

Women & Health



ISSN: 0363-0242 (Print) 1541-0331 (Online) Journal homepage: http://www.tandfonline.com/loi/wwah20

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To cite this article: Jelena Milosavljevic MPharm, Natasa Bogavac-Stanojevic PhD, Dusanka Krajnovic PhD & Ana Mitrovic-Jovanovic PhD (2016): Serbian Gynecologists' and Pharmacists' Beliefs about Emergency Contraception, Women & Health, DOI: 10.1080/03630242.2016.1176099

To link to this article: http://dx.doi.org/10.1080/03630242.2016.1176099

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Accepted author version posted online: 11 Apr 2016.



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## Serbian gynecologists' and pharmacists' beliefs about emergency contraception

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#### ABSTRACT

Emergency contraception (EC) in Serbia is available in two products, one of which, Levonorgestel, has nonprescription status, and Ulipristal acetate is a prescription-only medicine. Considering their dispensing statuses, gynecologists and pharmacists are health care professionals (HCPs) with the widest impact on EC use. Yet little is known about their beliefs and practices regarding these medicines. We surveyed 166 gynecologists (during October 2012 -October 2013) and 452 community pharmacists (during January - April 2014). Results showed significant differences between these two groups, suggesting that provision of EC to users may be inconsistent. Gynecologists were more convinced than pharmacists that EC would reduce the abortion rate (86% vs. 53%, p < .001). However, they were more concerned than pharmacists that easy access to EC would cause less regular contraceptive use (66% vs. 29%, p < .001) and risky sexual behaviors: initiating sexual activity at a younger age (37% vs. 19%, p < .001) and having more sexual partners (33% vs. 12%, p < .001). Additionally, more pharmacists than gynecologists (12% vs. 2%, p < .001) said they would not provide EC to anyone under any circumstance, even to victims of sexual assault. These results indicated a need for reevaluating and establishing official guidelines for dispensing practices.

Keywords: Emergency contraception, Levonorgestrel, Ulipristal acetate, Serbia

Received 10 Aug 2015

Revised 16 Feb 2016

Accepted 20 Feb 2016

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# **INTRODUCTION**

Use of emergency contraception (EC) is a controversial issue in health care. It is administered postcoitally when regular contraception fails or is not used; therefore, it has some potential to reduce unintended pregnancies. Accurate and reliable information concerning numbers of abortions in Serbia is not available due to the lack of records from private clinics. According to official data 20,335 abortions were reported in 2012 (Institute of Public Health of Serbia 2013), though it is estimated that the true number is many times higher (Rasević and Sedlecky 2009).

These abortions were mainly a consequence of non-use of effective methods for pregnancy prevention (Rasević and Sedlecky 2009). The contraception use rate has been reported to be 61%, of which only 21.5% used some modern method, such as oral contraceptives or intrauterine devices (UN DESA 2013). EC is available on the market in two products: Levonorgestel (LNG), with nonprescription status for those older than 16 years of age, and Ulipristal acetate (UPA), which can be dispensed only by prescription (Milosavljević, Ilić and Krajnović 2014). Yearly consumption of these products has been growing with 103,231 packs of LNG and 162 packs of UPA sold in 2012 (ALiMS 2012).

Considering the dispensing statuses of these two EC drugs, both gynecologists and pharmacists may directly affect access to EC. Responsibilities of these health care professionals (HCPs) include providing prescriptions, dispensing the medicines and educating patients. However, in Serbia no officially approved clinical guidance documents are available for family planning; so, clinical practice can differ from one to another HCP. Also from investigations in other countries, it is evident that personal characteristics and beliefs of HCPs can influence their practice regarding EC and sometimes also lead to users being denied EC (Lawrence, Rasinski, Yoon and Curlin 2010, Hussainy et al. 2011, Bissell, Savageand and Anderson 2006, Ehrle and Sarker 2011). A USA study (Lawrence, Rasinski, Yoon and Curlin 2010) showed that gynecologists who believed access to EC would cause risky behavior were more conservative in providing EC. Also male and religious physicians were more reluctant to offer EC. Similarly, personal beliefs, religion, age and gender were shown to be important factors related to pharmacists' provision of EC in an Australian study (Hussainy et al. 2011).

Recently, the European Medicines Agency recommended non-prescription status for UPA (European Medicines Agency 2015). This change is expected to be implemented soon in Serbia as well, but no evidence has been provided to indicate if pharmacists are ready for that. To date, no data have been published of which we are aware on gynecologists' and pharmacists' attitudes and practices regarding EC in Serbia. Therefore, the primary objective of this study was to assess differences in beliefs of Serbian obstetricians-gynecologists (called 'gynecologists' in the remainder of the text) and community pharmacists about EC. The secondary objective was to determine which traits of HCPs were related to their beliefs regarding EC.

### **METHODS**

A descriptive, cross-sectional survey, designed as a knowledge, attitude, and practice study was conducted with gynecologists and community pharmacists. This study protocol was approved by the Institutional Ethics Committee of the Faculty of Pharmacy of the University of Belgrade.

Due to differences in organization and in working conditions of gynecologists and pharmacists, the data collection procedure varied between the two study groups.

### **Gynecologists**

We distributed a questionnaire to a convenience sample of 550 gynecologists who attended six regional educational meetings of the Gynaecology and Obstetrics Section of the Serbian Medical Society between October 2012 and October 2013. Participation was voluntary and anonymous. Doctors working in all kinds of healthcare facilities (either in the public or the private sector)

were present at the meetings and had the opportunity to partake in the survey. Information about the study was provided verbally and via an information sheet. Completing and returning the questionnaire was taken as informed consent. The attendees were asked not to complete the questionnaire more than once in the event that they already completed it at some previous conference. We received 183 completed questionnaires. The response rate was 33%. After excluding forms with missing main outcome variables, the final sample consisted of 166 surveys.

### **Pharmacists**

The questionnaire was administered to members of the Pharmaceutical Chamber of Serbia through their official website (http://www.farmkom.rs) during the period January - April 2014. Information about the voluntary and anonymous nature of the study was provided via an information sheet. Completing the questionnaire was taken as informed consent. To reach non-Internet users, the survey was also announced, and the link was provided in a journal published by the Chamber and distributed to all pharmacies. A total of 462 completed questionnaires were received and checked for pharmacists' practice type and the presence of potential duplicates based on sociodemographic characteristics, date and exact time of questionnaire completion. No duplicates were identified. Pharmacists practicing in settings other than community pharmacies were excluded; thus, our sample consisted of 452 respondents. As we used an Internet survey, it was not possible to calculate a conventional response rate. Based on the Chamber's data, they had 5,377 members on April 15<sup>th</sup>, 2014 (The Pharmaceutical Chamber of Serbia 2014); thus 452 participants would be a participation rate of 8%.

### Questionnaire

The instrument used for data collection was a modified version of the questionnaire developed by Lawrence et al. (Lawrence, Rasinski, Yoon and Curlin 2010). With permission of the authors, the original questionnaire was translated from English into Serbian by two independent translators. After reconciliation, a back translation was performed by a third translator. The draft version was pre-tested on ten gynecologists selected randomly. This process was completed in accordance with the ISPOR (International Society for Pharmacoeconomics and Outcomes Research) Principles of Good Practice in translation and cultural adaptation process (Wild et al. 2005). The same questions regarding EC were repeated in the questionnaire created for pharmacists and pre-tested on ten community pharmacists; no major changes were generated.

HCPs' beliefs about EC were assessed by the following statements: "compared with women who are similar but do not have access to EC, women who have access to EC: (1) will have lower rates of unintended pregnancy; (2) will be less likely to use other contraceptive methods; (3) will initiate sexual activity at a younger age; and (4) will have more sexual partners". HCPs rated their level of agreement using four-point Likert scales. We also asked HCPs to choose the option which best described their practice regarding EC, whether they offered it: "(1) to all women they believe are at risk of unplanned pregnancy, (2) only to women who tell them that they have had unprotected intercourse, (3) only to victims of sexual assault, (4) to nobody under any circumstances".

Information was gathered concerning the socio-demographic features of the participants, specifically, gender, age, region of residence, having children and marital status.

### Statistical analysis

Data were analyzed using the Statistical Package for Social Science Software (SPSS 22.0 for Windows, SPSS Inc., Chicago, IL, USA). First, descriptive statistics were calculated. Next, differences in socio-demographic characteristics by HCPs' beliefs, as well as socio-demographic characteristics, HCPs' beliefs and their practices pertaining to EC were analyzed using t-tests and chi-squared tests. Binary logistic regression was used to compute the independent associations of variables with HCPs' beliefs and practices by calculating Odds ratios (ORs) with 95% confidence intervals (CI). Variables found to be associated with HCPs' beliefs and practices in the bivariate analysis (p < .05) were included in multivariate logistic regression models. The multiple logistic regression models included the potential confounding variables: age, gender, marital status, having children and region. All independent variables were entered into the model at the same time. The association of variables was estimated as an adjusted odds ratio (aORs) with 95% CI. The Hosmer and Lemeshow test was used to assess model fit. Statistical significance was deemed to have been reached when the computed probability value was < .05.

# RESULTS

Among the respondents, pharmacists tended to be significantly younger than gynecologists (Table 1). Also, significantly more women were included in the pharmacists group (p < .001), while significantly more gynecologists than pharmacists were in a relationship (p < .001) and had children (p < .001).

A higher percentage of gynecologists (86%) than pharmacists (53%) believed that women with access to EC would have fewer unintended pregnancies. Gynecologists were more concerned than pharmacists that women with access to EC would be prone to risky behavior: not using other contraceptives (66% vs. 29%, p < .001), initiate sexual activity at a younger age (37% vs. 19%, p < .001) and have more sexual partners (33% vs. 12%, p < .001) (Table 2).

The majority of responders in both surveyed groups differed little in their dispensing practices. Just over half offered EC only to women after unprotected intercourse. A third offered it to all women at risk of unintended pregnancy. However, significantly more pharmacists than gynecologists (12% vs. 2%, p < .001) responded that they would not offer EC to anyone under any circumstance (Table 3).

After taking gender, age, marital status and children into account, responders in Southern and Eastern Serbia were less likely to believe that use of EC would lower rates of unintended pregnancy, but more likely to think that it would cause women to have more sexual partners than responders from other regions (Table 4). Pharmacists from Belgrade were less likely to consider that EC would cause the risky sexual behaviors of women initiating sexual activity at a younger age and having more sexual partners. After adjustment for age, marital status, children and region, male pharmacists were more likely to believe that women with access to EC would have more sexual partners. However, pharmacists' practice did not differ by gender, age, region, marital status, having children and beliefs, so further logistic regressions were not performed.

The unadjusted associations of gynecologists' beliefs with age, marital status and children were not sustained in multiple logistic regression models (Table 5). Their practice variation by gender was observed in univariate analysis: compared to female gynaecologists, male gynecologists were more likely to offer EC only to women who tell them that they have had unprotected intercourse (OR 2.069, 95% CI 1.033-4.141, p = .040). After adjustment for confounding variables, multivariable logistic regression showed no significant gender difference in EC offer by male and female gynecologists (aOR 1.650, 95% CI 0.754-3.613, p = .210). The relation of belief to gynecologic practice was observed in univariate (OR 2.776, 95% CI 1.573-4.897, p <.001) and multivariable analysis (aOR 2.825, 95% CI 1.328-6.012, p = .007); gynecologists who believed that EC would reduce the number of unintended pregnancies were more than 2.5 times as likely not to offer EC or to offer it only to victims of sexual assault in univariate (OR 2.776, 95% CI 1.573-4.897, p < .001) and multivariate analysis (aOR 2.825, 95% CI 1.328-6.012, p = .007); OR 2.776, 95% CI 1.573-4.897, p < .001) and multivariate analysis (aOR 2.825, 95% CI 1.328-6.012, p = .007).

## DISCUSSION

This is the first study of which we are aware which has examined attitudes and practice regarding use of EC among Serbian gynecologists and pharmacists. It was performed just before the change in UPA prescription status to assess readiness of HCPs for this implementation. Information was gathered from HCPs residing in all regions of Serbia.

Similar to results in the USA (Lawrence, Rasinski, Yoon and Curlin 2010), our results showed that both pharmacists and gynecologists expected EC to reduce the number of unintended pregnancies. Based on estimated EC efficacy in clinical trials (von Hertzen et al. 2002, Glasier et al. 2010), this conviction is quite understandable. However, the public health benefit of EC on the abortion rate has yet to be demonstrated. Paradoxically, the outcomes of studies in many countries have shown no changes in the rate of unintended pregnancies following the introduction of EC (Xiaoyu, Linan, Xiaolin and Anna 2005, Polis et al. 2007, Rodrigueza et al. 2013). A community intervention study in Scotland (Glasier et al. 2004) on a population of around 85,000 women indicated no measurable relation to the abortion rate. Also a systematic review, which covered 10 countries, found that easy access to EC was not related to a decrease the number of unintended pregnancies or abortions (Raymond, Trussell and Polis 2007). In the light of results from these studies, it is surprising that 86% of gynecologists in our research, far more than pharmacists (53%), believed that access to EC would reduce unplanned pregnancy rates. It is possible that gynecologists overestimate the effectiveness of EC.

The gynecologists in our study were more likely than pharmacists, as well as more likely than gynecologists who participated in research in the USA (Lawrence, Rasinski, Yoon and Curlin 2010) to believe that EC would discourage women from using other contraceptive methods. Results from other studies also identified concerns of HCPs about risky contraceptive behavior related to increased availability of EC (Bissell, Savage and Anderson 2006, Ehrle and Sarker 2011). However, studies with users showed that repeated EC use does not occur frequently (Rowlands et al. 2000, Abuabara et al. 2004). Also a meta-analysis of studies of providing EC found that greater access to EC was not related to condom use (Polis et al. 2007). A retrospective cross-sectional study from Hong Kong (Loand Ho 2012) involving 9201 women showed positive changes in regular contraceptive use after EC provision which was accompanied with proper contraceptive counselling.

One third of gynecologists in our study were concerned that women with access to EC would be prone to initiate sex at a younger age and to have more sexual partners. This was contrary to the attitude of pharmacists for whom the majority did not believe that greater access to EC would cause greater risk-taking. Such an attitude of pharmacists is similar to the beliefs of gynaecologists in the Lawrence et al. (2010) study, and as well as being supported by many other studies that have shown no relation between increased availability and use of EC with increase in risk-taking behavior or sexually transmitted infections (Polis et al. 2007, Rodrigueza et al. 2013, Raymond, Trussell and Polis 2007). This suggests that EC is just one of a multitude of factors that may be related to patients' sexual behaviors.

In comparison with the practice of gynecologists in the USA (Lawrence, Rasinski, Yoon and Curlin 2010), the HCPs in our study were more conservative with regard to providing EC. A significantly higher proportion of pharmacists than gynecologists (12% vs. 2%, p < .001) would not offer EC to anyone under any circumstance. Similar findings have been found in other studies, showing that provision of EC is not consistent, even for sexual assault victims (Hussainy et al. 2011, Woodell, Bowling, Moracco and Reed 2007). Additional deeper research with pharmacists is needed to understand their reasons for this rejection, as well as reevaluation of the dispensing regime.

Half of the HCPs in our study would offer it only after unprotected intercourse, and every third HCP would offer it to all women at risk of unplanned pregnancy. This finding is similar to pharmacists' practice in an Australian study (Hussainy et al. 2011) in which 69% of participants considered advanced provision of EC, to have it in case it will be needed, unacceptable for any

women in any circumstance. Although numerous studies have demonstrated that advanced provision of EC is safe (Raymond et al. 2006, Schwarz, Gerbert and Gonzales 2008, Jackson, Schwarz, Freedman and Darney 2003), no evidence yet exists that it decreases the number of unintended pregnancies (Polis et al. 2007, Raymond, Trussell and Polis 2007). However, all of these studies were conducted in developed countries with a high prevalence of use of regular contraceptives. In Serbia, where this prevalence is low, but the abortion rate is high, these circumstances make it a great opportunity for EC use. Further research is needed to evaluate the possible reduction of public health costs of unintended pregnancy by using EC.

In the present research, we found a difference between the views of male and female pharmacists on EC, which was similar to results from a previous study in the USA (Lawrence, Rasinski, Yoon, and Curlin 2010) in which males were more likely to say it increased risky behavior and were less likely to offer it. Previously we reported that gynecologists' attitudes and practice regarding contraception and abortions differed among regions in Serbia (Milosavljevic, Krajnovic, Bogavac-Stanojevic, and Mitrovic-Jovanovic 2015). Nevertheless, in the present study, we found no difference between gynecologists' views regarding EC in those regions. However, a significant difference was observed in pharmacists' views. In the least developed regions, Southern and Eastern Serbia, where gynecologists were more oriented to abortion than to contraception (Milosavljevic, Krajnovic, Bogavac-Stanojevic, and Mitrovic-Jovanovic 2015), pharmacists did not favor use of EC. These findings may indicate that patients' needs may go unmet, which would require development of a health policy to address these needs. Access to the health care system itself should not be influenced by the personal characteristics or beliefs of HCPs. Personal attitudes should not be the leading principles in clinical practice, but rather clinical evidence should guide clinical practice. Adequate clinical guidance documents in this field are thus necessary.

This study had limitations which should be considered when interpreting the results. First, the relatively low overall response rates could have resulted in participation bias, potentially reducing the accuracy and generalizability of the findings. Also, self-reports are imperfect indicators, and social desirability and recall biases were possible. Further, the use of a convenience sample of gynecologists attending meetings might have resulted in overestimating the respondents' positive attitude to EC because these groups may have been better informed about contraception, again potentially reducing the accuracy and generalizability of the findings. Finally, the survey questions were developed for this study and were quite nonspecific, which could have resulted in misclassification and/or lack of clarity of the findings and their interpretation. Further research is needed to examine what HCPs would do in more specific situations.

# CONCLUSION

Although we found that both HCP groups expected that use of EC would reduce the abortion rate, significant differences were observed between the beliefs of gynecologists and of pharmacists, which suggested the possibility of non-uniform provision of EC. Gynecologists were more concerned than pharmacists that EC would cause more risky contraceptive and sexual behaviors. However, contrary to their beliefs, a significantly higher proportion of pharmacists than gynecologists would not offer EC, which may indicate a need to reevaluate dispensing practices and to establish official practice guidelines.

#### Acknowledgements

We would like to thank those gynaecologists and pharmacists who participated in our studies. The contribution of Dr. Steve Quarrie, who revised the manuscript for English language and grammar is gratefully acknowledged. J. Milosavljevic is an employee of Bayer d.o.o. Dr. Mitrovic-Jovanovic gave lectures supported by Bayer d.o.o. and Richter Gedeon Nyrt. The remaining authors report no conflicts of interest. The authors alone are responsible for the content and the writing of the paper.

### Funding

The research of D. Krajnovic was partially supported by the Ministry of Education and Science of the Republic of Serbia (Project No.41004).

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CC,

	Pharmacists ( $N = 452$ )	Gynaecologists ( $N =$	<i>p</i> value
		166)	×
Gender, <i>n</i> (%)	452	152	<.001
Female	426 (94)	99 (65)	
Male	26 (6)	53 (35)	
Age group (years), <i>n</i> (%)	425	158	<.001
≤35	160 (38)	5 (3)	
36-50	189 (44)	96 (61)	
≥51	76 (18)	57 (36)	
Partnered status, n (%)	446	158	<.001
With partner	276 (62)	123 (78)	

Table 1 Characteristics of the surveyed pharmacists and gynaecologists

Without partner	170 (38)	35 (22)	
Children, n (%)	448	149	<.001
Yes	266 (59)	127 (85)	95.
No	182 (41)	22 (15)	5
Region, <i>n</i> (%)	447	156	.108
Vojvodina	80 (18)	31 (20)	
Belgrade	206 (46)	69 (44)	
Sumadija and Western Serbia	96 (21)	23 (15)	
Southern and Eastern Serbia	65 (15)	33 (21)	
Patients under 18 years, %		11% ( <i>SD</i> = 12%)	

<i>n</i> (range)	1.5 (0-19)	×

Table 2. Beliefs of HCPs regarding EC

	1	1	
	Pharmacists	Gynecologists	
	( <i>n</i> = 452)	( <i>n</i> = 166)	<i>p</i> value
	N (%)	N (%)	2
Compared with women who are similar but do not have	e access to eme	ergency contracep	tives
Women who have access to emergency	242 (53)	142 (86)	<.001
contraceptives will have lower rates of unintended	2		
pregnancy. (agree)			
Women who have access to emergency	133 (29)	109 (66)	<.001
contraceptives will be less likely to use other			
contraceptive methods. (agree)			
Giving women or girls access to emergency	84 (19)	62 (37)	<.001
contraceptives will cause them to initiate sexual			
activity at a younger age than if they did not have			
access to emergency contraceptives. (agree)			
Women who have access to emergency	56 (12)	55 (33)	<.001

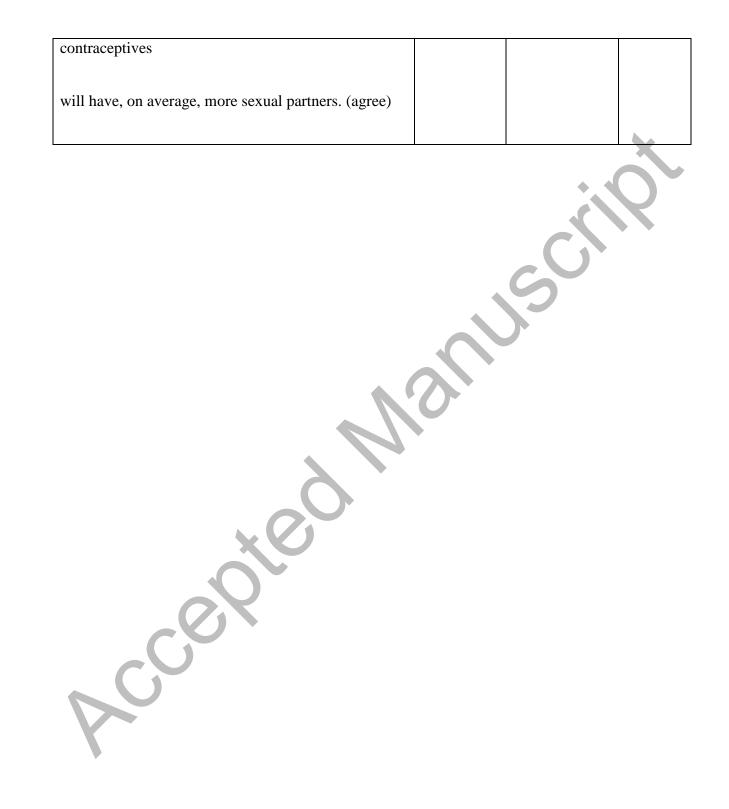


Table 3. Practice of HCPs with respect to EC

	Pharmacists	Gynecologists	<i>p</i> value
			X
	( <i>n</i> = 442)	( <i>n</i> = 164)	
	N (%)	N (%)	
Emergency contraception is offered to all women	142 (32)	61 (37)	.210
who			
who			
the HCP believes are at risk of unplanned pregnancy.			
	0		
Emergency contraception is offered only to women	232 (52)	91 (55.5)	.440
who			
say they have had unprotected intercourse.			
Emergency contraception is offered only to victims of	16 (4)	9 (5.5)	.293
sexual assault.			
	<b>70</b> (10)		0.0.1
Emergency contraception is offered to nobody under	52 (12)	3 (2)	<.001
any circumstance.			

Table 4. Unadjusted Odds ratios (OR) and Adjusted\* odds ratios (aOR) and 95% Confidence Intervals (CI) for factors associated with pharmacists' (n = 452) beliefs regarding EC

Characteristic	OR	95%CI	<i>p</i> value	aOR*	95%CI	<i>p</i> value	
Women will have lower rates of unintended pregnancy							
Region - Vojvodina	1.421	0.644-3.135	.384	S	0		
Region - Belgrade	1.404	0.792-2.491	.246				
Region - Sumadija and	1.224	0.591-2.533	.587				
Western Serbia		5					
Region -Southern and Eastern Serbia	0.348	0.181-0.672	.002	0.377	0.193-0.737	.004	
Women will be less likely to us	se other c	contraceptive me	ethods				
Region - Vojvodina	0.768	0.473-1.249	.287				
Region - Belgrade	0.979	0.671-1.428	.911				

Region - Sumadija and Western Serbia	0.942	0.593-1.497	.801			
Region -Southern and Eastern Serbia	1.596	0.908-2.804	.104			Ś
Women will initiate sexual acti	vity at a	younger age		C	0	
Region - Vojvodina	1.199	0.727-1.976	.477			
Region - Belgrade	0.597	0.401-0.889	.011	0.579	0.387-0.865	.008
Region - Sumadija and Western Serbia	1.383	0.864-2.215	.177			
Region -Southern and Eastern Serbia	1.434	0.827-2.486	.199			
Women will have more sexual	partners		Ι	Γ		
Gender-Male	3.786	1.670-8.582	.001	3.746	1.654-8.483	.002

Region - Vojvodina	0.989	0.560-1.747	.969			
Region - Belgrade	0.567	0.361-0.891	.014	0.610	0.385-0.967	.035
Region - Sumadija and Western Serbia	1.245	0.738-2.101	.411			2
Region -Southern and Eastern Serbia	2.122	1.199-3.753	.010	1.890	1.045-3.421	.035

\* Adjusted for gender (female-0, male-1), age (continuous variable), marital status (without partner–0, with partner–1) and children (without children-0, having children-1)

Table 5. Unadjusted Odds ratios (OR)) and Adjusted\* odds ratios (aOR) and 95% Confidence Intervals (CI) for factors associated with gynecologists' (n = 166) beliefs regarding EC

Characteristic	OR	95%CI	<i>p</i> value	aOR*	95%CI	<i>p</i> value		
Gynecologists offer EC to all women they believe are at risk of unplanned pregnancy								
Gender - Male	.496	.241-1.018	.056	. (	5			
Age	0.965	0.781-1.194	.745	$\langle \rangle$				
Belief in lower rates of unintended pregnancy	0.887	0.595-1.321	.555					
Gynecologists offer EC or	Gynecologists offer EC only to women who tell them that they have had unprotected intercourse							
Gender - Male	2.069	1.033-4.141	.040	1.650	0.754-3.613	.210		
Age	0.675	0.371-1.230	.199					
Belief in lower rates of unintended pregnancy	0.738	0.502-1.085	.122					

Gender - Male	0.771	0.191-3.116	.716			X
Age	1.322	0.855-2.143	.209			R
Belief in lower rates of unintended pregnancy	2.776	1.573-4.897	<.001	2.825	1.328-6.012	.007

\* Adjusted for gender (female-0, male-1), age (continuous variable), marital status (without partner–0, with partner–1) and children (without children-0, having children-1)

3

Gynecologists offer EC only to victims of sexual assault/ to nobody under any circumstances