

# Six years after deregulation of emergency contraception in Switzerland: Has free access induced changes in the profile of clients attending an emergency pharmacy in Zürich?

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**ABSTRACT**

**Objectives** Emergency contraception (EC) has been freely accessible in Swiss pharmacies since November 2002. Today some groups are still concerned that free access might result in less use of efficient contraceptive methods, overuse and more risky sexual behaviour.

**Methods** Profiles of EC users one and six years after deregulation were analysed with regard to age, contraceptive methods used, reasons for EC use, and last contact with a gynaecologist. Data were collected from a centrally located pharmacy. Written official assessment forms concerning 1500 women (750 in 2004 and 750 in 2009) were analysed.

**Results** Free access to EC use had no impact on regular contraceptive behaviour. The percentage of pill and condom users was very high (85%). The percentage of EC-users without any contraception (17–18%) was the same over the years. In 2009, condom rupture was reported more frequently ( $p < 0.001$ ). In addition significantly more women had used EC previously in their history.

**Conclusion** Free access to EC has not resulted in less use of efficient contraceptive methods. In the context of falling abortion rates our results are reassuring. This also applies to adolescents, who mainly used EC as a back-up method and seldom in the context of unprotected intercourse.

**KEY WORDS** Emergency contraception; Norlevo®; Levonorgestrel; Contraception; Adolescents; Community pharmacy; Switzerland

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## INTRODUCTION

Worldwide, about 41 million unplanned pregnancies are terminated each year<sup>1</sup>. Approaches to solve this problem include improvement of primary prevention (contraception) and emergency contraception (EC). EC is defined as the use of hormones or of a copper intrauterine device with the aim of preventing pregnancy shortly after unprotected intercourse. The relatively high effectiveness of levonorgestrel emergency contraception (LNG-EC) when used at a dose of 1.5 mg within 24 hours after unprotected coitus drops by about 50% with each 24 hours of delay in its use<sup>2-5</sup>. Thus optimal use of EC requires easy access within the community. Access is much easier and quicker, and the rate of non-use might decline, if the requirement to go to a doctor is removed.

The safety of LNG-EC allows sale over the counter (OTC). After several years of controversial discussion the LNG-regime was licensed for OTC sale in Switzerland in November 2002. One precondition for OTC sales was the obligation for the pharmacists to take a medical history and to perform a pregnancy test. Assessment forms were developed for collection of patient data which have to be stored for five years. One entertained the hope that free access in our country would be associated with a reduction of the time interval between unprotected coitus and access to the product, and with a lowering of the threshold to using EC. Both these factors would increase the successful application of the method. Opponents of free access argue that because pharmacies can not offer contraceptive counselling, EC might be used as a substitute for regular contraception, and efficient contraceptive methods might be underused, especially by teenagers<sup>6,7</sup>. Some also fear that very easy access might result in misuse or overuse.

To provide objective information in the context of these ideological discussions, we collected factual data on EC use in Switzerland. We considered potential variations in the use of efficient contraception, repeat use of EC, EC use in teenagers, and access to gynaecologists as the main topics of interest. In addition we evaluated changes in recent years in the time elapsing between unprotected intercourse and treatment.

Today, most women in Switzerland are aware that EC is available without prescription in pharmacies. In one emergency pharmacy in Zürich the annual number of EC packages sold increased from 2068 in

2004, to 3368 in 2009. For our study we used data from this pharmacy in the biggest city of Switzerland.

## METHODS

Prior to deregulation of EC in Switzerland, an unprecedented national education programme was organised for pharmacists. The Swiss Association of Pharmacists released an official one-page written patient assessment form and a descriptive workflow with the aims to standardise the counselling interview and to support pharmacists in the decision-making process of delivering EC or not. The form is confidential but not anonymous. It includes information about the first day of the last menstruation, contraceptive use during the last months, the time of unprotected intercourse, the date of the last gynaecological visit, medical diseases, and regular medications.

For the present retrospective analysis we used data from these written assessment forms collected in an emergency pharmacy with extended opening hours (17 hours/day), situated close to the main station in the centre of Zürich. Its central situation, the high sales rates and longer opening hours made this pharmacy suitable for our study because of the great number and social diversity of its EC clients. After a pregnancy test appeared to be negative and the assessment form was completed the clients received the LNG-EC pill. Because free EC access is limited to women aged 15 years or more, younger clients were not included in the study. The assessment form gathered information on the name, age and address of the EC user; the date of her last menstruation; the contraceptive method used; the moment at which unprotected intercourse had taken place; the previous use of EC, if any, and the last contact with a gynaecologist. For ethical reasons personal data (name, address) were removed from the copy for the medical student who entered the data into our statistical programme. We considered an interval of five years as adequate for detecting possible variations in the users' profile. Written assessment forms of 1500 women were analysed: 750 forms from the year 2004, and 750 from 2009. For both years data pertaining to the last 750 EC visits were taken into consideration. The study was performed in accordance with the guidelines of the local ethical committee of the Kanton Zürich.

## Statistical analysis

The data were analysed using SPSS 17.0 software (SPSS Inc., Chicago IL). Values are indicated as percentages and absolute numbers or as means  $\pm$  standard deviations, where appropriate. Comparisons between groups were analysed using unpaired t-test or Wilcoxon rank sum test as appropriate. Pearson  $\chi^2$  test or Fisher's exact test were performed to compare frequencies. Age groups were categorised as follows: 16–20 years, 21–30 years, 31–40 years and  $> 40$  years. We evaluated whether the groups differed with regard to time since unprotected sexual intercourse, use of contraception, and last visit to a gynaecologist. In addition, we analysed in the group of nonusers of hormonal contraception the percentage of women using EC during cycle days 1–7, 8–20,  $\geq 21$ . Differences were considered statistically significant when  $p$ -values were  $< 0.05$ .

## RESULTS

A total of 1500 written assessment forms were analysed. Data response rates for the two periods together were: age 1499/1500 (100%), repeated use 1491/1500 (99%), ordinary contraceptive use 1440/1500 (96%), reason for contraceptive failure 1058/1500 (71%), time to EC access 1486/1500 (99%), last gynaecological contact 1252/1500 (84%), and menstrual cycle phase 1402/1500 (94%). As shown in the tables, the questionnaires were more completely filled out in 2009 than in 2004.

Mean ages and standard deviations were 23.4 ( $\pm 5.9$ ) years (range 15–48) for the women who sought EC in 2004 ( $n = 749$ ) and 24.3 ( $\pm 6.6$ ) years (range 15–49) for those seen in 2009 ( $n = 750$ ) ( $p = 0.012$ ). In 2004, the vast majority (87%) of the EC users were aged less than 31 years, with as many as 41% being less than 21 years old. Five years later, 83% of the users were aged 30 years or younger, and 35%, 20 years or younger. The percentage of EC users aged over 40 years was low in both years ( $n < 22$ ) (Table 1).

Table 1 provides information on the contraceptive habits of the women, classified by age categories. The contraceptive method usually employed in our study sample was mostly the condom ( $> 65\%$  in both years). The proportion of users of combined hormonal contraceptives was rather low (16%); 6–7% applied double protection. Usual contraceptive use did not change

significantly in the analysis of the whole group, nor in the age-categorised analysis. In both groups, natural family planning methods (among others, the Knaus-Ogino method and the basal body temperature method) were resorted to by 1% of the women. In 2% ( $n = 15$ ) of the cases, in 2004, and 3% ( $n = 38$ ) of the cases, in 2009, no contraception at all was used. Altogether no statistically significant difference in the contraceptive methods was found.

In an additional analysis the groups were compared with regard to the efficacy of the contraceptive methods. User numbers of very efficient contraceptive methods (oral contraceptives alone or combined with condoms) were compared with user numbers of less efficient methods (male condoms alone, natural family planning methods, no contraception). The differences between the groups were not significant with 23% ( $n = 156$ ) of efficient contraceptive users in 2004 vs. 23% ( $n = 174$ ) in 2009, and 75% ( $n = 523$ ) users of less efficient contraceptive methods in 2004 vs. 74% ( $n = 549$ ) in 2009.

The reasons for EC use are presented in Table 2. Condom rupture was reported significantly more frequently (60%) in 2009 than in 2004 (39%). In contrast, omission of intake of the oral contraceptive decreased from 37% in 2004 to 11% in 2009 ( $p < 0.0005$ ). The number of EC users without regular contraception did not increase.

The mean lapse of time to EC access was 17.0 ( $\pm 13.1$ ) hours (range 15 min–72 h) in 2004 and 18.0 ( $\pm 15.0$ ) hours (range 30 min–87.25 h) in 2009. No significant difference in time to access was found between the different age subgroups (Table 3).

The proportion of clients receiving EC within 48 h (24 h) was 98% (82%) in 2004 and 95% (78%) in 2009.

With regard to the last gynaecological contact, 91% ( $n = 597$ ) of the 2004 EC users stated they had ever visited a gynaecologist in comparison with 89% ( $n = 655$ ) of those purchasing EC in 2009. Most EC users who had never visited a gynaecologist were aged less than 21 years. Interestingly this proportion of clients even increased in the youngest age group from 21% ( $n = 54$ ) in 2004 to 29% ( $n = 75$ ) in 2009 ( $p = 0.029$ ). In contrast, only 3% ( $n = 8$ ) and 2% ( $n = 7$ ) of the EC users aged 21–30 years had never been to the office of a gynaecologist. Only one person in the group aged 31–40 years, but none aged  $> 40$  years, had never submitted to a gynaecological visit or control (Table 3).

Table 1 Contraceptive method currently being used

	Overall		#20 years		21–30 years		31–40 years		> 40 years	
	2004 (n = 694) <sup>†</sup>	2009 (n = 746)	2004 (n = 277)	2009 (n = 261)	2004 (n = 328)	2009 (n = 357)	2004 (n = 84)	2009 (n = 108)	2004 (n = 4)	2009 (n = 21)
Combined hormonal contraceptives*	16% (111)	16% (120)	18% (50)	17% (45)	17% (55)	18% (65)	6% (5)	8% (9)	25% (1)	5% (1)
Male condoms	71% (493)	68% (510)	73% (202)	72% (189)	68% (223)	63% (225)	77% (65)	75% (81)	50% (2)	75% (15)
Combined hormonal contraceptives**	6% (45)	7% (54)	7% (19)	8% (21)	7% (24)	9% (32)	2% (2)	1% (1)	–	–
Intrauterine device	–	–	–	–	–	–	–	–	–	–
Natural family planning methods	1% (8)	1% (9)	–	–	1% (4)	1% (3)	4% (3)	5% (5)	25% (1)	5% (1)
Other methods	3% (22)	4% (30)	1% (3)	1% (4)	4.0% (13)	4% (14)	7% (6)	9% (10)	–	10% (2)
No contraception	2% (15)	3% (23)	1% (3)	1% (2)	3% (9)	5% (18)	4% (3)	2% (2)	–	5% (1)

\*Includes combined oral contraceptive, vaginal ring, transdermal contraceptive patch. \*\*Simultaneous use. <sup>†</sup>Age was not indicated in one of the 694 cases. Data are presented as % (n). Unknown contraceptive method: 2004: 56 cases; 2009: 4 cases

**Table 2** Reason for use of emergency contraception

	Overall		≤20 years		21–30 years		31–40 years		>40 years						
	2004 (n=308)*	2009 (n=750)	2004 (n=120)	2009 (n=263)	2004 (n=151)	2009 (n=358)	2004 (n=35)	2009 (n=108)	2004 (n=1)	2009 (n=21)					
Forgot the pill	37% (113)	11% (80)	<0.0005	41% (49)	11% (29)	<0.0005	38% (57)	13% (46)	<0.0005	17% (6)	4% (4)	0.01	100% (1)	5% (1)	0.09
Condom rupture	39% (120)	60% (450)	<0.0005	35% (42)	60% (159)	<0.0005	36% (54)	60% (213)	<0.0005	66% (23)	64% (69)	0.85	–	43% (9)	0.39
No contraception	18% (54)	18% (138)	0.74	15% (18)	18% (48)	0.44	20% (30)	16% (57)	0.28	17% (6)	23% (25)	0.45	–	39% (8)	0.44
Other reasons	7% (21)	11% (82)	0.04	9% (11)	10% (27)	0.74	7% (10)	12% (42)	0.08	–	9% (10)	0.06	–	14% (3)	0.68

\*Age was not indicated in one of the 308 cases. Data are presented as % (n)

**Table 3** Mean time to EC access, mean time since last contact to gynaecologist and repeat use of EC

	Overall		≤20 years		21–30 years		31–40 years		>40 years		
	2004	2009	2004	2009	2004	2009	2004	2009	2004	2009	
Time to EC access (hours)*	17.0 ± 13.1 (n=743)**	18.0 ± 15.0 (n=743)	17.3 ± 12.5 (n=300)	18.3 ± 15.2 (n=260)	16.4 ± 13.4 (n=345)	18.1 ± 14.6 (n=356)	18.1 ± 13.9 (n=93)	17.5 ± 16.6 (n=106)	21.1 ± 18.3 (n=4)	16.4 ± 12.5 (n=21)	0.74
Time since last contact to gynaecologist (months)*	8.2 ± 9.4 (n=597)	8.7 ± 10.3 (n=655)	7.3 ± 8.4 (n=204)	7.7 ± 6.5 (n=181)	8.3 ± 8.0 (n=308)	8.5 ± 8.5 (n=348)	10.5 ± 14.8 (n=81)	11.0 ± 18.4 (n=106)	6.0 ± 4.3 (n=4)	7.7 ± 6.6 (n=20)	0.68
Already used EC before (positive answers/answered charts)	50% (370/745)**	60% (440/746)	40% (118/300)	50% (130/262)	54% (188/346)	65% (232/357)	65% (61/94)	62% (66/107)	50% (2/4)	60% (12/20)	0.72

\*Mean and standard deviation. \*\*Age was not indicated in one of the cases

The mean time elapsed since the last contact with a gynaecologist was 8.2 ( $\pm 9.4$ ) months (range 0–120 months) in the 2004 group and 8.7 ( $\pm 10.3$ ) months (range 0–80 months) in the 2009 group (Table 3).

EC was used on cycle days 1–8 by 16% of the women in 2004 and 14% in 2009, on days 9–16 by 45% and 48%, respectively, and after day 16 by 38% in both groups. None of these differences was statistically significant.

The number of repetitive EC users rose from 49% in 2004 to 59% in 2009 ( $p = 0.001$ ) (Table 3). Within the subgroups of users aged  $\leq 20$  years and 21–30 years this increase was significant.

No association was found between repetitive EC use and having visited a gynaecologist within the last twelve months. Furthermore, the reasons for EC use were not associated with re-use.

## DISCUSSION

We analysed the profile of EC users attending a highly frequented pharmacy in the centre of Zürich shortly after deregulation, and five years later. In contrast to the negative expectations of some, OTC supply caused neither a change in contraceptive behaviour nor an increase in the percentage of users without prior contraception. Reasons for obtaining EC varied over the years and the percentage of re-users rose by around 10%. EC was used mainly as a back-up method, and not as a substitute for other methods. Our results do not lend support to the hypothesis that women might abandon regular contraception as a consequence of easy EC availability<sup>8</sup>. Jackson *et al.* demonstrated that even an advanced supply of EC did not adversely affect routine use of contraception<sup>9</sup>.

The percentage of clients without any contraception (17–18%) in the present study is similar to or even lower than those reported by other authors<sup>10–13</sup>. In our view it is reassuring that the size of this user group has remained stable since the introduction of OTC access.

Another, often regarded as critical, question is that of repeated EC use. Rates of repeat use are always higher when calculated as a percentage of women who have previously used EC<sup>14,15</sup>. In the general population re-user rates are much lower. Analysis of a research database in the United Kingdom revealed that 4–6% of women had ever used EC, and less than 1% had used it more than twice during a year<sup>16</sup>. Reasons for repeat EC use included contraceptive failure

as well as non-use of birth control methods. Condoms, the contraceptive method used most in our study, are associated with a failure rate of 4–13%<sup>17</sup>. Therefore, it is not surprising that even though contraceptive prevalence in our population is high, half of the EC clients were not first-time users. A re-user rate of around 50% is consistent with data from other European studies<sup>18</sup>. EC as a back-up method aims to prevent unintended pregnancies when contraceptive methods may have failed. Repeated use should not be a matter of concern. Nevertheless greater attention and more counselling would be advisable in cases of repeat use without regular contraception. It is reassuring that we did not observe an association between re-use and not having had contact with a gynaecologist who, in Switzerland, is the main person responsible for counselling.

Over the study period, omitting to take contraceptive pills became less frequently the reason for seeking EC, whereas condom rupture was mentioned substantially more often, particularly by women younger than 31 years. Two developments might explain these findings. Forgetting to take the pill does not necessarily imply a need for EC and it is unlikely, that pill users have become more compliant over the years. We therefore speculate that improved and more experienced counselling provided by pharmacists might have resulted in fewer recommendations to use EC after forgetting pills. A possible explanation for the greater representation of condom users is that, with easier access, more couples using condoms as protection also resort to EC.

Time to access is usually longer in pill users because pill omission is noticed later than condom rupture<sup>19</sup>. The time lapse to access has not decreased over time, but can be regarded as acceptably short, with 95% of women coming to the pharmacy within 48 hours. Time to access was presumably longer in previous years, when EC had to be prescribed.

In 2002, when the Yuzpe regimen was used in Switzerland, 90% of adolescent girls residing in the country were aware of the existence of EC and 64% had resorted to it at least once<sup>20</sup>. The condom was the contraceptive method used most frequently on the occasion of the first sexual intercourse whereas the pill was used rather in stable relationships<sup>20</sup>.

The present study shows that EC use did not increase in adolescents using no contraception. In other countries, adolescent access to EC was not associated with

more unprotected intercourse or a decrease in condom use<sup>21–23</sup>. In comparison with data from Sweden (54%) the proportion of young EC users without contraception (18%) in our study was extremely low<sup>11</sup>.

On the other hand, a 10% increase in adolescent re-users together with the fact that 29% of the young girls had never visited a gynaecologist could be a reason for concern. In Switzerland never having visited a gynaecologist might imply never having had contraceptive counselling or never having received information on prevention of sexually transmitted infections, and a lack of access to more efficient hormonal methods. A major reason why young adolescents do not see a doctor is believed to stem from their reluctance to discuss contraception with their parents. Our assessment form did not collect information about the duration of relationships, at the time when EC was necessary. If most of the young women in our sample have only occasional sexual contacts it is understandable that they do not seek counselling for more efficient hormonal methods. Nevertheless these young re-users might represent a critical group that should receive more attention and perhaps more detailed counselling in the pharmacy.

With regard to contraceptive behaviour and percentage of EC users without regular contraception most of our data confirm the results of a smaller Swiss study ( $N = 729$ ) that investigated EC use from 2003 to 2006 in 18 pharmacies located in urban and rural areas<sup>19</sup>. The current study not only includes a greater number of clients and extends the observation interval, it also provides age-related data and discusses access to counselling by including information on visits to a gynaecologist.

The strengths of the present study are the size of the study groups, the long observation period and the age-categorised analysis of the data. The separate evaluation of data from potentially critical groups, such as adolescents or EC clients without contraception, provides arguments for discussion on what could be improved in the future.

A potential weakness of the study could be the involvement of only one pharmacy. Thus our data may not be representative of EC use in all regions of Switzerland. However, we strongly believe that, because of its central localisation in the main train station, clients of this pharmacy include people from rural and urban areas, as well as those with different social backgrounds and of different ages. Around 215,000 employees and roughly 25,000 students travel daily to Zürich. The extended

opening hours of this pharmacy allow EC clients from urban and rural areas to receive EC in an anonymous setting, just before going to work or before taking the evening train back. The high sales rates in comparison to those of other pharmacies situated in Zürich (personal communication) additionally support our view that a large proportion of the clients of this pharmacy are commuters. For ethical reasons it was not possible to collect address data, which would have provided facts instead of speculations with regard to this question. For the interpretation of the collected data it would be helpful to have information about the development of annual EC sales rates. In Switzerland, OTC sales are still controversial. According to our personal experience and information, the increasing sales rates of LNG-EC can lead to awkward public discussions. This probably explains why neither the association of pharmacists nor the pharmaceutical company concerned, are willing to publish their annual sales rates. The sales rates of EC of the pharmacy in our study rose by around 30% over the study period (an additional 1000 packages in 2009).

The annual abortion rate in Switzerland is one of the lowest in the industrialised world. This may be one reason for the late approval of OTC provision of EC in comparison with other countries<sup>22–24</sup>. During our study period, the abortion rate dropped from 10,646 cases (7/1000) in 2004 to 10,187 (6.4/1000) in 2009. In addition the rate of abortions in young women (15–19 years) fell from 5.7/1000 to 5.0/1000. In the area of Zürich where our data were collected, the decrease in teenage abortions was even more important (incidence 6.1/1000 vs. 5.4/1000)<sup>25</sup>. Free EC access might be one factor contributing towards the observed decrease in abortion rates.

In conclusion, we could demonstrate that EC supply in pharmacies is not associated with negligence of regular contraception in Switzerland. Increased use of EC can be considered opportune, because it is not associated with a lesser use of hormonal methods or condoms. This is also true for adolescents, who use EC mainly as a back-up method and seldom in the context of unprotected sexual intercourse.

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