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ORIGINAL RESEARCH

Switching emergency contraceptives to non-prescription status and unwanted pregnancy among adult and teenage women: A long-term European comparative study

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Abstract

Aim: Unwanted pregnancy is an important social issue, not least among teenagers. Emergency contraceptives (EMCs) can prevent from unintended pregnancy, if taken quickly after unprotected sex. This study's objective was assessing abortion/birth rates among adult and teenage women in Europe before/after an EMC switch to non-prescription status.

Methods: National authorities were consulted for EMC consumption data and abortion/live birth statistics. Rates (n=26 countries) in the year before the switch (= year of reference) were compared with rates before/after the change (up to ± 15 years). The focus was laid on the European Union and further countries closely related to the European Union.

Results: All countries with available data (n=12) experienced a substantial increase of EMC consumption after the switch. On average, abortion rates among women aged 15–49 years were 83% higher 15 years before (compared with the year of reference) and 14% lower 15 years after the switch. Correspondingly, teenage abortion rates were 35% higher 15 years before and 40% lower 15 years after the switch. In 2017, no country had higher teen abortion rates than at time of the switch. Teen birth rates continued decreasing at almost the same rate after the switch as before.

Conclusion: An EMC switch to non-prescription status increases EMC use and may contribute reducing unwanted pregnancy among teenage girls.

Keywords: *Emergency contraceptives, Europe, levonorgestrel, over-the-counter, prescription status, ulipristal acetate.*

Conflicts of interest: None declared.

Introduction

For 2008, about 41% of pregnancies worldwide were estimated to be unplanned (1). Four years later, this proportion was stable at 40%, highest in Latin America (56%) (2). Unwanted pregnancies are an important social issue in Europe as well (rate estimated at 45%), and many are likely to end in induced abortion (50%) or unplanned birth (about 38%). Especially among teenagers, the rate of unintended pregnancy is supposed to be very high (roughly 80% of all pregnancies among American teenagers are unwanted) (1). Using long lasting oral reversible hormonal contraceptives regularly could be an ongoing protection from unwanted pregnancy, but this reliable method is not used by all fertile women (in 2012, by 82.5% in Portugal, but only by 33.2% in Lithuania) (3). One effective option avoiding unintended pregnancy after unprotected sex is quickly taking an emergency contraceptive (EMC). In Europe, mainly two active ingredients are used for emergency contraception, levonorgestrel (LNG) and ulipristal acetate (UPA), which have to be taken within 72 hours (LNG) or 120 hours (UPA) after unprotected sex.

As time is a crucial factor and EMCs are considered to have a good safety profile, the European Medicines Agency (EMA) recommended switching UPA (ellaOne®) from prescription-only to non-prescription status in November 2014 to speed up access to EMCs. The following legally binding decision of the European Commission valid (in principle) throughout the European Union (EU) made UPA available as an over-the-counter (OTC) drug across the EU (3,4). About 20 years ago, when LNG or UPA were not (freely) available for emergency contraception, pregnancy rates among teenagers were higher in many European

countries compared to 2017, e.g. 55 per 1000 adolescents aged 15–19 years (England and Wales), or 68 per 1000 adolescents aged 15–19 years in Hungary (5), and most teen pregnancies ended in abortions or presumably unplanned births.

One hope linked with facilitated access to EMCs was reducing abortion/teen births rates. However, also concerns were expressed regarding prescription-free availability of EMCs, moral worries as well as medical fears, e.g. that changes in sexual behaviour especially among adolescents could also lead to misuse and hence increase abortion rates instead of decreasing them (6), or that sexually transmitted infections might rise again (7,8).

This study's objective was to analyse the potential impact of an EMC switch to non-prescription status on unwanted pregnancy. This was done by assessing abortion rates among women aged 15–49 years and abortion and live birth rates among adolescents <20 years in Europe since and also before the switch of EMCs to non-prescription status. Within Europe, we mainly focused on the European Union (EU) and the European Free Trade Association (EFTA). A further aim was collecting EMC consumption data since their market introduction.

Methods

Consumption of EMCs

EMC consumption was investigated at the national medicines authorities (direct contact or yearly consumption reports). Another source for data on EMC use were drug consumption databases and EMC-related publications (9,10).

Year of reference

Following EMCs with their Anatomical Therapeutic Chemical Classification codes (ATC) were under research:

1. ATC code G03AD01 (LNG); approved first in Eastern Europe in 1979 and marketed in Western Europe since the 1990s.
2. ATC code G03AD02 (UPA); approved in Europe in 2009 and recommended by the EMA in November 2014 to have non-prescription status.
3. ATC code G03AA07 (levonorgestrel + ethinylestradiol); dedicated preparations (brand names Tetragynon[®], Schering PC4[®]) marketed as prescription-only products in several European countries (since the 1980s) and first EMC with non-prescription status in Iceland (in 1998).

The year/month of an EMC switch to non-prescription status (date one out of the three EMCs mentioned above was made available without medical prescription for the first time) was checked at the national medicines authorities (homepage or contact by e-mail). Additionally, EMC-related publications were screened. The year preceding the switch was defined as ‘Year of reference’ for comparing development of rates after/before the switch, if the switch became operative between January and October. For countries where the switch came into force in November or December, the year of switch was defined as ‘Year of reference’, as a switch towards the end of the year may hardly have had an impact on the same year’s abortion statistics. The year of switch was defined being the first year ‘after’ a switch. Hence, statistics after the switch were compared with figures in the

‘Year of reference’ ended. Correspondingly, to take into account long-term trends, also rates in the years before the switch were compared with rates of the ‘Year of reference’ ended.

Analysis of rates

To obtain statistics on abortions and teen births, the homepages of national statistical offices were consulted or respective authorities were contacted directly (data sources available as supplementary material). For analysis of induced abortion rates (spontaneous abortions were not considered, as not mentioned in many abortion statistics) among the whole fertile female population, the total number of legally induced abortions was sought and referred to 1000 women aged 15–49 years. If stratified data were available, induced abortions performed to the countries’ residents only were considered. Population structures were obtained from national statistical offices. Respectively, the number of induced abortions and live births (still births were excluded, since not available for all countries) among adolescents <20 years was referred to 1000 women aged 15–19 years.

If absolute numbers for abortions/live births were not available, rates were adopted as reported by the countries’ authorities.

Generally, abortion and live birth rates for women aged 15–19 years presented in this study mostly include the figures for girls <15 years, as this is mainly the method how authorities report the rates for this age group. However, abortion/birth figures for girls <15 years are almost negligible for the calculation of teenage abortion/birth rates.

Abortion statistics for residents from Ireland and Northern Ireland were extracted from the annual abortion reports of the United Kingdom, since Ireland and Northern Ireland

have very restrictive abortion laws and only few abortions were performed in Ireland and Northern Ireland.

Rates for countries (e.g. England and Wales, the Netherlands, Sweden) generally reporting rates among women aged 15–44 years (instead of 15–49 years) were recalculated for the 15 to 49-year-old female population. For some years, figures on abortions or live births were not available from the national authorities. Therefore, rates were extracted from graphs provided by national health/statistical authorities or calculated based on figures from the historical Johnston archive (11), the World Health Organization (12), Eurostat (13), or the World Bank (14). Data were collected up to the year 2017.

Results

History of EMC accessibility

Exactly 26 countries were included in this comparative study (23 EU countries, 3 EFTA countries). Iceland (1998) and France (1999) were the first countries making EMCs available without medical prescription. According to the Icelandic medicines agency, the first EMC available (Tetragynon[®]) was classified as OTC medicine immediately after receiving marketing authorization in June 1998, as well as LNG, which was freely available since January 2003. Among the last European countries changing at least one EMC (UPA or LNG) to OTC status were Germany, Italy, and Croatia (all in 2015). Hungary decided keeping the prescription-only status for all EMCs, Poland switched UPA to OTC status in April 2015, but the new Polish government abolished the

decision and re-switched UPA to prescription-only status again in July 2017 (LNG never received OTC status in Poland). The most recent European countries making EMCs accessible without medical prescription were Malta (December 2016) and Andorra (June 2018).

In Gibraltar, a self-governing British Overseas Territory, EMCs were switched to OTC status in August 2017 only, about 8 years after the switch in the neighbouring country Spain, and more than 16 years later than in the United Kingdom itself.

Rates after the switch

In the year before the switch, total abortion rates ranged between 3.2 (Croatia) and 31.5 (Estonia) abortions per 1000 women aged 15–49 years. The mean for the 26 included countries was 11.8. Exactly 19 countries experienced a reduction of abortion rates since the switch. The sharpest decline was observed in Latvia (-63% within 15 years). In 7 countries, abortion rates among the total female population were slightly higher in 2017 (or in the year with most recent available figure) compared with the year of reference (Table 1).

The development of abortion rates among adolescents aged 15–19 years revealed a relatively uniform picture (Table 1). In all countries except Belgium and Greece (for which most recent figures were available for 2011 and 2012 only) abortion rates fell. The biggest reductions since the switch were visible in Latvia (-73%) and Norway (-67%). On average, abortion rates dropped from 12.0 at time of the switch to 6.9 abortions/1000 adolescents aged 15–19 years in 2017.

Table 1. Induced abortion and live birth rates at time of the OTC switch compared with rates in 2017

Country	Switch	Reference	Rates in the year of reference ^a			Rates in 2017 ^a		
			Abortions 15-49	Abortions 15-19	Births 15-19	Abortions 15-49	Abortions 15-19	Births 15-19
Belgium	Apr 01	2000	5.6	6.9	10.7	7.8*	8.4*	5.8
Bulgaria	Jan 06	2005	22.4	15.6	40.4	16.0	14.3	39.7
Croatia	Apr 15	2014	3.2	1.8	10.3	2.7	1.5	9.3
Czech Republic	Nov 11	2011	9.6	7.1	11.3	8.2	5.6	11.9
Denmark	Jun 01	2000	12.5	14.2	7.9	12.1***	11.3***	2.8
Estonia	Sep 03	2002	31.5	28.9	23.0	13.9	10.8	10.1
Finland	Jan 02	2001	8.9	15.5	10.7	8.2	7.6	4.9
France ^b	May 99	1998	13.4	13.2	7.1	14.4	10.4	4.7
Germany	Mar 15	2014	5.6	4.4	6.1	5.8	4.0	6.3
Greece	Jun 05	2004	6.0	2.1	10.8	6.8**	2.4**	9.0
Iceland	Jun 98	1997	13.6	20.6	24.3	13.3	12.6	6.0
Ireland	Feb 11	2010	3.7	3.2	14.4	2.6	1.4	6.9
Italy	Apr 15	2014	7.0	5.4	5.6	6.2	4.3	4.3
Latvia	May 03	2002	25.1	17.0	21.5	9.2	4.6	15.0
Lithuania	Jul 08	2007	11.7	7.3	19.5	6.9	3.2	12.2
Netherlands	Jan 05	2004	7.4	8.2	4.6	7.2	5.3	2.0
Norway	Jul 00	1999	13.4	19.0	11.7	10.6	6.3	3.0
Romania	Nov 06	2006	28.3	23.1	40.1	12.4	10.2	38.5
Slovak Republic	Apr 04	2003	9.8	6.6	20.8	5.8	4.3	27.3
Slovenia	Mar 11	2010	9.0	6.7	4.9	8.1	4.0	4.0
Spain	Sep 09	2008	9.7	12.7	13.2	8.7	8.8	7.2
Sweden	Apr 01	2000	15.6	21.1	5.0	16.8	13.0	3.1
Switzerland (Cantone Berne) ^c	Oct 02	2001	5.2	4.9	3.4	5.0	3.2	2.1
UK (England & Wales)	Jan 01	2000	14.1	23.7	29.3	14.4	14.7	12.7
UK (Scotland)	Jan 01	2000	9.6	18.4	29.3	9.9	12.9	13.0
UK (Northern Ireland)	Jan 01	2000	3.7	4.8	25.6	2.2	2.1	12.4
Mean			11.8	12.0	15.8	8.9	6.9	10.5

^aRates are displayed per 1000 women of the respective age group (figures for girls <15 years are normally included)

^bFrance métropolitaine (=France without Guadeloupe, Martinique, Guyane, La Réunion, Mayotte)

^cNo long-term abortion data available for Switzerland as a whole

Rates in bold letters are higher compared with rates in the year of reference

* 2011 figures

** 2012 figures

***2015 figures

Live birth rates among women aged 15–19 years fell in most countries. Only the Czech Republic and Germany had slightly higher rates in 2017 compared with the year of reference. However, the Slovak Republic had clearly higher birth rates after the switch and was the only country in this study where the

sum of teenage abortion and live birth rates was higher in 2017 compared to the year of reference.

Further abortion and live birth rates for some European countries with incomplete statistics are displayed in Table 2.

Table 2. Induced abortion and live birth rates for further European countries

Country	Switch	Reference	Rates in the year of reference ^a			Rates in 2017 ^a		
			Abortions 15-49	Abortions 15-19	Births 15-19	Abortions 15-49	Abortions 15-19	Births 15-19
Andorra	Jun 18	2017	na	na	3.4	na	na	3.4
Austria	Dec 09	2009	no stat	no stat	10.4	no stat	no stat	6.8
Cyprus	?	---	no stat	no stat	---	no stat	no stat	6.6
Hungary	Still Rx	---	na	na	na	12.6	16.1	23.2
Luxembourg	May 05	2004	no stat	no stat	10.9	no stat	no stat	5.2
Malta	Dec 16	2016	na	na	13.6	na	na	12.5
Poland ^b	Apr 15	2014	na	na	13.4	na	na	11.1
Portugal	Oct 00	1999	na	na	21.1	6.7	5.5	8.0

Rx=prescription-only

na=not applicable (abortion illegal or EMCs available with prescription only)

no stat=no official data available

?=EMCs have OTC status, but date of switch not determinable

^aRates are displayed per 1000 women of the respective age group (figures for girls <15 years are normally included)

^bEMCs were re-switched to prescription-only status in July 2017

Long-term analysis of rates

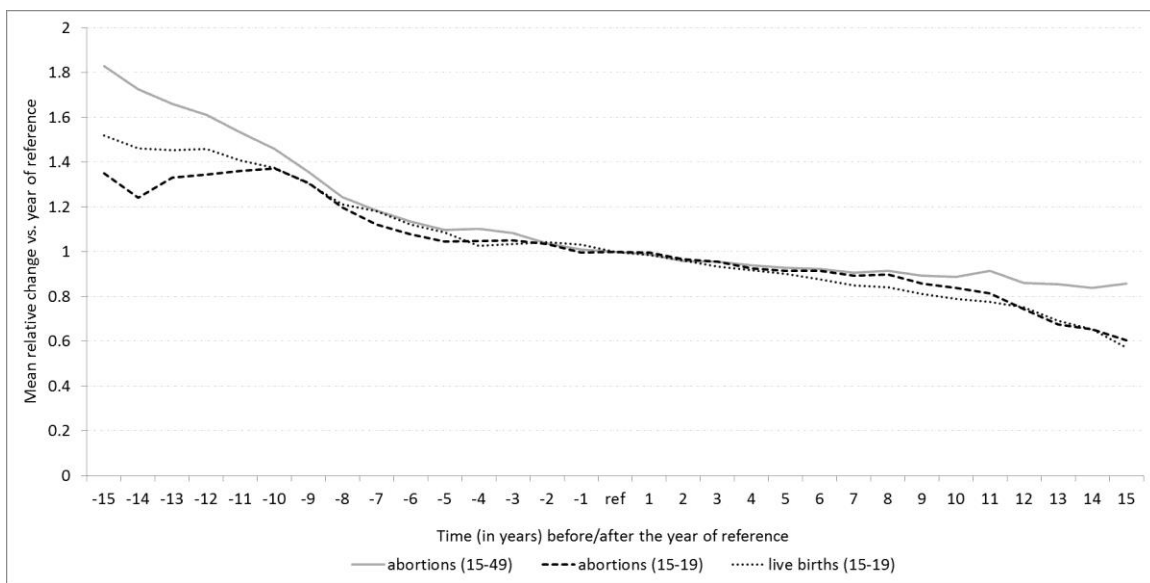
Fifteen years before the switch, the average abortion rates were 26.9 per 1000 women aged 15–49 years (data available for n=25 countries) and 15.2 per 1000 girls aged 15–19 years (data available for n=20 countries), ranging from 4.4 (Northern Ireland) to 153.8 (Romania) for all age groups and from 1.6 (Greece) to 55.0 (Romania) for teenagers. Live birth rates (mean=24.4; data available for n=26 countries) were lowest in Switzerland (3.0) and highest in Bulgaria (69.9).

In the mean, abortion rates among women aged 15–49 years were 83% higher 15 years before the switch in comparison with the year of reference, whereas 15 years after the switch, rates were 14% lower compared with the year of reference (Figure 1). The corresponding percentages for abortions among teenagers were +35% (15 years before switch) and -40% (15 years after the switch). Hence, the falling trend for abortions among teenagers was visible already before the EMC switch, but the mean decline was stronger after the switch. In contrast, for all age groups the trend towards lower abortion

rates was almost stopped after the switch (also when considering that the slight decline after the switch is mostly attributable to the decline among adolescents, which are included in the figures for the total age groups).

On average, live birth rates declined at almost the same rate after the switch as they did already before the EMC change to OTC status.

Figure 1. Long-term analysis of abortion/live birth rates for n=26 European countries 15 years before and after the year of reference.*



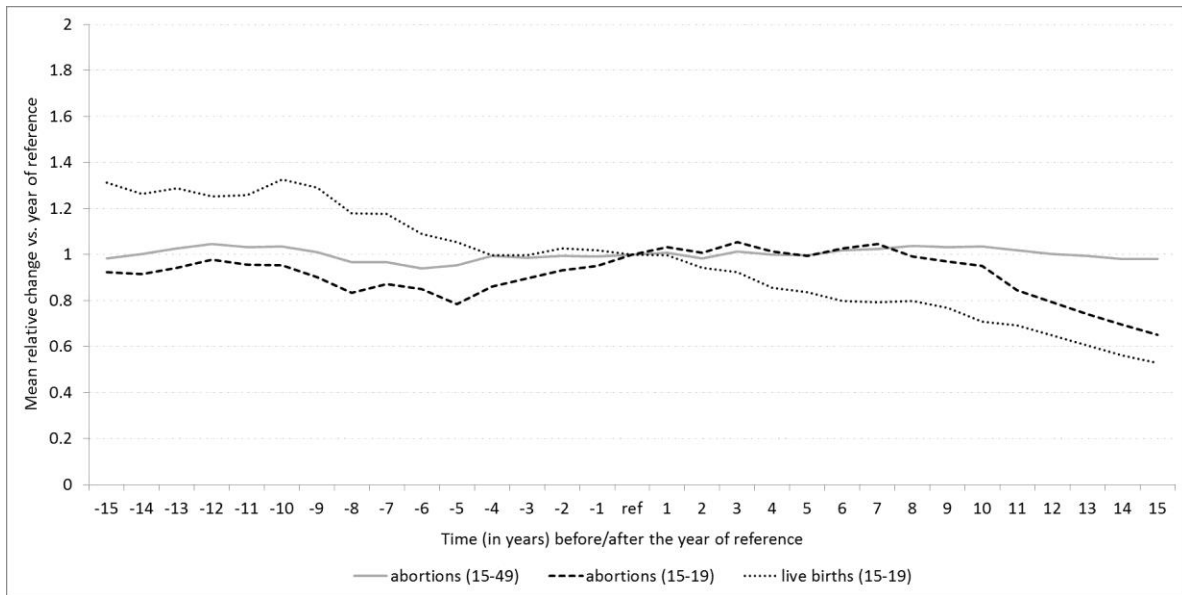
*For the calculation of the mean relative change (rate in the year concerned/rate in year of reference), each country contributes the relative change according to availability of data (e.g. Denmark for all years from -15 to +15, Ireland from -15 years to +7 years, etc.).

In most countries from Eastern Europe, abortion rates declined extremely after the fall of the Berlin Wall in 1989, which might be explained by the fact that regular contraceptives were used less compared with Western Europe. Hence, abortion might have been regarded being a common option for family planning.

For eight countries from Western Europe only (Finland, Denmark, Iceland, Norway, Sweden, Switzerland, United Kingdom (England & Wales), United Kingdom (Scotland)), a full history of 15 years before

and after the EMC switch is available. These countries (Figure 2) may therefore provide a picture which is biased less by social turmoil as it might have been if including also data from Eastern Europe (Figure 1). Moreover, almost all dispensing pharmacists from these eight countries may have respected non-prescription rules before the switch, which may possibly not be the case if viewing at all 26 included countries.

Figure 2. Long-term analysis of abortion/live birth rates 15 years before and after the year of reference for eight countries with a complete ± 15 year-history before/after the EMC switch.*



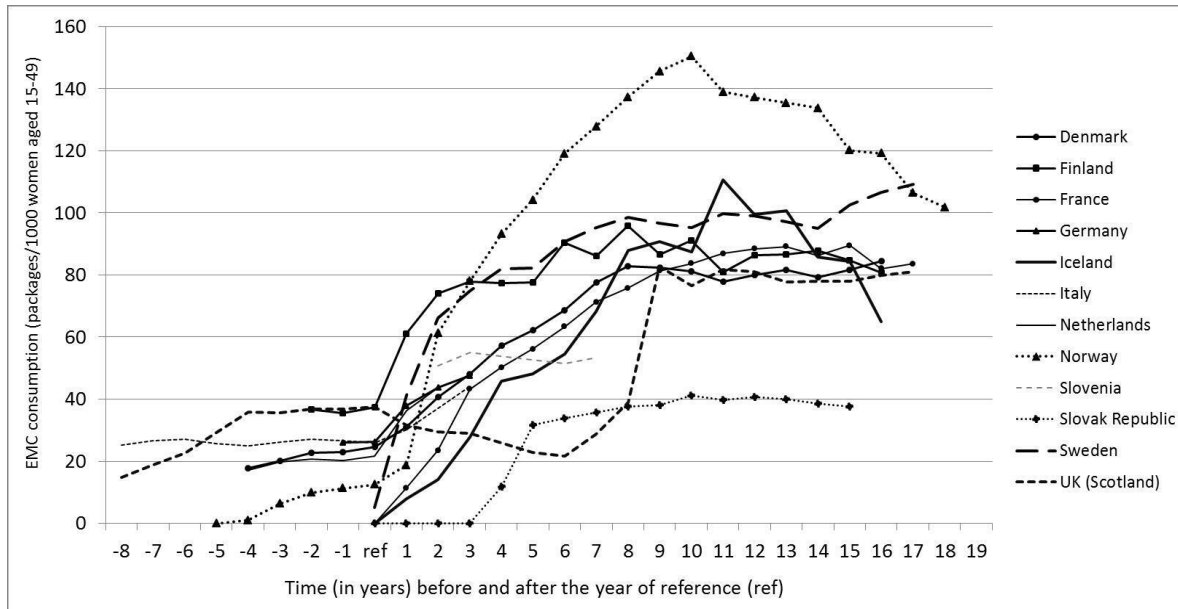
*The eight included countries are Finland, Denmark, Iceland, Norway, Sweden, Switzerland, United Kingdom (England & Wales), United Kingdom (Scotland).

EMC sales figures

For 12 countries, precise consumption numbers or sufficiently reliable estimations were available (Figure 3). Almost all countries showed a quick and strong increase of sales after the switch and reached an almost stable consumption peak after 8–10 years, seven countries evening out at about 80–100 used EMCs per 1000 women aged 15–49 years per year. Norway, showing the biggest increase, is observing a reduction of EMC use since reaching the peak ten years after the switch, now also approaching a level of 100 EMCs per 1000 women aged 15–49 years. Across the included countries, a direct linear correlation of EMC consumption and

abortion rates is, however, not visible, as e.g. France and Finland have now similar per capita EMC consumptions, but different abortion rates. The results (Figure 3) are approximately in line with corresponding results from a study providing estimations of EMC consumption in 2013 for almost all EU countries (15). Nevertheless, several countries with the lowest per capita consumption of EMCs in 2013 are currently among the EU countries with the highest teenage abortion and/or live birth rates (Romania, Bulgaria, Hungary, Slovakia, England & Wales, Czech Republic, Poland).

Figure 3. EMC consumption over time (figures include ATC codes G03AD01, G03AD02 and G03AA07).*



*For Scotland, the consumption may be underestimated between 2001 (year of switch) and 2008 (introduction of free-of-costs program) as figures for EMCs sold without prescription are not available and hence are not included in data provided by the National Health Service in Figure 3.

For further countries with no long-term data on EMC consumption, there have been reports of markedly higher EMC use after the switch, e.g. Switzerland, Portugal, Spain (16-18).

Discussion

Emergency contraception is a highly controversially discussed topic, to which various societal institutions such as medical/pharmaceutical societies, the churches, or feminist organizations contribute their opinion, which may sometimes be based more on personal beliefs or interests rather than on crude facts. The issue of barrier-free access to EMCs deserves, however, a sober analysis, evaluating its potential risks and benefits, as

discussed for LNG in a 2003 publication (19).

The efficacy of EMCs containing LNG or UPA has been proven sufficiently by several studies (20,21). Similarly, the EMA estimated that for women taking UPA within five days after unprotected sex, it would be able to prevent about three-fifths of pregnancies. Based on the positive risk-benefits ratio, the EMA recommended UPA to be changed to non-prescription status throughout Europe (22).

In contrast to some concerns expressed before, facilitated access to EMCs did not increase teen abortion rates in general, e.g., due to a change of sexual behavior, incorrect or excessive use of EMCs instead of ongoing hormonal contraception (23). No country (except Belgium and Greece, where latest

available figures are from 2011/2012 and may have fallen since then) showed long-term trends towards higher abortion rates among teenagers after the switch, and in only seven countries total abortion rates were slightly higher in 2017 than at time of the switch.

Interestingly, in Andorra, having very restrictive abortion laws, live birth rates were almost stable from 2000 to 2008 for younger and older women as well. Since 2009, rates began falling strongly until 2017 for the two youngest age groups (-60% for teenagers; -63% for women aged 20–24 years), while live birth rate for women aged 25–49 years fell by only 20%. Two EMC-related events may explain the drop especially among young girls: firstly, EMCs were available in Andorra at least with a medical prescription since 2008 (switch to OTC in 2018 only), and secondly, EMCs received OTC-status in the bordering state of Spain in 2009, easily accessible in case of need for women residing in Andorra.

A 2016 study found a direct correlation within Germany of higher EMC use with lower abortion rates. German regions with highest use (Bavaria, Baden-Württemberg) showed the lowest abortion rates, those with lowest use had the highest abortion rates (Saxony-Anhalt, Mecklenburg-Vorpommern) (24). On the other hand, the question arises whether in countries with a substantial growth of EMCs sales after the switch abortion/teen birth rates should not have declined stronger and faster after the switch than observed in reality (e.g. France). Possibly, country-specific social factors have also great weight, and perceptible reductions of abortion rates should not be expected quickly, anyway, as it takes roughly 8–10 years on average until EMC consumption reaches an almost stable maximum.

Additionally, it may also take several years until most girls have learned using EMCs correctly (quick administration; taking a second dose in case of emesis within 3 hours after the first dose; respecting interactions with other medicines; etc.).

With concern to EMCs' action of mechanism, the WHO asserted clearly that LNG and UPA have no abortifacient effects (25). However, this debate has not been fully settled yet, and some authors state that EMCs' actions of mechanism (especially with regard to UPA) might potentially be interpreted as being abortifacient (26–28). Nevertheless, even if EMCs should have abortifacient effects, the question rises, how many of the women not taking an EMC (because of restricted access) after unprotected sex would finally anyway seek abortion service if getting pregnant unintentionally. Hence, it could be discussed if a hypothetical early-stage abortion would not be preferable to having a real abortion at a later stage of pregnancy, which of course is a serious and stressing decision.

Unwanted pregnancy represents an economic burden for society as well, as shown for Norway (for teenagers, direct and indirect costs estimated at €1573 per unwanted pregnancy) and the UK (direct health care costs estimated at £1663 per unwanted pregnancy) (29,30). Thus, it may be worth it also from an economic point of view assessing whether EMCs should be covered by social security (at least for teenagers), although an increase of EMC consumption after a switch, of course a welcome business for the producing pharmaceutical companies, may be a challenge for those social security systems fully covering EMCs (31). However, some studies/figures showed that barrier-free access to EMCs seems sometimes to be more important rather than full coverage (32,33).

It is, finally, an ironic twist of fate, that the very country (Hungary), where modern LNG-containing EMCs had been developed and approved first in 1979 is now one of the very few European countries keeping the prescription-only status for LNG and UPA (34,35). Remarkably, in contrast to most of the other countries, abortion rates among Hungarian teenagers fell only slightly since 2001 (16.1 in 2017 vs. 19.7 in 2001), and teen live births rates are almost on the same high level (23.2 in 2017 vs. 22.0 in 2001) as one and a half decades ago. Today, both teen abortion and live birth rates in Hungary are among the highest in Europe.

Limitations

For this study, recent/historical abortion statistics for most EU and EFTA countries were collected from national statistical offices or health authorities, which are supposed to provide the best possible national data on abortion and birth statistics. To our knowledge, this is the first study comparing on European level the development of abortion rates with respect to the year EMCs were made available without medical prescription. However, no data were available for the EFTA country Liechtenstein and for two micro-states closely related to the EU (San Marino, Monaco).

The quality and methods of data collection may vary across the European countries as well as legal definitions of ‘abortion’ or differences between officially reported numbers of legally induced abortions and estimated numbers of induced abortions actually performed (e.g. Greece) (36).

Several aspects may have interfered with the use of EMCs and development of abortion rates over time. However, according to age-stratified consumption data from Denmark and Sweden (precise data from other

countries are scarce), use of conventional hormonal contraceptives (which may also have changed over time) was not directly linked to the development of abortion/birth rates during the respective observation periods.

No reliable information is available about how the legal status of pharmaceuticals is respected by pharmacies in the included countries. In some countries, prescription-only status may exist pro forma only (37), thus self-medicated EMCs may have influenced abortion/live birth rates already before the formal switch to over-the-counter status.

Finally, the exact levels of awareness about and correct use of EMCs were not available, and it is likely that time to reach high levels of awareness about OTC availability of EMCs and their correct use differ between countries.

Conclusions

This study cannot provide evidence of a causal link between an EMC switch and subsequent changes in abortion/live birth rates. However, pooled data, timely correlation of drops in abortion/live birth rates with EMC switch and the increase of EMC use after the switch suggest that over-the-counter availability of EMCs contributes reducing unwanted pregnancy especially among teenagers. Further studies are necessary to explain why in many countries the reduction of abortion rates was limited mainly to younger age groups (according to Danish data, per capita use of EMCs is highest among teenagers, thus possibly older women use generally EMCs less in other countries, too). Also, the question should be addressed why in some countries the decline of abortion rate was visible several years after the EMC switch only, despite of an

immediate and substantial rise in EMC consumption after the change. Weighing the pros and cons, it seems that in sum, the benefits of OTC access to EMCs may prevail. Additional measures such as free-of-cost dispensing of EMCs to minors or intensive information campaigns may support achieving lower abortion rates, if the switch to non-prescription status proves being not sufficient. Reasonable self-medication, however, requires safe and affordable drugs,

access to high-quality advice about EMCs (e.g. in pharmacies) and/or well informed people.

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