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Original Research

Views and attitudes of oral contraceptive users towards their availability without a prescription in the Republic of Ireland

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ABSTRACT*

Background: Previous studies show that provision of oral contraceptive pill (OCs) without a prescription is safe, feasible and effective and that users are interested in obtaining contraception in this way, especially if a pharmacist screening is involved. A recent national survey conducted in the Republic of Ireland has highlighted that unintended pregnancy resulting from the failure of OCs could be linked to poor compliance due to costs and difficulty of access.

Objective: To evaluate views and attitudes of OC users towards the availability of OCs without a prescription in the Republic of Ireland.

Methods: A cross sectional survey was conducted using an opportunistic sample of OC users aged 18 to 50 years. Sixty community pharmacists were recruited nationwide. Data were collected using self-completed questionnaires. The questionnaires comprised information on: demographic data, need of the service, views on the availability of OCs without prescription, advantages and concerns around the service, role of pharmacists and cost implications for private and public patients.

Results: A total of 488 eligible OC users completed the survey. The majority of the respondents (71.7%; n = 350/488) reported to have missed a pill for reasons connected to the OCs prescription status and 55.5% (n = 268/488) of the respondents reported to have felt distressed on at least one occasion because they could not renew their OC prescription. A total of 87.9% (n = 429/488) of the respondents said they were in favour of OCs being available without prescription and 92% (n = 448/488) said they were likely to obtain OCs without prescription if available. Convenience and ease of access were indicated as the main advantages of availing of OCs without prescription, while safety was the biggest concern reported. Over 88% (n = 430/488) of the respondents indicated that pharmacists would be able to safely supply OCs without prescription. Private patients expected to save an average of 27.3% on their OC if obtained without prescription.

Conclusions. OC users in the Republic of Ireland are in favour of OCs being available without prescription and are willing to obtain it this way, providing that pharmacists supply them according to protocols that facilitate the safety and the efficacy of the supply. An easier and more convenient access to OCs could also reduce the likelihood of missed pills and bring considerable savings to users.

Keywords: Contraceptives, Oral; Health Services Accessibility; Health Knowledge, Attitudes, Practice; Nonprescription Drugs; Prescription Drugs; Ireland

INTRODUCTION

Oral contraception is one of the most used reversible contraceptive methods in developed countries.^{1,2} In several countries around the world, including the Republic of Ireland, the access to oral contraception is subjected to prescription, while in other countries the oral contraceptive pill (OC) is available without a prescription.³ In the recent years the availability of OCs without a prescription has been widely discussed and researched in the United States of America (USA)⁴⁻¹⁰ and in the United Kingdom (UK).¹¹⁻¹⁴

Previous studies show that supply of OCs without a prescription is safe¹⁵⁻²¹, feasible and effective^{4,14} and that users are interested in obtaining OCs in this way.^{5,22-24} In terms of safety, the literature indicates that women can self-screen for contraindications to OCs and can do it as well as healthcare professionals.^{15,18,19} Furthermore, a recent US study concluded that the low prevalence of medical contraindications supports provision of OCs without a prescription.²¹ Research has also shown that access to contraception services without prescription would not increase sexual risk-taking behaviour²² nor reduce health preventive screening.²³

It is the opinion of the Women's Health Practice and Research Network of the American College of Obstetrician and Gynaecologists (2012) that "based on currently available data", OCs should be available without prescription⁴ because it is safe and may increase adherence and continuation rate. A similar opinion²⁵ is held by the American Medical Association, who indicated that the Food and Drug Administration agency (USFDA) should encourage pharmaceutical companies to submit the necessary data for a switch to a non-prescription status for OCs. These committee opinions are supported by studies that suggest that removing prescription requirements for OCs would lead to increased continuation and compliance²⁶ and could reduce the rate of unintended pregnancies.²⁷ Some US publications suggest that moving OCs to a non-prescription status could be a strategy to reduce the likelihood of unplanned pregnancies and voluntary interruption of pregnancies.^{7,28} However other publications¹², based on previous experience with emergency contraception, suggest that the easier access to oral contraception would not make any difference to the rate of unplanned pregnancies. The real impact of the availability of OCs without prescription on the rate of unintended pregnancies is yet to be shown.

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The American College of Clinical Pharmacy (ACCP) has openly supported the availability of OCs without a prescription, but with the condition that they would be sold under the supervision of a pharmacist.⁶ Current medical eligibility criteria for contraceptive use^{29,30,31} agree that eligibility should be assessed based on a correct anamnesis and on reliable measurements of blood pressure and body mass index. No other routine clinical examinations are required. As healthcare professionals, the ACCP believes that pharmacists are capable of performing the necessary screenings in order to provide OCs safely and effectively and the general public seems to positively evaluate the pharmacist competence in the provision of the service.^{5,16}

To date, only two studies evaluating the pharmacists' competence as a provider of OCs have been published. A 2008, a US study³² concluded that "community pharmacists can efficiently screen women for safe use of hormonal contraceptives and select appropriate products". The competence in providing oral contraception was confirmed by a UK study carried out in 2013¹⁴, where the provision of oral contraception services was piloted in community pharmacies. The final audit showed that pharmacists adhered to the protocol, made appropriate referrals and provided a high quality contraception service. Service users reportedly felt comfortable and satisfied and appreciated the privacy, convenience, ease of access, and lack of waiting times. Both studies concluded that provision of OCs by trained pharmacists is both safe and effective.

All the aforementioned studies on the subject have been carried out in countries such as USA, Mexico and UK, where socio-economic backgrounds are considerably different from the Republic of Ireland. It cannot therefore be assumed that the results of these studies can be extrapolated to the Republic of Ireland and further studies are required.

A recent national survey conducted in the Republic of Ireland has highlighted that unintended pregnancy resulting from the failure of OCs could be linked to poor compliance due to costs and difficulty of access.² The same study also showed that women prefer to obtain contraception from a pharmacy. In light of the literature findings, it was considered to be of value to carry out a study which explored the views and attitudes of OC users in the Republic of Ireland on the availability of OCs without prescription, and their likelihood to access such a service. The study also evaluated the perceived advantages and concerns about the provision of such a service and pharmacists' perceived skill level to safely and effectively supply OCs without prescription.

METHODS

This was a cross sectional descriptive study conducted nationwide with the collaboration of the Allcare Pharmacy network. A chain of community pharmacies with branches located across the Republic of Ireland in both urban and rural areas. The supervising pharmacists of the 64 pharmacies

belonging to the Allcare group were invited to participate by email. The 60 supervising pharmacists interested in the study were then provided with a consent form and a Standard Operating Procedure (SOP) containing information regarding the study aims, the methodology, the process of recruiting patients, the distribution and collection of the questionnaires as well as data protection.

Sampling

An opportunistic sample of OC users was presented with the questionnaire. All patients between 18 (age of consent in Ireland) and 50 (average age of menopause in Ireland)³³ years of age presenting a prescription for OCs for personal use were invited to participate to the study. Patients using Dianette® (cyproterone acetate/ethinylestradiol), licensed in Ireland only for treatment of acne, were excluded. The pharmacist on duty identified the patients who met the inclusion/exclusion criteria and invited them discretely to participate in the study. The pharmacist provided the potential participants with the anonymous questionnaire, an information sheet (containing purpose of the study and confidentiality disclaimer) and a pre-addressed return envelope. The participants were given the option to complete the questionnaire in a private area of the pharmacy and return it in the sealed envelope to the pharmacist or to take it away and return it by post. No help was given to the patient filling in the questionnaire. Supervising pharmacists received two reminders by email at four weekly intervals.

Sample size calculation suggested a sample requirement of 600.³⁴ A previous survey on contraception conducted in the Republic of Ireland², suggested a response rate of around 50%. Therefore 1200 questionnaires were distributed (20 questionnaires in each of the 60 participating pharmacies).

Questionnaire

The questionnaire design was based on previous literature⁵ and best practice guidance^{35,36}, taking into account that the questionnaire was going to be self-completed and the literacy of the respondents was unknown. Face and content validity of the questionnaire was assessed by an expert panel of four supervising pharmacists working in community pharmacies and with experience in research studies. Questionnaires included a combination of closed and open ended questions, Likert scales and multiple choice questions. The first part of the questionnaire collected demographic data such as age, county of residence, urbanization of the living area (urban, rural), and the reimbursement status (medical card or private). The second part of the questionnaire collected the views and the attitudes of the participant on the availability of OCs without prescription. The need of the service was evaluated by: 1) the distress perceived by respondents when not being able to renew their prescription for OC 2) the percentage of respondents who have experienced an interruption in their contraception for reasons linked to the prescription status of OC. The final part regarded only private patients and

Table 1. Demographic data of respondents (n=488)		
Age of respondents		
18-25 years		40.0%
26-35 years		42.3%
36-50 years		17.7%
Urbanization of living area		
Rural area		21.4%
Village/town		42.0%
City		36.6%
Reimbursement status		
Medical card		29.8%
Private		70.2%

collected information about the cost of the availability of OCs without prescription. The survey was piloted in 6 pharmacies for 2 consecutive weeks to ensure the process was robust and to identify any issues or biases within the questionnaires.

Data analysis

Data was entered into IBM SPSS v21 and analyzed using descriptive statistics. Multivariable analyses³⁷ were carried out to correlate outcome measures to demographic data. A Shapiro-Wilk test was performed to determine data distribution. For non-normally distributed data, non-parametric tests (Mann-Whitney test and Kruskal-Wallis test) were performed to determine statistical significance. For normally distributed data, parametric tests (t-tests and one way ANOVA) were performed.

Ethical approval was provided from Robert Gordon University School of Pharmacy and Life Sciences Ethical Review Panel. The Health Information Quality Authority of the Republic of Ireland confirmed that no local ethical approval was necessary for this study.

RESULTS

Response rate and demographics. Of the 64 supervising pharmacists invited, 93.75% (n=60) agreed to participate. Within the 60 Pharmacies recruited to the study a total of 488 patients returned the questionnaire giving a response rate of 40.67%. Demographic data is summarized in Table 1.

Need for the service: Results regarding the need of the service are summarized in Table 2. A total of 71.7% (n=350/488) of the respondents reported to

have experienced an interruption in their contraception for one or more reasons connected to the prescription status of OCs. The expiration of the prescription was indicated as the main reason for missing OCs (49.7%, n=242/488). This was more prevalent in cities (58.4%; n=104) compared to villages/towns (40.7%, n=88, Mann-Whitney $p < 0.001$). 29.2% (n=142/488) of respondents indicated difficulty with prescription renewal as the prime reason for missed doses, while the cost associated with renewing a prescription was stated as the least likely cause (14.6%, n=71/488). However, since medical card holders do not pay for their prescription, it is worth noting that the difference between medical card holders (4.8%, n=7) and private patients (18.8%, n=65) is statistically significant (Mann-Whitney $p < 0.001$). More than one in two respondents (55.6%, n=268/488) reported to have been distressed at some stage because they were not able to renew their prescription for OCs in time. Women between 36 and 50 years of age were statistically less likely to have felt distressed (40.5%, n=35) compared to the remaining age groups (Mann-Whitney $p < 0.005$) (18-25 years of age: 58.8% /n=114; 26-35 years of age: 58.5%/n=121). Respondents living in villages/town (48.3%, n=99) were also statistically significantly less likely to report distress than the ones living within cities (63.4%, n=113) (Mann-Whitney $p < 0.01$).

Support for availability of OCs without prescription and likelihood of obtaining OCs without prescription. Among all the participants, 87.9% (n=429/488) stated to be in favour of OCs being available without prescription (Table 3). Differences in responses were statistically significant between respondents living in rural area (80.8%, n=85) and the ones living in cities (89.9%, n=160) and villages/towns (89.7%, n=183, Mann-Whitney $p < 0.05$). Overall, in any subcategory, at least 80% of the respondents declared to be in favour of OCs being available without prescription. Among all the respondents, 92% (n=448/488) said they were likely to access OCs without prescription, if available. Differences are statistically significant between medical card holders and private patients (86.2%, n=125 and 94.4%, n=323 respectively, Mann-Whitney $p < 0.005$), between respondents in the 26-35 age bracket and the other two age groups (95.6%,

Table 2. Need of the service. Issues linked to prescription-only-medicine status of OC (n=488)								
	Compliance. Have you ever missed a pill because:						Have you ever felt distressed because you could not renew prescription	
	Prescription has run out		Could not renew prescription (GP surgery closed)		Could not afford to get prescription			
		%	n	%	n	%	n	%
Age								
18-25	50.3%	98	32.8%	64	13.8%	27	58.8%*	114
26-35	51.9%	107	28.2%	58	17.0%	35	58.5%*	120
36-50	43.0%	37	23.3%	20	10.5%	9	40.5%*	34
Urbanization								
Rural	52.9%	55	35.6%	37	10.6%	11	55.8%	58
Village/town	40.7%*	83	26.0%	53	14.2%	29	48.3%*	98
City	58.4%*	104	28.7%	51	16.9%	30	63.4%*	111
Medical Card								
Yes	50.3%	73	34.5%	50	4.8%*	7	52.1%	75
No	49.3%	168	27.0%	92	18.8%*	64	57.1%	193
All respondents	49.6%	241	29.2%	142	14.6%	71	55.6%	268
* p<0.05								

* $p < 0.05$

Table 3. Support of availability of OCs without prescription and likelihood to obtain OCs without prescription, if available. (n=488)					
		In favour of OC without prescription		Likely to obtain OC without prescription	
		%	n	%	n
Age					
	18-25	85.6%	167	89.7%*	175
	26-35	91.7%	189	95.6%*	197
	36-50	83.7%	72	88.4%*	76
Urbanization					
	Rural	80.8%*	84	86.5%*	90
	Village/Town	89.7%*	183	92.2%	188
	City	89.9%*	160	94.9%*	169
Medical Card					
	Yes	84.8%	123	86.2%**	126
	No	89.1%	304	94.4%**	322
All respondents		87.9%	429	92%	448
* p<0.05. **p< 0.005					

n=198 versus 89.7%, n=176 and 88.4%, n=114, Mann-Whitney p<0.05) and between respondents living in rural areas and the city (86.5%, n=90 versus 94.4%, n=168, Mann-Whitney p<0.05).

Results of the subsection of the questionnaire related to advantages and concerns are summarized in Table 4.

Advantages: A total of 80.2% (n=390/488) of the respondents thought that it would be easier/more convenient to obtain OCs without prescription. The difference between age groups is statistically significant between 26-35 years old and 36-50 years old (85.4%, n=176 versus 72.1%, n=62, Mann-Whitney p<0.05). Women living in the city reported this advantage more frequently (87.1%, n=155) than women living in rural areas (76.9%, n=80, Mann-Whitney p<0.05) or living in villages/town (76.5%, n=156, Mann-Whitney p<0.05 and p<0.05). One in two respondents (49.4%, n=240) also thought that obtaining OC without prescription would save time. Almost half of the respondents (45.1%, n=219/488) thought that if OCs were available without prescription, they would be less likely to miss the pill. The only statistically significant difference was between medical card holders (37.2%, n=54) and private patients (48.4%, n=165, Mann-Whitney p<0.05).

Concerns: A third of the respondents (33.3%, n=162/488) had concerns about the safety of the supply of OCs without a prescription and 25.1% (n=122/488) of the respondents was concerned about the possible abuse or misuse of OCs if available without a prescription. Differences

between medical card holders and private patients were statistically significant (Mann-Whitney on safety, p<0.005, on abuse/misuse p<0.001).

Switch to a different OC: Participants were asked if they would consider switching contraceptive in case an OC different from the one they were currently using would become available without prescription. The results are summarized in Table 5. A total of 74% (n=356/488) of the participants were open to switch after consultation either with their GP or their pharmacist.

The Role of the Pharmacist: Results related to the role of the pharmacist are summarized in Table 6. Over 88% (n=430/488) of the respondents thought that pharmacists would be able to safely supply their pill without prescription. There is a statistically significant difference between private (90.6%, n=309) and medical card patients (83.4%, n=121, Mann-Whitney p<0.05). A total of 88.9% (n=431/488) of the respondents declared to be comfortable to discuss side effects of OCs with their pharmacist.

Cost Issues: Data on cost issues are shown in Table 7. The views of the respondents were considerably discrepant on the issues concerning the costs of obtaining OCs without prescription: 50.8% (n=245/488) thought it would cheaper, with a marked difference between the responses given by medical card holders (16.6%, n=24) and the ones given by private patients (64.8%, n=221, Mann-Whitney p<0.001). A total of 20.8% (n=101/488) of the respondents thought instead that obtaining OCs without prescription would be more expensive.

Table 4. Advantages and concerns on the availability of OCs without prescription (n=488)					
	easier/ more convenient	save time	less likely to miss a pill	Safety concerns	Possible abuse/misuse
	% (n)	% (n)	% (n)	% (n)	% (n)
Age					
18-25	78.5% (153)	49.2% (96)	41.5% (91)	28.2% (55)	27.2% (53)
26-35	85.4% (176)*	52.9% (109)	50.5% (117)	35.0% (72)	22.8% (47)
36-50	72.1% (62)*	40.7% (35)	39.5% (38)	40.7% (35)	25.6% (22)
Urbanization					
Rural	76.9% (80)*	42.3% (44)	38.5% (49)	38.5% (40)	31.7% (33)
Village/town	76.5% (156)	47.1% (96)	43.6% (97)	29.9% (61)	22.1% (45)
City	87.1% (155)*	55.6% (99)	50.6% (99)	33.7% (60)	24.2% (43)
Medical Card					
Yes	78.6% (114)	46.9% (68)	37.2% (24)*	23.4% (34)**	15.2% (22)**
No	80.9% (276)	50.4% (172)	48.4% (221)*	37.5% (128)**	29.3% (100)**
All respondents	80.2% (390)	49.4% (240)	45.1% (245)	33.3% (162)	25.1% (122)
* n≤0.05 **n≤ 0.005					

Table 5. Open to switch to a different OCs if only a OCs different from the one the patient is currently using was available without prescription (n=488)		
	%	n
Consulting GP	36.4%	175
Consulting pharmacist	37.6%	181
Consulting GP or pharmacist	74.0%	356
No	26.0%	125

Over a third (35.4%, n=51) of the respondents who currently have a medical card were concerned with the reimbursement on medical card of OCs if available without prescription.

Around 84.9% (n=413/488) of all the respondents indicated a mean price of 12.08EUR/month as reasonable for the OC. Differences in responses between groups were not statistically significant except between medical card holders and private patients (Mann-Whitney $p < 0.001$). Medical card holders indicated a mean cost between of 9.31EUR, while private patients reported a mean cost of 13.15EUR.

Private patients were also asked to indicate the average cost of 6 months' supply of their OCs, including the initial GP visit. A total of 79.43% (n=271) of private patients responded. The mean of this cost was 110.08EUR (SD=21.52) for six months' supply. In order to give an estimate on how much savings, as an average, private patients were expecting from the deregulation of OCs, data from private patients who indicated both the maximum cost they would be willing to pay for six months' supply of OCs without prescription and the current cost of six months' supply of OCs (including prescription's cost) were analysed. Out of 252 respondents, the average savings expected over six months was 30.01EUR (SD=33.90EUR). This corresponds to an average saving of 27.3%.

DISCUSSION

The results of the study highlight that women resident in the Republic of Ireland strongly support the availability of OC without prescription.

Need of the service: One major finding of this study is certainly the potentially high demand for the service, especially in urban settings, probably due to a more hectic lifestyle. Since pharmacies have longer opening hours and provide services without appointments, the availability of OCs without prescription could considerably reduce the stress women experience when having to renew their prescriptions. Easier access could also reduce interruption in contraception, leading to increased compliance. It is difficult to determine if the availability of an OC without prescription would actually reduce its cost, depending on the potential increase in price of the OC and the likely addition of

a pharmacist's consultation fee. However, the elimination of costs associated with the renewal of the prescription could bring overall savings to the users.

Support for availability of OCs without prescription: In the survey, statistically significant differences emerged between demographic groups. Respondents living in urban areas as well as private patients, were significantly more in favour and more likely to obtain OCs without prescription. This may be due to the convenience of such a service. However, at least 80% of the respondents were both in favour and likely to access OCs without prescription, regardless of their age, geographical area, urbanization and medical card status. This high percentage is impressive, especially if compared to a recent similar US study⁵ where 58.7% of current OC users indicated to be likely to obtain OCs without prescription if available. However, unlike the present study, the US research analysed responses from women regardless of their choice of contraceptive.

Advantages: The majority of the respondents saw important advantages especially in terms of convenience, ease of access and time saving. These advantages were more relevant for younger women living in the city. All these results, confirm the findings of a 2010 national survey on contraception in Ireland², where 15% of women have reported to have some level of difficulties in accessing contraceptive services, mainly due to access/locality.

A total of 45.1% of the respondents thought that they would be less likely to miss their pill if available without prescription, suggesting that availability of OCs without prescription could increase compliance and reduce the rate of unintended pregnancies as it reduces the likelihood of missing doses. Recent publications^{17,22} advocate access to OCs without prescription as a strategy to reduce unintended pregnancies by increasing the number of pill users, to improve continuation and to reduce gaps in use.

Concerns: Results show that despite the desire of obtaining the contraceptive pill without having to obtain a prescription from the GP, several women are concerned that this could impact on the safe and effective use of oral contraception. Private patients were significantly more concerned about the safety and the potential abuse/misuse of OCs than medical card holders. The concerns women voiced in the survey will be important to address if a pharmaceutical company applies for the deregulation of OCs from prescription only medicines to non-prescription status.

The concerns identified by the respondents highlight the importance of supplying the OCs under the

Table 6. The role of the pharmacist in providing OCs without prescription (n=488)			
	Medical card		All respondents
	Yes	No	
Pharmacist able to supply pill safely without prescription	83.4% (121)*	90.6% (309)*	88.5%
Comfortable to discuss side effects with pharmacist	84.8% (123)	90.6% (308)	88.9%
Comfortable with pharmacist changing OCs	53.1% (77)	62.2% (212)	59.5%

* $p < 0.05$

Table 7. Indication of price patients would be happy to pay to obtain an OCs without prescription and current cost of OC			
	Medical card		All respondents
	Yes	No	
Indication of price of OC without prescription (n=413)	9.31EUR ^a	13.15EUR ^b	12.08EUR [*]
Current cost of 6 months' supply of OCs ^{**} (n=271)	-	110.08	110.08
Saving expected over 6 months ^{**} (n=252)	-	30.01EUR (27.3%)	
[*] mean price, p<0.001, ^a SD=5.90, ^b SD=6.24			
^{**} including cost of prescription for six months' supply			

supervision of a qualified and competent healthcare professional. Since February 2011, hormonal emergency contraception is available in Ireland without prescription. Shortly after deregulation, the Irish pharmaceutical regulatory body (The Pharmaceutical Society of Ireland) issued clinical guidelines to pharmacists in order to provide emergency contraception safely and effectively. A similar approach would be likely to be taken if a contraceptive pill would become available without prescription.

Switch to a different OC: It is interesting to note that almost three out of four respondents stated to be open, after consultation with their healthcare professional, to switch contraceptive pill in case an OC different from the one they were currently using would become available without prescription. This shows a good relationship and trust between patients and their own healthcare professionals. This aspect has also important implications in terms of market share and financial benefits for a pharmaceutical company intending to apply for the deregulation of a contraceptive pill. In the Republic of Ireland, the deregulation of a medicinal product from prescription-only-medicine to non-prescription must be sought by the market authorization holder of the medicinal product. The deregulation of a particular brand of contraceptive pill could mean that a significant number of OCs users would consider switching to that brand, after consultation with their healthcare professional. However he patient's choice would be limited if only one preparation became available without prescription.

The role of the pharmacist: A large amount of respondents (88.5%) thought that pharmacists would be able to safely supply OCs without a prescription. The perception from the users is that pharmacists are knowledgeable and competent and could supply OCs making sure, through appropriate SOPs that the contraceptive pill is dispensed safely and effectively. This is confirmed by the fact that 88.9% of the respondents are comfortable in discussing side effects of the OCs with pharmacists. The results of the study are overall consistent with the literature^{5,14,16,33}: women think their pharmacist would be able to supply OC without prescription and counsel them about choices and side effects.

The confidence and trust in the pharmacists on the subject is even more prominent when we consider that up to 59.5% of the respondents would be happy if their pharmacist changed their pill in case the pill available without prescription was different from the one they were currently using. However this is somehow surprising if compared to the data collected in Table 5 where only 37.6% stated to consider switching OCs by consulting their pharmacist. This discrepancy in the answers, in conjunction with the relative high percentage (13%)

of unsure respondents, could indicate that this question probably needed to be more explicit (i.e. would the pharmacist change my pill with or without a consultation with my GP?).

Cost issues: More than 50% of the respondents thought that obtaining OCs without prescription would be cheaper. Understandably this advantage is reported more frequently by private patients who have to take into account GP visits in the budget expenditure for their OCs. Medical card patients (patient with income below a certain threshold) do not pay for obtaining prescription and pay only a government levy of 2.50EUR per one month's supply of OC.

However one in five respondents is concerned about the possible increase in price if OCs were available without prescription and one in three medical card holders is afraid that their contraceptive pill, if available without prescription, might no longer be reimbursed by the government. These concerns are probably based on the experience of the deregulation of levonorgestrel for emergency hormonal contraception that resulted in an increased price of the medication when sold without a prescription. At the same time though, a formulation of levonorgestrel for EHC remained available on prescription at a reduced price and reimbursable under the medical card scheme. The increase in price was partially due to commercial reasons of the manufacturer and partially due to the pharmacist consultation fee. The increase in price though is offset against the cost of the GP visit that varies between 40-60EUR. According to the levonorgestrel and other deregulation experiences (pantoprazole, esomeprazole), the availability of an oral contraceptive without prescription will probably not impact on its reimbursement under the medical card scheme.

The study found that private patients would expect to be able to access oral contraception without prescription for 13.15EUR, bringing an average saving in the region of 30% (32EUR) over a six month period. However different OCs have different prices, depending on wholesale price and pharmacy's mark ups and fees. Therefore it is difficult to establish what actual savings, if any, the deregulation would bring to each user and this is confirmed by the high SD of the data collected.

OC users who hold a medical card were generally less likely to access the OCs without the prescription, which is understandable because they would have to pay privately for the OCs. However, it is interesting to note that 71.3% of medical card holders would be happy to pay an average of 9.35EUR per one month supply of OCs without prescription. Considering that the current government levy that applies to each month supply

of OCs is 2.50EUR, almost three out of four medical card holders would be happy to pay an extra 6-7 EUR just for the convenience of obtaining their contraceptive pill without prescription.

Limitations of the study and further areas of research: The main survey questions were hypothetical and the actual uptake of OCs without prescription may be different from what it was measured. The study was directed exclusively to current OC users and we cannot exclude that an easier and cheaper access to OCs could also be of interest in women currently not using OCs because of issues of convenience or cost. Confounding factors that could influence results, (polypharmacy, allergies, medical condition that would require close monitoring by a medical practitioner) were not accounted for, and therefore could limit the validity of results. The target sample size (600) was not reached. Based on the confidence level of 95% and a sample size of 488, the confidence interval for the study was 4.4.

Future studies should include investigations of views and attitudes of pharmacists, GPs and pharmaceutical industries. In particular what tools in terms of training, Continued Professional Development and SOPs pharmacists feel they would need in order to safely supply OCs without prescription. Also, financial implications on all stakeholders should be an object of further studies.

CONCLUSIONS

Regardless of age, reimbursement status and living area, OC users resident in the Republic of Ireland are in favour of OCs being available without prescription and are willing to obtain it this way, providing that pharmacists supply them according to protocols that facilitate the safety and the efficacy of the supply. The provision of OCs without prescription under the supervision of the pharmacist could increase further access and convenience, guaranteeing a safe and effective service. The easier and more convenient access to OCs could also reduce the likelihood of missed pills and it would expand the role of pharmacist as competent healthcare professional in the provision of contraception services. The market implications are also quite significant. Accessing OCs without prescription could bring considerable savings to the users. Financial impact on pharmacists, GPs and pharmaceutical companies remains to be assessed.

Given the accumulating evidence documenting the safety and effectiveness of OCs supplied without prescription, as well as the demand among women for this option, it will be interesting to see if a pharmaceutical company will pursue an application for deregulation of an OC in the near future or if the Irish regulatory body of competence HPRA (Health Products Regulatory Authority) would seek expression of interest on the matter from pharmaceutical companies as recently done for a series of potential deregulations.³⁸

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CONFLICT OF INTEREST

The author is employed by the Allcare pharmacy group, which has collaborated in distributing and collecting the surveys. The author had no other conflict of interest at any stage of the study, including its submission for publication.

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VISIÓN Y ACTITUDES DE LOS USUARIOS DE CONTRACEPTIVOS ORALES HACIA SU DISPONIBILIDAD SIN RECETA EN LA REPUBLICA DE IRLANDA

RESUMEN

Antecedentes: Estudios previos mostraron que la provisión de contraceptivos orales (OC) sin receta es segura, factible y efectiva y que las usuarias están interesadas en obtener contracepción de este modo, especialmente si está involucrado el consejo farmacéutico. Una reciente encuesta conducida en la República de Irlanda ha subrayado que los embarazos indeseados resultado de un fallo de los OC podrían estas ligados a cumplimiento bajo debido a costes y dificultad de acceso.

Objetivo: Evaluar la visión y actitudes de las usuarias de OC sobre la disponibilidad de OC sin receta en la Republica de Irlanda.

Métodos: Se realizó un estudio transversal con una muestra oportunist de usuarias de OC de 18 a 50 años. Se reclutaron 60 farmacias comunitarias en toda la nación. Se recogieron los datos en un cuestionario auto-cumplimentado. Los cuestionarios comprendían información sobre: datos demográficos, necesidad de servicio, visiones sobre la disponibilidad de los OC sin receta, ventajas y preocupaciones sobre el servicio, papel del farmacéutico e implicaciones para los pacientes públicos o privados.

Resultados: Un total de 488 usuarios de OC elegibles completaron la encuesta. La mayoría de los respondentes (71,7%; n=350/488) reportaron haber omitido una pildora por razones relacionadas con el estado de prescripción de los OC y el 55,5% (n=268/468) de los respondentes reporto haber sentido desasosiego al menos en una ocasión por no poder renovar su prescripción de OC. Un total de 87,9% dijo que estaba a favor de que los OC estuviesen disponibles sin receta y el 92% (n=448/488) dijo que probablemente comprarían OC sin receta si estuviesen disponibles. La comodidad y la facilidad de acceso aparecieron indicadas como las ventajas principales de disponibilizar OC sin receta, mientras que la seguridad era la mayor preocupación. Más del 88% (n=460/488) indicó que los farmacéuticos serían capaces de distribuir de modo seguro los OC sin receta. Los pacientes privados esperaban ahorrar una media del 27,3% en sus OC si los obtenían sin receta.

Conclusiones: Las usuarias de OC en la República de Irlanda están a favor de que los OC estén disponibles sin receta y están dispuestas a obtenerlos de este modo, aceptado que los farmacéuticos los proporcionen de

acuerdo a protocolos que faciliten la seguridad y eficacia del suministro. Un modo más fácil y más cómodo de acceso a los OC podría también reducir la probabilidad de píldoras omitidas y traería considerables ahorros a las usuarias.

Palabras clave: Anticonceptivos Orales; Accesibilidad a los Servicios de Salud; Conocimientos, Actitudes y Práctica en Salud; Medicamentos sin Prescripción; Medicamentos bajo Prescripción; Irlanda

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