnaro and Prati 2022, Sobotka *et al.* 2023; for abortions: Guzzetti *et al.* 2022, Ministry of Health 2022).

Although some couples may have postponed or cancelled their childbearing plans during the pandemic due to uncertainty about the future, an important part of the decline in conceptions was certainly caused by the generalized decrease in sexual relations between non-cohabiting people – almost half of women age 15-49 living in Italy (see the last column of Tab. 4) – as a result of the forced distancing between partners and the almost zeroing of casual sex. Finally, the sharp decline in conceptions for women over 40 is meanwhile due to the drastic reduction in access to assisted reproductive procedures during the lockdown (Castagnaro and Prati 2022).

Furthermore, in Italy, even the frequency of sexual relations of people living in couples seemingly declined during the lockdown: among a large representative sample interviewed by Amerio *et al.* (2021) at the very end of the lockdown, 21% (mostly men) said they had reduced sexual relations while only 9% (men and women equally) claimed to have had increased frequency. This reduction may also have

Fig. 2. *Monthly sales of ECPs in Italy during the years 2019, 2020, and 2021*



Source: Our elaborations of data provided by the Italian Medicines Agency (AIFA).

been due to the decrease in sexual relations with a partner outside the couple (an aspect not specified in the questionnaire). The marked drop in sales of phosphodiesterase inhibitors (i.e., medicines used for erectile dysfunction) for the three months of lockdown compared to the previous three months (-39% that becomes -56% if April 2020, the month entirely covered by lockdown, is compared with January 2020) also suggests that the global frequency of sexual intercourse decreased during this time (ONM 2020, p. 35). This deduction is also supported by another piece

Tab. 4. *Monthly conceptions ending in a birth or abortion in Italy by the age of women. Index number for January-July 2020 (value in 2019 = 100)*

	Conceptions ended in a birth							Conceptions ended in an abortion							(*)
	Jan	Feb	Mar	Apr	May	Jun	Jul	Jan	Feb	Mar	Apr	May	Jun	Jul	
15-19	93	*83*	**71**	**69**	**73**	*86*	94	101	90	**43**	**48**	*82*	91	*82*	0.1
20-24	94	91	**79**	**77**	*87*	100	91	100	*89*	**59**	**69**	*81*	92	104	7.1
25-29	92	90	*85*	*86*	93	99	94	90	98	**69**	**74**	*85*	*88*	98	34.2
30-34	97	93	*88*	91	97	109	104	98	100	*82*	*89*	91	99	103	62.9
35-39	97	92	*84*	*89*	95	109	107	105	98	*80*	91	*89*	93	103	73.7
40-44	96	*83*	**75**	*81*	*84*	101	105	95	90	**79**	91	90	103	105	74.5
45-49	93	**59**	**27**	**32**	**57**	91	110	90	148	**50**	*89*	103	95	*89*	72.3
15-49	96	90	*84*	*87*	93	105	101	98	96	**71**	*80*	*87*	94	101	51.2

(*) % women cohabiting with a male partner during 2020, calculated by ISTAT Labor Survey micro-data.
Note: in bold the index numbers < 80%; in italics the index numbers ≥ 80% and < 90%.
Sources: ISTAT, Live births recorded in the population registers; ISTAT, Individual data recorded in the hospitals.

of evidence, namely the sudden drop in the sale of condoms during the lockdown, recalling that the condom – in Italy – is largely used to protect relationships between non-cohabiting partners (Caltabiano *et al.* 2020; Castiglioni 2013). COOP, one of the largest Italian supermarket chains, has kindly processed the monthly data on condom sales for us in the two-year period 2019-20. In the quarter March-May 2020, sales were 28% lower than the same quarter of 2019 (-40% in April), while in the two-month period January-February the sales of 2020 were similar to those of 2019, and in the June-August quarter only 9% lower. These data did not occur at a time of general decline in sales, indeed during the lockdown, COOP recorded a boom in sales in Italy, as a large part of the Italian large-scale retail trade.

Finally, throughout the COVID-19 epidemic, unlike in some other countries (Aly *et al.* 2020; Sobotka *et al.* 2023), there was no restriction on access to the most popular contraception devices. As already specified, in Italy, these were sold in pharmacies (pill and condom), supermarkets, and other stores that were open during the lockdown (condoms). The consumption of contraceptive daily pills in Italy continued to increase, showing no break in 2020, going from 98 defined-daily-doses for 1,000 women aged 12-50 in 2015 to 138 in 2021 (ONM 2021, pp. 193-197). Furthermore, access to abortion services was guaranteed both during the strict lockdown and in the months that followed (Ministry of Health 2022).

As restrictions on movement were lifted and sexual activity presumably returned to pre-pandemic levels, the increase in the sale of ECPs (especially UPA) went hand in hand with the reduction in the rate of conception. The restrictions on personal movement during the COVID-19 outbreaks in spring and autumn 2020 strongly impacted ECP sales. The lockdown revealed that in Italy, a preponderant

part of ECPs is used after sexual intercourse by people who do not live together as a co-resident couple. Subsequent to the pandemic, the growth trend resumes, so much so that in 2021, more than 650 thousand single doses of ECPs (56% UPA, 44% LNG) were sold in Italy.

6. Summary and Discussion

We briefly summarize our empirical findings, then outline the trends observed in the Italian path towards the second contraceptive revolution and conclude with some indications of possible changes in health policy related to ECPs.

The spread of ECPs in Italy significantly increased when UPA (in March 2015) and LNG (in May 2016) became behind-the-counter medications, without prescriptions. Sales rose from 30,000 to 40,000 single-dose packs per month from 2014 to 2016, compared to the three-year period of 2012-14 when the number of doses sold remained constant. We estimate that this increase in 2016 could have avoided a maximum of 6,000 more unwanted pregnancies than in 2014 (16,000 compared to 10,000). A maximum of a quarter of the decline in the conception rate between 2014 and 2016 could be due to the greater diffusion of ECPs. Moreover, even if the decreasing trend in abortion rates and ratios in Italy is likely determined by the slow but steady spread of modern contraception, in addition to the factors mentioned in the second part of this article, the liberalization of ECPs contributed to accelerate the reduction in the abortion ratio in 2015.

The increase in ECP sales in Italy continued after 2016, and in 2021 exceeded a remarkable 650,000 single-dose packs sold (i.e., 5.5 for every hundred women aged 15-49, at similar levels to those estimated in other European countries such as France, 6.2% in 2016, and the Netherlands, 5.0% in 2017, but at much lower levels than the United Kingdom, 33% in 2014, where ECPs were and are free-of-charge, ECEC 2024), a higher number compared to the less than 500,000 doses five years earlier. In 2021, ECP use may have avoided a maximum of 21,500 unwanted pregnancies, contributing to making the abortion rate in Italy one of the lowest in Europe. This increase in sales, and in particular the preference for UPA – the sale of which has steadily exceeded LNG sales since early 2021 – was also bolstered by UPA becoming available as a behind-the-counter drug for minors without a prescription in October 2020.

As far as we know, no direct data are available on the characteristics of women and couples who use emergency contraception in Italy, except for a survey ten years ago on a limited number of users (Nappi *et al.* 2014). However, using monthly data on ECP sales in 2019-21, we show that during the strict COVID-19 lockdown of March-May 2020, sales of emergency contraceptive pills decreased by 38% compared to the same quarter in 2019, and the reduction in April 2020, the month of strict and complete lockdown, compared to April 2019, was 61%. Nonetheless, conceptions during the lockdown also declined significantly, especially those resulting in an abortion and those among women under the age of 25. This result suggests that – out of pandemic lockdown conditions – ECPs are widely used by non-cohabiting partners. This result shows that ECPs have played a non-marginal role in the second Italian contraceptive revolution, in particular by reducing un-

wanted pregnancies among people who do not live in a couple, mostly condom users and/or exposed to the risk of unprotected sexual intercourse.

Although recent surveys of nationally representative samples on the diffusion of contraception in Italy are not available, data on oral contraceptive sales and some surveys on particular groups (e.g. ISTAT 2019; Caltabiano *et al.* 2020) suggest that the drop in conception and abortion rates and the abortion ratio in Italy in the first part of the twenty-first century has mainly been due to the decline in coitus interruptus, and the spread of condoms (especially for casual and juvenile sexual intercourse) and the daily pill (particularly in consolidated couple relationships). That said, the contributions of ECPs has grown from year to year, and it may continue to do so, as there is considerable room for improvement for example by bridging current territorial gaps: strong regional differences characterize the Italian context, ranging from 6.4 ECPs sold yearly during 2019-21 for every 100 women aged 15-49 in Liguria to 3.6 in Sicily (our calculations using data kindly provided by the AIFA).

The effect of differing ECP availability on their use, on the incidence of unwanted pregnancies, and the use of ordinary contraception is difficult to measure, as this strongly depends on context, which can vary even within the same country (e.g., women of different social classes) (Cameron *et al.* 2012; Krassovics and Virágh 2016). For Italy – if we exclude the aforementioned and dated study by Nappi *et al.* (2014), conducted when there were less than half the number of sales of ECPs compared to today – there is a lack of research on ECP users and little is known about their socio-demographic characteristics (social class, age, relationship status, etc.) or the reasons they turn to this method (condom breakage, forgetting the daily pill, direct contraception, etc.).

Although filling this knowledge gap is important before proposing any changes to the rules that regulate ECPs, the results of our study allow for some final reflections on the methods of sale and diffusion of ECPs in Italy. The probabilities of conceptions for a single act of sexual intercourse followed by the use of LNG or UPA – as estimated by Glaiser *et al.* (2010) – show that the efficacy of ECPs alone in preventing conception is considerably lower when compared to that of other contraceptive devices (Trussell *et al.* 2011), e.g., the yearly probability of falling pregnant with perfect use of the daily pill is 0.01; an IUD, 0.006; a condom, 0.02. In contrast, for a woman who has sex one time a week, without avoiding her fertile days – once a week (about 52 times a year), without any other hormonal contraceptive device, the yearly probability of conception jumps to 1-(1-0.0215)52 =0.68 for LNG and 1-(1-0.0136)52=0.51 for UPA, if she uses only ECPs. These data confirm that ECPs should never replace ordinary contraception, as their efficacy in preventing unwanted conception (if used as the only method) is considerably lower than that of contraceptive devices such as daily pills, the IUD, or condom. Misconceptions about the contraceptive efficacy of ECPs are widespread in Italy: 49% of a sample of Italian women aged 16-45 interviewed by Nappi *et al.* (2014, Tab. 3) "agreed" or "strongly agreed" with the statement "ECP is 100% effective if taken the next day". This proportion was the higher among the interviewed samples: 43% in France, 42% in Spain, 37% in Germany, and 35% in the UK.

These data and considerations suggest that maintaining behind-the-counter

sales in pharmacies in Italy may be appropriate, given that this ensures interaction with the pharmacist, who under Italian regulations is required to warn users about the limited contraceptive power of ECPs and their unsuitability as an ordinary contraceptive method. It would further make sense to extend LNG without prescription to minors, as done for UPA in October 2020, as well as to lower the prices of ECPs in Italy. However, the free distribution of emergency contraception would not be desirable, because it could induce inappropriate use, as a substitute for far more effective methods, available in Italy only for a fee. Last but not least, extended information campaigns both on the high risk of pregnancy in case of unprotected intercourse and on the possibility of using ECPs are fundamental. To date, no such information campaign has ever been implemented in Italy, yet the main reason for inappropriate or poor use of ECPs (and of contraception tout court) is insufficient knowledge about the risk of pregnancy, available contraception, and – more generally – reproductive health. In this way, emergency contraception pills could make an even greater contribution to reducing unwanted pregnancies and abortions in Italy.

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Riassunto

Dieci anni di contraccezione d'emergenza in Italia (2012-21) nel contesto della seconda rivoluzione contraccettiva

Due pillole di contraccezione d'emergenza (ECPs) possono essere acquistate senza prescrizione medica in Italia da adulti: dal maggio 2015 (ulipristal acetato, UPA) e dal giugno 2016 (levonorgestrel, LNG). La liberalizzazione della vendita delle ECPs ha contribuito ad accelerare la seconda rivoluzione contraccettiva in Italia, riducendo principalmente le gravidanze indesiderate tra le persone single. Nell'ottobre 2020, la vendita di UPA è stata liberalizzata anche per i minori.

In questo lavoro, si misurano gli effetti della liberalizzazione di LNG e UPA, nonché del lockdown da COVID-19, sulle vendite delle ECPs, sui concepimenti e sugli aborti, utilizzando dati mensili sulle vendite e dati individuali sui concepimenti per esito, analizzando la discontinuità nei tassi di aborto tramite modelli di regressione. Si mostrano inoltre gli effetti del lockdown del 2020 sulle vendite di ECPs.

Le stime indicano che, al massimo un quarto del calo del tasso di concepimento tra il 2014 e il

2016 è stato attribuibile alla liberalizzazione, con una riduzione principalmente degli aborti. Le vendite di UPA sono aumentate dopo la liberalizzazione per i minori. Il lockdown di marzo-maggio 2020 ha ridotto le vendite di ECPs, i concepimenti e gli aborti, rivelando che una gran parte delle ECPs viene utilizzata dopo rapporti sessuali al di fuori delle coppie conviventi.

Summary

Ten years of emergency contraception in Italy (2012-21) in the context of the second contraceptive revolution

Two emergency contraception pills (ECPs) can be purchased without prescription in Italy by adults: since May 2015 (ulipristal acetate UPA) and June 2016 (levonorgestrel LNG). The liberalization of the sale of ECPs has contributed to accelerating the second contraceptive revolution in Italy, mainly reducing unwanted pregnancies for single people. In October 2020, the sale of UPA was liberalized to minors. We measure the effects of LNG and UPA liberalization as well as of the COVID-19 lockdown on sales of ECPs, conceptions and abortions by monthly data on sales and individual data on conceptions by outcomes, studying discontinuity of abortion ratios by regression models. We also show the effects of the 2020 COVID-19 lockdown on ECPs sales. At most, one quarter of the decline in the conception rate between 2014 and 2016 was due to liberalization, reducing mainly abortions. Sales of UPA increased after liberalization for minors. The lockdown of March-May 2020 reduced ECP sales, conceptions and abortions, revealing that a large part of ECPs are used after sexual intercourse outside cohabiting couples.

Parole chiave

Contraccezione d'emergenza; Aborto; Concezione; Liberalizzazione; COVID-19 lockdown.

Keywords

Emergency contraception; Abortion; Conception; Sales liberalization; COVID-19 lockdown.