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## **Smoking during pregnancy: Changes and associated risk factors in Spain, 1980 to 2016**

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## **Abstract**

**Background:** Trends for maternal smoking rates have varied substantially across industrialized countries. The objective was to describe how the prevalence of maternal smoking evolved in Spain during 1980-2016.

**Methods:** Data came from the Spanish Collaborative Study of Congenital Malformations. Our sample consisted of 40,934 mothers of newborns with no congenital defects from hospitals all across Spain. We estimated change points in trend and the mean annual change in smoking prevalence using *joinpoint* regression. Relevant potential factors (age, country of birth, education, parity, planned pregnancy, and alcohol consumption) were examined using multivariate logistic regression.

**Results:** Maternal smoking prevalence in 1980 and 2016 were 14.3% (95% Confidence Interval [CI]:11.9-17.0) and 20.4% (95%CI:15.9-25.8). We identified four periods with distinct trends: a sharp increase during the 80s, a plateau during the 90s, a decrease starting in 2000 and a slow down of such decrease from 2009 on. Smoking was significantly higher among young women, Spain-born, with low education, unplanned pregnancy, and alcohol consumption.

**Conclusions:** Currently in Spain maternal smoking remains very high. Tobacco consumption trend showed an increase during the 80s, a plateau during the 90s, and a reduction in the 2000s. Several sociodemographic and behavioral factors were associated to greater likelihood of smoking.

**Key words:** smoking, pregnancy, trends, risk factors, Spain

## INTRODUCTION

Tobacco consumption before and during pregnancy continues to be one of the main causes of fetal and maternal morbidity and mortality. Maternal smoking has been associated, with varying degrees of evidence from merely suggestive to sufficient, to a greater risk of congenital malformations (e.g., orofacial clefts, clubfoot, gastroschisis, atrial septal defects), ectopic pregnancy, miscarriage, preterm delivery, low birth weight, and sudden infant death syndrome, among others.<sup>1</sup>

Heightened awareness of the harmful effects of smoking during pregnancy has not translated into cessation. Lange and colleagues<sup>2</sup> estimated the 2015 worldwide prevalence of maternal smoking to be 1.7% and many times over (8.1%) in the World Health Organization (WHO) European region. In Spain, this rate reached 26.4% though this figure was derived from a meta-analysis of Spanish studies which included research based on regional or smaller geographic units consisting of highly heterogeneous populations.<sup>2</sup> Unfortunately, Spain lacks country-wide surveillance on maternal smoking. The latest study on its trends analyzed data from 1978-2002 series which captured great inter-regional variability.<sup>3</sup> Tobacco consumption among Spanish women in general has gone through substantial changes in the past decades,<sup>4</sup> thus determining the pattern of maternal smoking prevalence is an important epidemiological endeavor given the significant health consequences.

In industrialized nations, prevalence of maternal smoking has varied substantially across time. Despite an overall decrease in tobacco consumption, maternal smoking rates not always follow those of the general population and these divergences vary by country. For instance, the downward trend in maternal smoking in Denmark has followed that of the general population,<sup>5</sup> whereas in Sweden<sup>5</sup> and Australia<sup>6</sup> the reduction has been swifter. In contrast, maternal smoking rates in the USA<sup>7</sup> and Canada<sup>8</sup> are decreasing at a slower

pace than among their general populations. Finally, Finland became a trend outlier after seeing smoking prevalence among mothers-to-be remain stable despite national decreasing rates.<sup>5</sup>

Screening for tobacco consumption during pregnancy and recommending cessation interventions are currently well established practices.<sup>9</sup> However, for a sound approach to this health problem we first need to have reliable information on the highest risk groups to better target our interventions. Thus, the main aim of this work was to estimate the evolution and identify relevant factors, of maternal smoking in Spain between 1980 and 2016.

## **METHODS**

### **Data sources and study population**

Data come from the Spanish Collaborative Study of Congenital Malformations (ECEMC for its Spanish acronym).<sup>10</sup> In this hospital-based case-control study, for each newborn with a congenital malformation, a same-sex healthy control born after the case in the same hospital was also recruited. An obstetrician or neonatologist collected the data within the first three days after birth using a structured questionnaire and following standardized directions.

Our initial sample consisted of 41,381 new mothers from the ECEMC control group recruited across all 17 regions of Spain between 1980 and 2016. We excluded 1.1% of the participants for lack of data on tobacco consumption for a final sample of 40,934 women. However, specific analyses on the factors related to smoking were performed on a smaller sample of 28,088 mothers as some of the variables of interest were only added to ECEMC from 1987 on.

To confirm the representativeness of the sample, we compared participants' characteristics (age, working status, country of birth, and low birth weight) against those of childbearing age women in the general Spanish population according to the Spanish National Statistics Institute. No significant differences were found (Table 2S in supplementary material).

The ECEMC study was approved by the Research Ethics Committee of the Institute of Health Carlos III, Madrid, Spain (CEI PI 31\_2009).

### **Study Variables**

Our main outcome variable was tobacco consumption during pregnancy, defined as smoking at least once during pregnancy. Maternal age at delivery was dichotomized as <30 or  $\geq$ 30 years of age. Educational attainment was grouped into three categories: low (no schooling or primary studies), intermediate (secondary studies or high school diploma), and high (at least some college). In the analyses for smoking-related factors we also included maternal place of birth (Spain- or foreign-born), parity (primiparous, multiparous), planned pregnancy (yes/no), and alcohol consumption during pregnancy (yes/no).

### **Data Analyses**

As part of the analyses of smoking trend between 1980 and 2016, we estimated a maximum of three statistically significant changes in trend using joinpoint regression models,<sup>11</sup> estimating the mean annual change (MAC) in smoking prevalence in absolute terms. We also ran the analyses by age group and by age-standardized educational attainment (based on the age distribution of the population of interest).

To analyze relevant factors related to maternal smoking we calculated odds ratios (OR) with their corresponding 95% confidence intervals (CI) adjusted simultaneously by the variables of interest (maternal age, place of birth, educational attainment, parity, planned pregnancy, alcohol consumption). Additionally, to detect time-related changes in the associations under study, we included interaction terms for these variables with a variable for time (1987-1996 and 2007-2016). We used a p-level of 0.05 for statistical significance.

Analyses were performed using Joinpoint software (v. 4.6) (April 2018; Statistical Methodology and Applications Branch, Surveillance Research Program, National Cancer Institute) to describe the evolution in time of maternal tobacco consumption between 1980 and 2016. Logistic regression models were defined using the statistical package STATA (v. 15.0) (StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC). STATA's module "survey data" was used to correct for the sample characteristics (hospital-based participant clusters).

## **RESULTS**

Sample characteristics such as socio-demographics and alcohol consumption are presented in Table 1 by study time period (1987-1996, 1997-2006, 2007-2016). Table 1S (supplementary material) shows the distribution of mothers according to smoking status by study year.

We observed four distinct periods of overall prevalence of tobacco consumption: an increase between 1980 and 1989 (MAC: +1.6%;  $p < 0.001$ ), followed by a stable period (1990-2001), a decrease between 2002 and 2008 (MAC: -1.4%;  $p = 0.003$ ), and a slower-paced decrease between 2009 and 2016 (MAC: -0.1%;  $p > 0.05$ ) (Table 2 and Figure 1).

In 1980, smoking prevalence was 14.3% (95%CI: 11.9-17.0), its lowest value, it reached its highest point at 31.9% (95%CI: 28.2-35.8) in 2001, and ended the study period in 2016 at a prevalence of 20.4% (95%CI: 15.9-25.8) (Table 2).

Table 2 and Figure 1 show the evolution by age group. Consumption in women aged 30 or older presented four distinct periods (not quite matching those for the overall consumption described earlier): an increase between 1980 and 1989 (MAC: +2.3%;  $p<0.001$ ), a plateau between 1990 and 2000, a drop between 2001 and 2007 (MAC: -1.7%;  $p<0.001$ ), and a small non-significant increase after 2008. Smoking rates in women younger than 30 presented only two periods: an increase between 1980 and 1989 (MAC: +1.5%;  $p<0.001$ ) followed by a reduction between 1990 and 2016 (MAC: -0.4%;  $p<0.001$ ).

Next, we studied changes in maternal smoking by education. In women with low educational level we observed four different periods: an increase between 1980 and 1988 (MAC: +1.7%;  $p<0.001$ ) followed by three periods with no significant mean annual changes. Tobacco consumption among women with intermediate educational level experienced two marked periods: a stable period between 1980 and 1996 with no statistically significant MAC and a substantial decrease in consumption starting in 1997 until 2016 (MAC: -0.8%;  $p<0.001$ ). Finally, consumption prevalence among highly educated mothers experienced a continuous decrease throughout the entire study period with no points of inflexion (MAC: -0.8%;  $p<0.001$ ).

By the end of the study period (2016), the smoking prevalence was 33.0% (95%CI: 21.5-46.8) for women with low educational level, 21.2% (95%CI: 15.4-28.4) for the intermediate level mothers, and 14.4% (95%CI: 9.7-20.7) for women with high educational attainment (Table 2 and Figure 1).

Table 3 shows the association between tobacco consumption, socio-demographic characteristics and alcohol intake. First, we present results for the entire study period and then stratified results by two study periods (1987-1996 and 2007-2016; the decades on each extreme) to assess changes in the observed associations. Looking at the entire period, women aged  $\geq 30$  reported lower smoking prevalence compared to the younger group (OR=0.72; 95%CI: 0.67-0.77). Likewise, women with higher educational achievement were less likely to have smoked than those with low educational levels (OR=0.59; 95%CI: 0.53-0.66). The same was found for women whose pregnancy was planned versus unplanned (OR: 0.68; 95%CI: 0.64-0.73) and those who reported alcohol consumption were more likely to have smoked during pregnancy (OR: 1.65; 95%CI: 1.48-1.84). No association between smoking prevalence and parity was found.

Also, no significant differences were found in either time periods regarding age and maternal alcohol consumption. In contrast, we did identify changes in the magnitude of the association as the following statistically significant interactions show: country of birth ( $p < 0.001$ ): OR=3.58 in 2007-2016 versus 1.11 in 1987-1996 in Spanish natives; schooling ( $p < 0.001$ ): OR=0.33 in 2007-2016 versus 0.97 in 1987-1996 between highest and lowest educational level; parity ( $p = 0.04$ ), although the OR did not vary substantially; and planned pregnancy ( $p = 0.003$ ): OR=0.56 versus 0.72 in the last and first period, respectively.

## **DISCUSSION**

### **Main finding of this study**

Our data captured important changes in the evolution of maternal smoking prevalence in Spain between 1980 and 2016. Starting with moderate prevalence, one in every 7 pregnant women smoked in 1980, tobacco consumption increased rapidly during the 80s only to

plateau during the 90s and start a decrease in the 2000s. However, prevalence in 2016, when 1 in 5 expectant mothers smoked, was still higher than the 1980 starting point.

Another aspect worth pointing out is that maternal smoking prevalence evolved inversely with regards to educational achievement. At the study's onset, mothers with high educational levels exhibited the highest smoking prevalence; however, towards the end, smoking was more prevalent among mothers with low educational level, exacerbating smoking-related health disparities. Other factors related to higher smoking rates were younger maternal age, being a native-born, unplanned pregnancy, and alcohol consumption.

### **What is already known on this topic**

Smoking patterns for expectant mothers and the general population of other countries vary. For instance, Denmark saw parallel decreasing trends between 1991 and 2010 for both maternal smoking and general female population, while Sweden experienced a steeper reduction in consumption among mothers-to-be than the general population.<sup>5</sup> Australia reported a similar pattern between 1994 and 2007.<sup>6</sup> In contrast, Finland's population cut back on smoking while consumption during pregnancy stayed the same during 1987-2010 period.<sup>5</sup> Norway's maternal smoking rate underwent a temporal decrease, similar to that of the general population only to change direction and experience an increase in prevalence putting the trend on a convergence path with the general population smoking rates.<sup>5</sup> Between 2000 and 2010, the U.S. saw a small decrease in maternal smoking rates, from 13.3% to 12.3%, in the context of a more substantial reduction in the general female population.<sup>7</sup> Canada experienced a very similar phenomenon between 1995 and 2010.<sup>8</sup> The variability observed among countries most likely reflects differences in design, implementation, and adherence to preventative

policies and smoking cessation targeting the general population as well as pregnant women.

Ample previous work on maternal smoking reports associations with a considerable number of sociodemographic factors. Among these, maternal age has been one of the predictors most delved into. Our findings support what has been consistently observed,<sup>5,7,8,12-18</sup> i.e., that younger age is associated with a higher likelihood of maternal smoking. However, research from Canada<sup>14</sup> reported that prevalence increased with age and research from Brazil<sup>19</sup> concluded that age failed to play a role, suggest otherwise.

### **What this study adds**

In Spain, compared to the general population, maternal smoking trends have followed a similar path (figure 1S in supplementary material), though the two patterns have started to converge in recent years. As the smoking epidemic developed in Spain, the prevalence of female smokers increased rapidly during the 70s and 80s, plateauing in the 90s at the high of 30-35% among childbearing age women. This rate distribution supports the theoretical model portraying the smoking epidemic,<sup>20</sup> though Spain experienced a time lag compared to surrounding countries.<sup>4</sup>

In addition to this cross-sectional association, consumption trends between 1980 and 2016 reported here reveal a non-homogeneous pattern: the group of youngest mothers-to-be start with far higher prevalence rates which start to drop earlier and faster than those of women  $\geq 30$  years of age, with no substantial differences in the prevalence in recent years. The opposite pattern was observed in Canada in 1995-2010 where smoking rates dropped among pregnant women  $\geq 25$  years of age but slightly increased among younger ones.<sup>8</sup>

Another well-studied predictor is socioeconomic level, usually defined by educational level or occupation. Consistently, lower socioeconomic stratum women are at higher risk of maternal smoking.<sup>7,14–17,19,21–25</sup> Further, as seen in our study, authors have also reported an increase in inequity across time as the differences in prevalence between the lowest and highest status levels have continued to grow. For instance, studies by Brown and colleagues in Canada,<sup>8</sup> Ekblad et al.,<sup>5</sup> Moussa et al.,<sup>23</sup> and Grotvedt et al.<sup>18</sup> in Northern European countries, Moshin et al. in Australia<sup>6</sup>, and Silveira et al. in Brazil<sup>26</sup> have consistently reported that consumption trends decrease more in women in higher socioeconomic positions; hereby increasing related health disparities. In Spain, the reverse relationship between smoking prevalence and educational level has also been observed in the general female population. Higher educated women born between 1940 and 1980 had the higher smoking rates, in contrast, the relationship reverses for women born after 1980, i.e., the lower the educational level, the higher the smoking rates.<sup>27</sup>

Despite not receiving as much research attention, country of birth is also a relevant factor to identify high risk groups. Our study revealed higher probability of smoking among Spain-born than foreign-born expectant mothers, supporting previous work from Australia,<sup>28</sup> Canada,<sup>14</sup> Germany,<sup>16</sup> and Norway.<sup>18</sup> A study in Sweden concluded that among immigrant pregnant women, the longer they had resided in the country, the more higher their smoking rates until reaching Sweden-born expectant mothers. This presents a worrisome undesirable contribution of cultural assimilation to health disparities.<sup>29</sup>

In our results we also observed an association between parity and maternal smoking, though it varied by time period. Between 1987 and 1996, mothers with already at least one child were at a lower risk of maternal smoking than nulliparae women. However, this difference in risk vanished for the more recent past (2007-2016). Past work also shows debatable results, some authors reported higher risk of smoking among multiparae

women,<sup>14,16,30,31</sup> whereas others found higher risk among nulliparae<sup>5</sup> or no association at all.<sup>25</sup>

Recent research also links unplanned pregnancies with higher likelihood of maternal smoking.<sup>19,32</sup> This is highly relevant given that use of healthcare services for prenatal care is already lower among women whose pregnancies were not planned,<sup>33</sup> making detection and control of maternal tobacco consumption more challenging.

Speaking of toxic substances, alcohol consumption has also been linked to higher likelihood of maternal smoking.<sup>34-36</sup> In addition, consumption of alcohol or any other harmful substances during pregnancy has been associated to poor self-care and limited knowledge on the harmful effects of tobacco during pregnancy.<sup>37</sup> Thus, it is likely that any substance use could be found in a subgroup of expectant mothers already vulnerable to begin with.

### **Limitations of this study**

First, it is important to point out that its cross-sectional design precludes drawing causal associations. Second, the sample is not random and, thus, may not represent pregnant women in Spain. However, the socio-demographic characteristics of our sample are very similar to the population of pregnant women according to census data (Table 2S in supplementary material). Further, because of the large size of the sample and the fact that all the Spanish regions were represented, the estimates of smoking prevalence among expectant mothers derived from our sample are highly likely to closely reflect those of a truly representative sample.

Third, tobacco consumption self-reported data are a limitation which could underestimate prevalence, as seen when compared to objective tests such as cotinine levels in blood, urine, or saliva.<sup>38</sup> However, self-reported smoking data has shown satisfactory validity

and reliability levels and offers a simple, non-invasive, and affordable method of measuring tobacco consumption at the population level.<sup>39,40</sup> Finally, we observed a decreasing trend in the number of participants as years of study went by. This is likely related to the decreasing number of pregnancies in the population overall during the study period and to the increasing number of voluntary interruptions of pregnancies for different reasons including fetal congenital malformations, the detection of which substantially improved during the decades-long study period.

Among the strengths of the study we would like to mention that, as far as we are aware of, this is the longest series examining smoking among expectant mothers worldwide. Importantly, the continuance of a specific standard methodology regarding data collection guarantees the comparability of the data along over three decades and allows for analyses using standard criteria

## **CONCLUSIONS**

The evolution of tobacco consumption during pregnancy in Spain over the last 35 years, describes a rapid increase during the 80s, plateauing during the 90s, and a decrease during the 2000s. This pattern has been less favorable among low-education women, which worsens health disparities. In addition to low education, young maternal age, being Spain-born, unplanned pregnancies and the concurrent consumption of alcohol were also associated to higher smoking prevalence. Identifying high risk groups should inform prevention and cessation interventions during pregnancy targeted to the more vulnerable groups of future mothers identified in this study.

## **Conflict of interest**

None declared.

This article presents independent research. The views expressed are those of the authors and not necessarily those of the Institute of Health Carlos III.

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**Table 1. Distribution of socio-demographic variables and alcohol consumption in pregnant women in Spain, periods 1987-1996, 1997-2006, and 2007-2016**

	<b>1987-1996</b> (n=28,088)	<b>1997-2006</b> (n=11,625)	<b>2007-2016</b> (n=6,387)
	<b>%</b>	<b>%</b>	<b>%</b>
<b>Maternal age</b>			
< 30 years	62.6	42.8	35.8
≥ 30 years	37.4	57.2	64.2
<b>Country of birth</b>			
Foreign-born	2.4	8.9	18.6
Spain-born	97.6	91.1	81.4
<b>Educational level</b>			
No school/Primary	64.9	46.7	28.5
Secondary/High School	23.6	33.1	40.9
University studies	11.5	20.2	30.7
<b>Parity</b>			
First pregnancy	43.6	45.1	45.3
Second or higher pregnancy	56.4	54.9	54.7
<b>Planned pregnancy</b>			
No	29.7	21.2	18.7
Yes	70.3	78.8	81.3
<b>Alcohol consumption</b>			
No	86.7	90.7	93.7
Yes	13.3	9.3	6.3

**Table 2. Evolution of tobacco consumption in pregnant women in Spain, overall, by age groups, and educational level, 1980-2016**

	Time Period	Year	Prevalence		MAC (%)	p-value
			%	95%CI		
Overall						
	Period 1	1980	14.3	11.9 – 17.0	1.6	< 0.001
		1989	31.3	28.3 - 34.5		
	Period 2	1990	31.3	28.2 - 34.6	-0.1	NS
		2001	31.9	28.2 - 35.8		
	Period 3	2002	27.7	24.8 - 30.8	-1.4	0.003
		2008	19.2	16.6 - 22.2		
	Period 4	2009	20.8	17.6 - 24.5	-0.1	NS
		2016	20.4	15.9 - 25.8		
Maternal age						
< 30 years	Period 1	1980	19.4	16.2 - 23.0	1.5	< 0.001
		1989	34.4	31.1 - 38.0		
	Period 2	1990	33.5	29.9 - 37.4	-0.4	< 0.001
		2016	28.7	22.1 - 36.3		
≥ 30 years	Period 1	1980	3.1	2.0 - 4.7	2.3	< 0.001
		1989	25.5	21.5 - 29.9		
	Period 2	1990	27.0	22.2 - 32.5	0.2	NS
		2000	28.0	24.6 - 31.7		
	Period 3	2001	29.4	24.8 - 34.4	-1.7	< 0.001
		2007	19.0	15.2 - 23.5		
	Period 4	2008	15.1	12.1 - 18.6	0.3	NS
		2016	17.6	12.8 - 23.8		
Educational level						
No school/ Primary	Period 1	1980	12.7	10.3 – 15.7	1.7	< 0.001
		1988	28.2	23.6 – 33.2		
	Period 2	1989	31.9	28.5 – 35.6	0.2	NS
		2000	34.4	30.2 – 38.9		
	Period 3	2001	34.6	29.1 – 40.5	-1.1	0.054
		2008	22.5	17.4 – 28.6		
	Period 4	2009	22.5	17.6 – 28.5	0.9	NS
		2016	33.0	21.5 – 46.8		
Secondary/High School graduate	Period 1	1980	31.4	20.0 – 45.6	-0.0	NS
		1996	33.7	27.9 – 40.0		
	Period 2	1997	33.4	29.1 – 38.0	-0.8	< 0.001
		2016	21.2	15.4 – 28.4		
University studies	Period 1	1980	23.5	12.4 – 40.8	-0.8	< 0.001
		2016	14.4	9.7 - 20.7		

CI: Confidence interval

MAC\*: Mean Annual Change Percentage in absolute values, estimated using *joinpoint regression*.

Year: First and last year of each period

NS: Not significant.

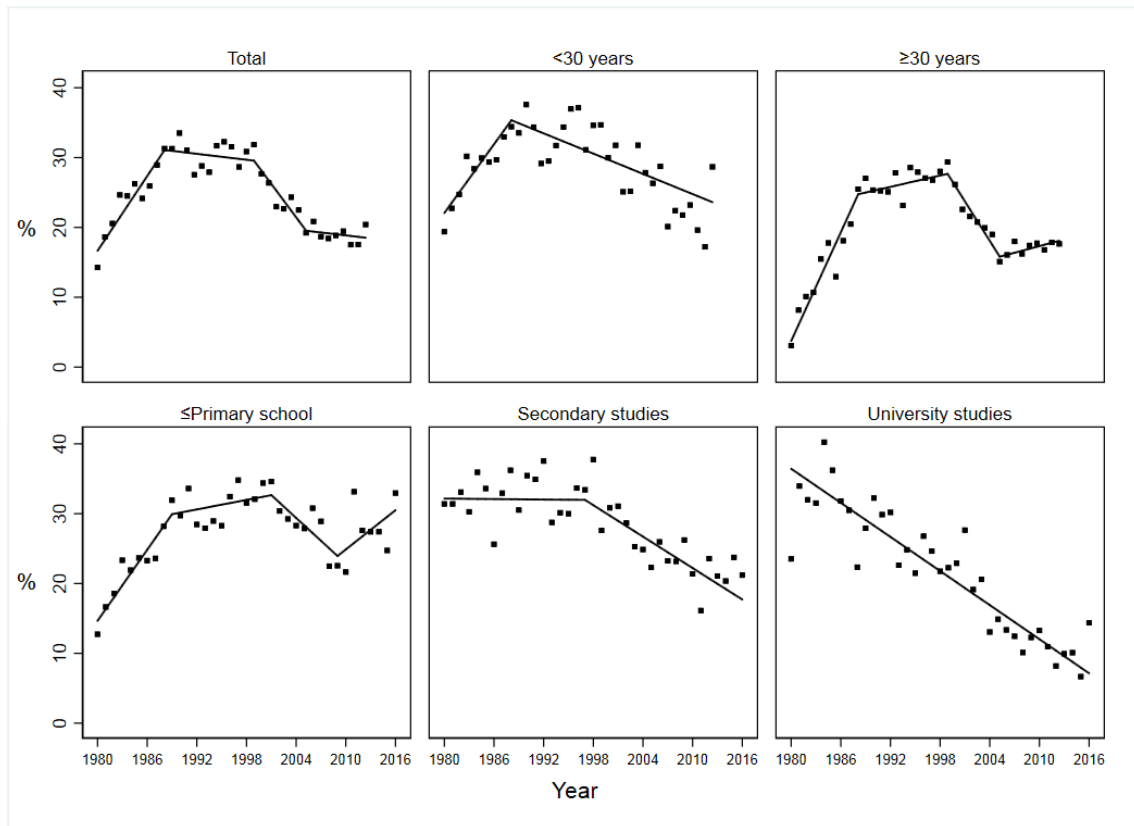
**Table 3. Characteristics of expectant mothers associated with tobacco consumption during pregnancy in Spain, periods 1987-1996, 1997-2006, and 2007-2016**

Maternal characteristics	Period		
	1987-2016 (n=28,088)	1987-1996 (n=11,625)	2007-2016 (n=6,387)
	aOR (95%CI)	aOR (95%CI)	aOR (95%CI)
<b>Maternal age</b>			
< 30 years	1 (ref)	1(ref)	1(ref)
≥ 30 years	0.72 (0.67-0.77)	0.70 (0.63-0.78)	0.72 (0.59-0.86)
<b>Country of birth</b>			
Foreign-born	1 (ref)	1 (ref)	1 (ref)
Spain-born	2.41 (1.93-3.01)	1.11 (0.82-1.50)	3.58 (2.65-4.85)
<b>Educational level</b>			
No school/Primary	1 (ref)	1 (ref)	1 (ref)
Secondary/High School	1.00 (0.91-1.10)	1.21 (1.08-1.35)	0.78 (0.66-0.92)
University studies	0.59 (0.53-0.66)	0.97 (0.81-1.16)	0.33 (0.27-0.40)
<b>Parity</b>			
First pregnancy	1(ref)	1(ref)	1(ref)
Second or higher pregnancy	1.01 (0.94-1.08)	0.89 (0.80-0.98)	1.11(0.88-1.40)
<b>Planned pregnancy</b>			
No	1(ref)	1(ref)	1(ref)
Yes	0.68 (0.64-0.73)	0.72 (0.65-0.80)	0.56 (0.48-0.66)
<b>Alcohol consumption</b>			
No	1(ref)	1(ref)	1(ref)
Yes	1.65 (1.48-1.84)	1.49 (1.29-1.71)	2.06 (1.56-2.71)

**aOR:** Odds ratios for tobacco consumption during pregnancy estimated using logistic regression adjusted simultaneously for all the variables in the table.

**CI:** Confidence interval

**Figure 1. Evolution of the prevalence of maternal smoking, overall and by age group and educational level, 1980-2016**



**Table 1S (supplementary material). Prevalence of maternal smoking, 1980-2016**

Year	Sample size	Maternal smoking	
	n	%	95%CI
1980	1240	14.3	11.9-17.0
1981	1277	18.6	15.5-22.3
1982	1434	20.6	16.5-25.3
1983	1622	24.7	22.0-27.6
1984	1534	24.5	21.4-28.0
1985	1437	26.2	22.5-30.3
1986	1217	24.2	20.3-28.5
1987	1006	25.9	22.2-30.1
1988	1040	28.9	25.4-32.7
1989	1176	31.3	28.3-34.5
1990	1461	31.3	28.2-34.6
1991	1492	33.5	30.1-37.1
1992	1417	31.1	27.2-35.2
1993	1245	27.6	24.6-30.7
1994	1194	28.8	25.7-32.2
1995	1182	27.9	24.6-31.5
1996	1123	31.7	27.9-35.8
1997	1255	32.3	28.7-36.0
1998	1138	31.5	28.0-35.3
1999	1221	28.7	25.6-31.9
2000	1144	30.9	28.1-33.8
2001	1086	31.9	28.2-35.8
2002	1102	27.7	24.8-30.8
2003	1016	26.4	23.6-29.3
2004	1153	23.0	20.1-26.2
2005	1103	22.7	20.0-25.6
2006	1085	24.3	20.8-28.2
2007	1071	22.5	19.1-26.4
2008	962	19.2	16.6-22.2
2009	873	20.8	17.6-24.5
2010	835	18.7	14.9-23.1
2011	787	18.4	14.5-23.1
2012	764	18.8	13.5-25.8
2013	663	19.5	15.7-23.9
2014	582	17.5	13.2-22.9
2015	507	17.6	13.4-22.7
2016	490	20.4	15.9-25.8

CI: Confidence interval

**Table 2S (supplementary material). Comparison of the characteristics of the study's sample expectant mothers and mothers from the general population (birth registry) (National Statistics Institute (NSI), years 1980, 1997, and 2016)**

	1980		1997		2016	
	NSI	ECEMC	NSI	ECEMC	NSI	ECEMC
	%	%	%	%	%	%
<b>Maternal age</b>						
≤19	7.1	5.8	3.1	2.5	2.0	1.8
20-24	29.1	30.6	11.0	12.7	7.0	6.7
25-29	32.2	32.0	31.9	32.9	17.7	18.0
30-34	19.7	17.6	38.1	35.5	34.6	37.4
35-39	8.9	10.6	14.0	14.8	30.3	28.9
≥40	3.0	3.3	2.0	1.6	8.4	7.1
<b>Working status*</b>						
Homemaker	20.9	22.5	45.7	49.4	25.0	32.4
Works outside the home	79.1	77.5	54.3	50.6	75.0	67.6
<b>Country of birth</b>						
Spain-born	NA	99.3	96.2	94.2	76.3	83.9
Foreign-born	NA	0.7	3.8	5.8	23.7	16.1
<b>Low birth weight**</b>						
No	96.5	95.7	93.7	93.9	91.8	94.6
Yes	3.5	4.3	6.3	6.1	8.2	5.4

**NSI:** National Statistics Institute. Birth registry data

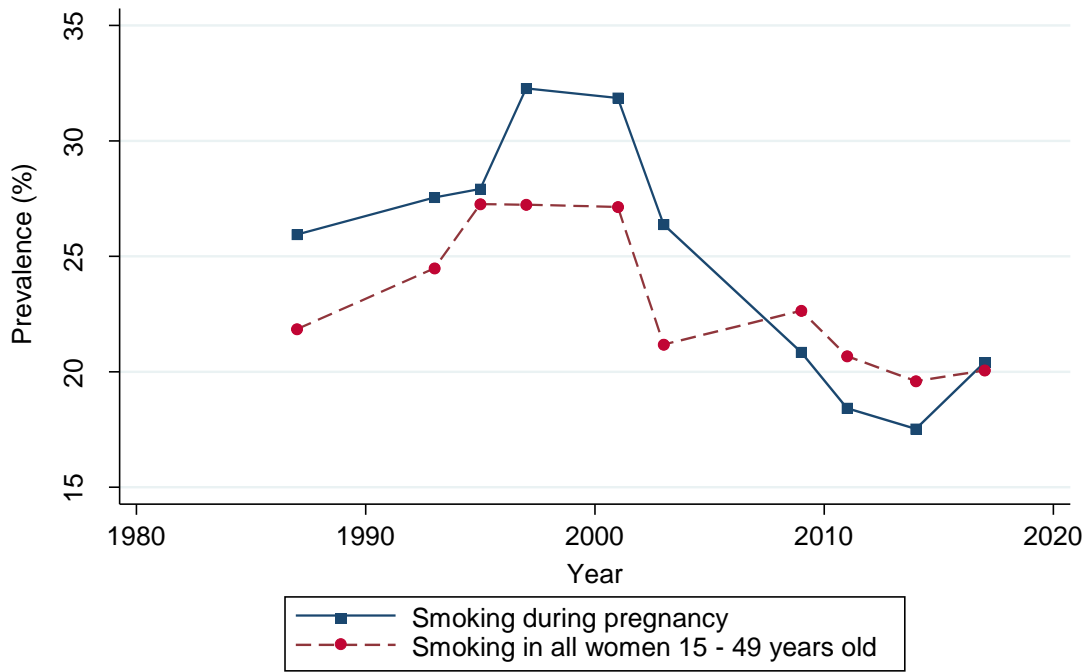
**ECEMC:** Spanish Collaborative Study of Congenital Malformations

**NA:** Not Available

**Working status\*:** During pregnancy

**Low birth weight\*\*:** Newborn <2.500 Kg

**Figure 1S (supplementary material). Comparison of the evolution of prevalence of maternal smoking\* versus smoking rates in childbearing-age women in the general population (15-49 years old)\*\*.**



\* ECEMC: Spanish Collaborative Study of Congenital Malformations

\*\* Spanish National Health Survey and European Health Survey for Spain