Smoke-Free Legislation in Spain and Prematurity

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abstract

BACKGROUND AND OBJECTIVE: Spain implemented a partial smoking ban in 2006 followed by a comprehensive ban in 2011. The objective was to examine the association between these smoke-free policies and different perinatal complications.

METHODS: Cross-sectional study including all live births between 2000 and 2013. Selected adverse birth outcomes were: preterm births (<37 gestational weeks), small for gestational age (SGA; <10th weight percentile according to Spanish reference tables), and low birth weight (<2500 g). We estimated immediate and gradual rate changes after smoking bans by using overdispersed Poisson models with different linear trends for 2000 to 2005 (preban), 2006 to 2010 (partial ban), and 2011 to 2013 (comprehensive ban). Models were adjusted for maternal sociodemographics, health care during the delivery, and smoking prevalence during pregnancy.

RESULTS: The comprehensive ban was associated with preterm birth rate reductions of 4.5% (95% confidence interval [CI]: 2.9%–6.1%) and 4.1% (95% CI: 2.5%–5.6%) immediately and 1 year after implementation, respectively. The low birth weight rate also dropped immediately (2.3%; 95% CI: 0.7%–3.8%) and 1 year after the comprehensive ban implementation (3.5%; 95% CI: 2.1%–5.0%). There was an immediate reduction in the SGA rate at the onset of the partial ban (4.9%; 95% CI: 3.5%–6.2%), which was sustained 1 year postimplementation. Although not associated with the comprehensive ban at the onset, the SGA rate declined by 1.7% (95% CI: 0.3%–3.1%) 1 year postimplementation.

CONCLUSIONS: The implementation of the Spanish smoke-free policies was associated with a risk reduction for preterm births and low birth weight infants, especially with the introduction of the more restrictive ban.

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WHAT'S KNOWN ON THIS SUBJECT: Secondhand smoke exposure during pregnancy is associated with health complications affecting perinatal and neonatal outcomes. However, previous studies fail to provide uniform evidence on the impact of smoke-free policies on low birth weight and prematurity. Additional research is needed.

WHAT THIS STUDY ADDS: The implementation of 2 Spanish smoking bans (partial and comprehensive) was associated with a risk reduction for preterm births and low birth weight infants. This health benefit was especially evident with the introduction of the more restrictive ban.

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Worldwide, secondhand smoke (SHS) is responsible for close to 600 000 annual deaths. The young are particularly affected because the greatest SHS prevalence and SHS-related disease burden are found in children <5 years of age.[1] Solid evidence supports the fact that SHS exposure during pregnancy is associated with a diverse array of complications during gestation as well as in the perinatal and neonatal periods. Specifically, there is a high risk for preterm, low birth weight, small for gestational age (SGA) infants, as well as for sudden infant death syndrome.[2,3]

In Spain, the prevalence of fetal SHS exposure is high. It is estimated that between 2004 and 2008, 1 in every 2 nonsmoking women was exposed to SHS during the third trimester of her pregnancy,[4] and 1 in 5 pregnant women smoked during pregnancy in 2013.[5]

Smoking bans designed to protect nonsmokers from involuntary SHS exposure is one of the main initiatives for tobacco control. Many countries, in compliance with the 2003 World Health Organization Framework Convention on Tobacco Control,[6] have implemented laws regulating tobacco consumption in public places. The Spanish law on health measures against smoking took effect on January 1, 2006,[7] and banned smoking in the workplace except in the hospitality sector, where a partial ban was implemented. The law substantially reduced SHS exposure in the workplace, but had little impact on reducing this environmental risk in hospitality establishments.[8,9] To additionally reduce SHS exposure, a reform of the original law[10] took effect on January 2, 2011. This reform banned tobacco consumption in almost the totality of public places, a measure that was vastly successful in reducing SHS exposure in bars and restaurants (>90% reduction in vapor-phase nicotine and particulate matter ≤2.5 μm in diameter in hospitality venues).[11]

Several studies have evaluated the impact of smoke-free policies on perinatal complications, such as low birth weight and prematurity.[12] Published studies to date have failed to provide uniform evidence on the impact of smoke-free policies on low birth weight and prematurity,[12] with some articles reporting favorable results,[13–16] others reporting no change,[17–19] and others reaching different conclusions depending on the health indicator examined.[20–24]

Spain is one of a few countries with 2-stage smoking ban legislation, high compliance, and a 5-year gap between a less restrictive to a complete ban. The main objective of this study was to examine whether the 2 Spanish smoking bans put in place to reduce SHS exposure were associated with reductions in the rates of preterm, low birth weight, and SGA births.

METHODS

Study Design and Participants

In this population-based study, we analyzed cross-sectional data from the Spanish Birth Registry (Spanish National Statistics Institute) from January 2000 to December 2013. Data from 5 293 700 records included clinical information on all live births occurring between week 22 and week 44 of gestation in Spain. SGA analyses included only infants born in the period between 26 and 42 weeks of pregnancy because weight reference tables to define this indicator are based on that gestational time.

Variables

Outcome variables included preterm birth (<37 weeks' gestational age), low birth weight (<2500 g), and SGA births (<10th weight percentile according to Carrascosa et al[25]). Based on the existing literature, we included those relevant covariates available in the database. These included the mother's age grouped in 5-year intervals and socioeconomic status based on the mother's and father's occupation, separately. Occupational status was categorized as follows: groups I and II (managerial positions, technical staff, and professionals), group III (administrative staff), and groups IV and V (manual workers). We also adjusted for: birth location (health center, private home, or another location), health professional–assisted birth or not, singleton or multiple birth, and the region where the mother resided. Preliminary analyses showed that these variables were significantly related to the outcomes under study (statistically significant *P* value), and they could vary between the time periods: preban (2000–2005), partial ban (2006–2010), and full ban (2011–2013). Finally, we included the annual prevalence of tobacco consumption during pregnancy using information from controls participating in the Spanish Collaborative Study on Congenital Malformations by the Research Center for Birth Defects.[5,26]

Statistical Analyses

Poisson models allowing for overdispersion were used to assess rate changes in the 3 adverse birth outcomes over time. The segmented models allowed for different log-linear rate trends during the 2000–2005 preban period, the 2006–2010 partial ban period, and the 2011–2013 comprehensive ban period, while adjusting for maternal sociodemographics, health care during the delivery, and smoking prevalence during pregnancy. From these models, we estimated the percent changes in perinatal complication rates at the partial ban's implementation and 1 year after by comparing the estimated rates at these time points with the

TABLE 1 Sociodemographic and Health Care Characteristics of Preterm, SGA, and Low Birth Weight Births in Spain, 2000 to 2013

Variables	Preterm[a]		SGA[b]		Low Birth Weight[a]	
	No *N* = 4 885 779	Yes *N* = 416 595	No *N* = 4 804 257	Yes *N* = 489 443	No *N* = 4 887 658	Yes *N* = 414 716
Mother's age, mean, y (SD)	31.1 (5.2)	31.5 (5.6)	31.1 (5.2)	31.0 (5.4)	31.1 (5.2)	31.6 (5.5)
Mother's occupation, %						
Groups[c] I–II	22.1	20.8	22.2	19.7	22.0	21.0
Group III	17.9	17.3	17.9	17.5	17.9	18.0
Groups IV–V	24.8	25.0	24.7	26.5	24.8	25.7
Other	35.2	36.9	35.2	36.3	35.4	35.3
Father's occupation, %						
Groups[c] I–II	23.8	22.7	24.0	21.0	23.8	22.7
Group III	8.2	8.0	8.2	7.7	8.2	8.0
Groups IV–V	53.2	53.4	53.0	55.4	53.2	53.5
Other	14.8	15.9	14.8	15.8	14.9	15.8
Place of delivery, %						
Health care center	99.6	99.6	99.6	99.6	99.6	99.7
Other than a health care center	0.4	0.4	0.4	0.4	0.4	0.3
Health professional–assisted birth, %						
Yes	100.0	99.9	99.9	99.9	100.0	99.9
No	0.0	0.1	0.1	0.1	0.0	0.1
Multiple birth, %						
Singleton	98.0	74.0	97.0	87.7	98.4	69.8
Multiple	2.0	26.0	3.0	12.3	1.6	30.2
Time period, %						
2000–2005	42.1	41.8	42.0	43.0	42.3	39.9
2006–2010	37.3	38.3	37.4	36.8	37.3	38.6
2011–2013	20.6	19.9	20.6	20.2	20.4	21.5

[a] Births at 22–44 weeks' gestation.
[b] Births at 26–42 weeks' gestation.
[c] Groups I to V, from higher to lower qualification.

projected rates from the preban period.[27] Similarly, the percent rate changes at the comprehensive ban's implementation and 1 year after were calculated by relating the estimated rates at these time points to the projected rates from the previous partial ban period.

Sensitivity analyses were performed. To determine the robustness of the models, we reran the models varying the specifications and compared the association estimates. First, we excluded multiple births. Second, we evaluated the association estimates by building 3-, 6-, and 9-month lags between birth and the bans' implementation into the model.

Additional analyses were performed to estimate the differences in coefficients by the sex of the newborn, whether the mother worked outside the home, and the parent's socioeconomic position based on occupation, evaluating the statistical significance of the interaction. We performed analyses with Stata version 14 (Stata Corp, College Station, TX) and R version R3.3.1 (R Foundation).

RESULTS

Table 1 shows participants' sociodemographic characteristics and health care services. The average age of the mothers was 31 years, and although occupations varied, the most common reported occupation was "other," which captured those who have not held a paying job before. The most common occupation of fathers was manual labor. The vast majority of births were singleton, took place in health care centers, and were assisted by health professionals.

In the 2000–2013 time period, the preterm birth rate was 7.9%, 9.2% of births were SGA births, and 7.8% of newborns had low birth weight (Table 1). Figure 1 presents how the 3 outcomes under study evolved throughout time, displaying the annual gross rates and the segmented linear trends for 2000 to 2005 (preban), 2006 to 2010 (partial ban), and 2011 to 2013 (comprehensive ban). The corresponding changes in rate ratios (crude rates) are summarized in Table 2. SGA birth is the variable with the greatest stability over time, with a slight decreasing trend. In contrast, the rate for low birth weight increased during the preban period only to remain constant for the last 4 years of the study. The trend for preterm births also increased until peaking in 2007 to 2009 and decreased moderately thereafter.

Table 2 shows the changes in perinatal complications over the 3 periods under study: preban, partial ban, and comprehensive ban. The comprehensive ban was associated with an immediate reduction (percent change of adjusted rates) in the preterm birth rate of

−4.5% (95% confidence interval [CI]: −6.1% to −2.9%), and this reduction was sustained 1 year after implementation (−4.1%; 95% CI: −5.6% to −2.5%). Similarly, there was an immediate reduction in the rate of low birth weight infants (−2.3%; 95% CI: −3.8% to −0.7%) with the implementation of the comprehensive ban, and the rate decreased slightly more 1 year after implementation (−3.5%; 95% CI: −5.0% to −2.1%).

Finally, the implementation of the partial ban was associated with an immediate reduction in the SGA birth rate (−4.9%, 95% CI: −6.2% to −3.5%). The rate continued dropping throughout the first year, but at a more modest pace (−4.2%, 95% CI: −5.7% to −2.7%). Although we did not observe changes in the SGA birth rate at the onset of the 2011 comprehensive ban, the rate fell by −1.7% (95% CI: −3.1% to −0.3%) 1 year later.

The results from the sensitivity analyses were similar to those from the general models after excluding multiple births from the analysis. Estimate changes were not observed either when models included the 3-, 6-, and 9-month lags between delivery and implementation of the ban.

The associations described above were not modified by the newborn's sex, having a mother working outside the home or not, or parental socioeconomic position based on occupation. The tested interactions failed to reach statistical significance.

DISCUSSION

The onset of the partial ban was associated with a reduction in the SGA rate, and the reduction was maintained throughout the first year after the ban was put in place. The expansion of this law into a comprehensive ban was associated with an immediate reduction in the

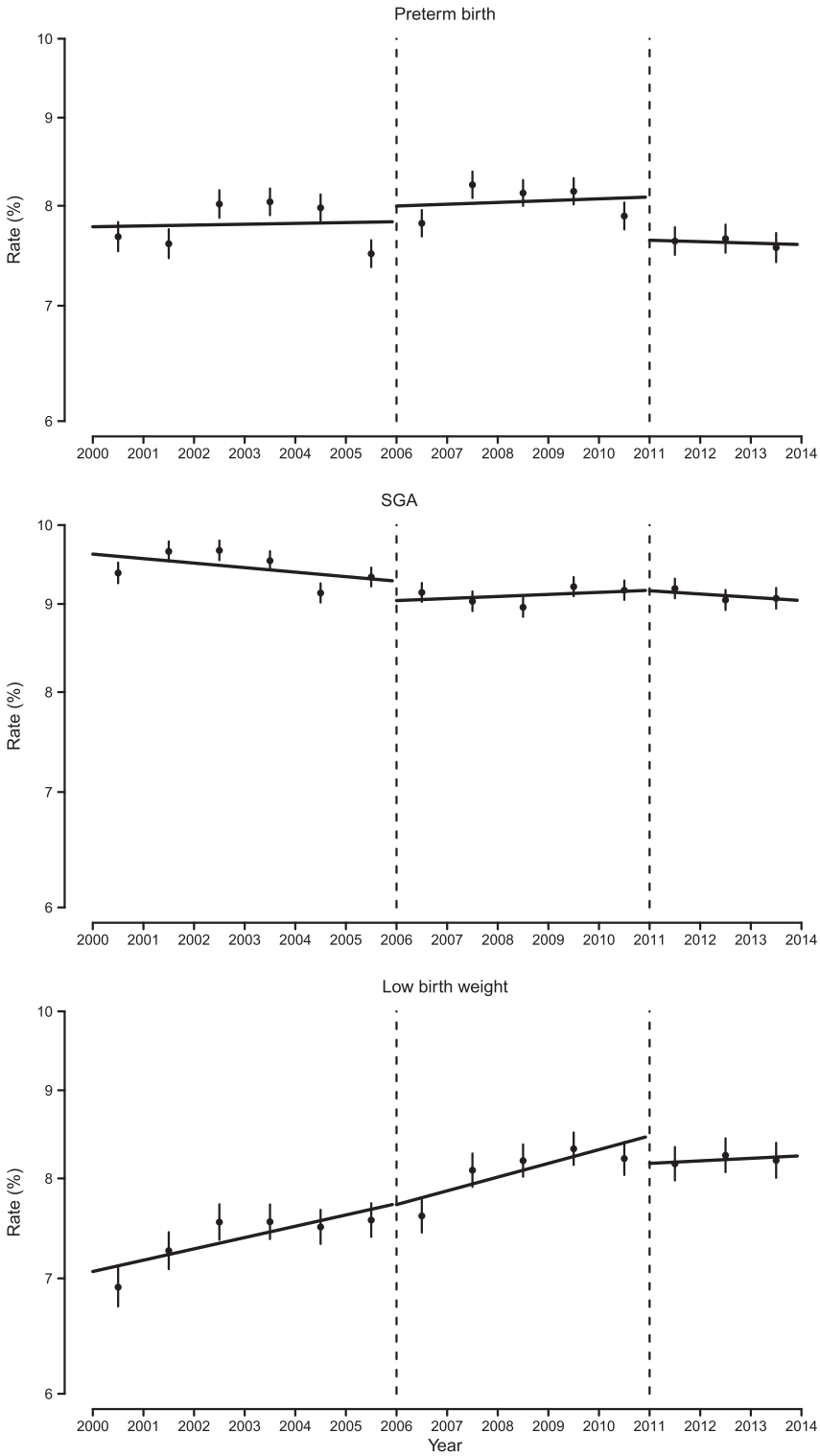

FIGURE 1
Gross rates and time-segmented linear trend for 3 perinatal complications: preterm birth, SGA newborn, and low birth weight newborn in Spain, 2000 to 2013. Annual gross rates for each year (the dots represent the point estimates and the vertical lines represent the 95% CIs). The 3 lines display the segmented linear trends within the 2003–2005 preban, 2006–2010 partial ban, and 2011–2012 comprehensive ban periods with no adjusted variables. Vertical dashed lines represent the dates at which the partial and comprehensive smoking bans came into force on January 1, 2006 and January 2, 2011, respectively.

TABLE 2 Percent Changes in Perinatal Complication Rates Immediately and 1 Year After the Implementation of the 2006 Partial Smoking Ban and the 2011 Comprehensive Smoking Ban in Public Places: Preterm, SGA, and Low Birth Weight Newborns

	2006 Partial Smoking Ban[a]		2011 Comprehensive Smoking Ban[b]	
	Percent Change: Immediate (95% CI)	Percent Change: 1 Year Later (95% CI)	Percent Change: Immediate (95% CI)	Percent Change:1 Year Later (95% CI)
Crude rates				
Preterm births	2.1 (−0.8 to 5.1)	2.2 (−0.7 to 5.2)	−5.6 (−8.9 to −2.1)	−6.0 (−8.9 to −2.9)
SGA newborns	−2.6 (−3.9 to −1.3)	−1.8 (−3.1 to −0.5)	0.0 (−1.6 to 1.7)	−0.7 (−2.2 to 0.8)
Low birth weight newborns	−0.2 (−2.4 to 2.1)	0.2 (−2.1 to 2.5)	−3.5 (−6.1 to −0.8)	−4.9 (−7.2 to −2.5)
Adjusted rates[c]				
Preterm births	4.6 (2.9–6.2)	5.5 (3.8 to 7.4)	−4.5 (−6.1 to −2.9)	−4.1 (−5.6 to −2.5)
SGA newborns	−4.9 (−6.2 to −3.5)	−4.2 (−5.7 to −2.7)	0.7 (−0.8 to 2.2)	−1.7 (−3.1 to −0.3)
Low birth weight newborns	0.6 (−1.0 to 2.1)	1.2 (−0.4 to 3.0)	−2.3 (−3.8 to −0.7)	−3.5 (−5.0 to −2.1)

Spain, 2000 to 2013. Results were obtained from overdispersed Poisson models with different log-linear rate trends within the 2000–2005 preban period, the 2006–2010 partial ban period, and the 2011–2013 comprehensive ban period.

[a] Percent changes in perinatal complication rates and 95% CIs at the time of implementation and 1 year postimplementation compared with the projected rates from the preban period.

[b] Percent changes in perinatal complication rates and 95% CIs at the time of implementation and 1 year postimplementation compared with the projected rates from the previous partial ban period.

[c] Adjusted for maternal age, socioeconomic status based on mother's and father's occupational status, mother's region of residence, place of delivery, health professional–assisted birth, multiple birth, and annual prevalence of tobacco consumption during pregnancy.

preterm and low birth weight rates, both of which sustained the reduction 1 year after implementation.

Despite the existing evidence on the harmful effects of tobacco consumption during pregnancy, as well as of the role of SHS exposure in pregnancy complications and perinatal health,[2,28–30] research on the impact of local and national smoking bans is scarce, and findings are inconsistent depending on the type of ban and the health indicators examined.[31] Half of the studies on smoking bans and prematurity report a reduction in births earlier than 37 gestational weeks once the ban is implemented,[15,16,22–24] and the other half fail to detect an association.[17–21]

Four studies detected a protective association between smoking bans and low birth weight,[13,15,16,21] however, 7 articles failed to find any benefits.[17–20,22–24] Finally, of the 5 studies that evaluated the effect of bans on SGA rates, most reported a protective effect[14–16] versus those that failed to provide evidence.[19,22] Overall, findings are highly inconsistent; however, studies based on proximate countries, with similar smoking regulations to Spain and high levels of compliance, as is the case in Ireland,[14,23] Scotland,[15] and England,[13] have also observed falling rates in perinatal complications.

The mechanisms through which smoke-free legislation works to improve perinatal health include maternal tobacco consumption, changes in SHS exposure, or both if the mother smokes. Only a few studies that evaluated the impact of smoking bans have differentiated between these mechanisms. In Norway, Bharadwaj et al[21] reported that most of the benefit stemmed from changes in maternal tobacco consumption, and only a reduced portion of the benefit came from changes in SHS exposure. However, MacKay et al,[15] in Scotland, reported improvements in prematurity and SGA indicators in mothers whether they smoked or not.

The fact that the associations between the 2 smoking bans and birth outcomes differed is worth elaborating on. Based on a meta-analysis on the effects of smoke-free regulations on cardiovascular and respiratory diseases, Tan and Glantz[32] reported a dose-response relationship where benefits increased as regulations grew more restrictive. Few countries have introduced smoke-free legislation in stages from a less restrictive to a broader legislation, from only affecting the workplace to designating bars, restaurants, and other public places as a "smoke-free space." Amaral[20] in California and Cox et al[22] in Flanders, Belgium, reported conflicting results. The former study links a decrease in newborns' average birth weight with the less restrictive ban, whereas the latter study associates a reduction in preterm birth rates with the gradual increase in public spaces that are designated "smoke-free".

In our study, we observed a stronger beneficial association between the comprehensive smoking ban and preterm and low birth weight birth rates, but not SGA rates; however, we found a beneficial association between the preceding partial ban and SGA rates. Future studies should explore these findings further.

It is also noteworthy that the association between smoking bans and perinatal outcomes did not vary by maternal socioeconomic position given that these types of complications are more prevalent in mothers from low socioeconomic groups.[33,34] Similarly, SHS exposure in adults tends to be higher among the lowest educational level or socioeconomic groups.[35] These findings imply a broadening of existing socioeconomic disparities regarding a wide variety of health

outcomes. Nonetheless, our results are consistent with those reported by McKinnon et al[16] in Quebec, Canada, where they found no evidence of effect modification by maternal educational level either.

Our results should be interpreted in the context of the study's limitations. First, given the cross-sectional design of the study, no causal inference can be drawn. Second, although the birth registry includes sociodemographic information about the mother, it does not collect tobacco consumption habits during pregnancy. However, we used data from the Spanish Collaborative Study on Congenital Malformations by the Research Center for Birth Defects on smoking prevalence among pregnant women as an ecological control. Third, we could not differentiate between spontaneous and provider-initiated preterm deliveries due to data limitations. The latter is important because tobacco addiction is a risk factor for spontaneous preterm births. MacKay et al[15] examined spontaneous preterm births only and detected a statistically significant association between Scottish smoking bans and preterm births that was only slightly lessened after adjusting for preeclampsia. Fourth, variables not taken into account may contribute to residual confounding, such as cesarean delivery rates (25% in Spain), which are related to gestational time and newborn's weight. However, cesarean delivery rates do not seem to be related to the smoking bans because the incidence of cesarean delivery grew gradually, peaking in 2006, only to stabilize thereafter. Also, the use of tocolytic drugs for suppression of premature labor could modify the association under study. But, again, there seems to be no temporal relationship between the bans and the use of this family of drugs or, more specifically, oxytocine receptor antagonists (eg, Atosiban), which may reduce birth weight.[36]

Finally, other changes in fetal medicine practice over the study period could have confounded the association (eg, recognition and earlier treatment of high blood pressure leading to better placental function, or aspirin administration in early pregnancy to prevent preeclampsia). However, in this period, the Clinical Practice Guideline for Care in Pregnancy and Puerperium in the Spanish National Health System[37] did not change their recommendations on blood pressure monitoring (to prevent hypertension from complicating pregnancies) or the use of low-dose aspirin in early pregnancy. However, between 2000 and 2013, Spanish hospitals have experienced steady negative linear trends in admission rates for hypertension complications during pregnancy (*International Classification of Diseases, Ninth Revision, Clinical Modification* code 642) and for preeclampsia (*International Classification of Diseases, Ninth Revision, Clinical Modification* codes 642.4 and 642.5). Coincidentally, the trends for hypertension complications during pregnancy stabilized starting in 2010 and for preeclampsia starting in 2008, time periods that include the post–comprehensive ban years under study (2011 to 2013) and during which we observed the more substantial effects of the smoke-free policies on our outcomes of interest. This information suggests the independence of our findings from the improved management of those clinical conditions. Likewise, the Clinical Practice Guideline for Care in Pregnancy and Puerperium did not change the recommendations on the management of growth restriction, with the addition of Doppler assessment.[37]

Although we are not aware of any changes in obstetric practices coinciding with the implementation of the 2 smoking bans, we cannot rule out the risk of unknown bias due to other factors not controlled in the analysis potentially related to outcomes.

Our study also has important strengths. First, this large population-based study analyzed data from a comprehensive and highly relevant nationwide data set. Second, Spain is one of a few countries with 2-stage smoking ban legislation and a 5-year gap between a partial and a comprehensive ban. Third, this smoke-free regulation was effective in reducing exposure to SHS in the workplace and in hospitality venues.[8,9,11] Fourth, the substantial follow-up period, starting 6 years before the implementation of the first policy and terminating 2 years after the implementation of the second one, allowed for the separate evaluation of the 2 phases of the smoke-free legislation.

CONCLUSIONS

Our results show a risk reduction for preterm births and low birth weight newborns coinciding with the implementation of the smoke-free regulations in Spain. This finding is especially true with the second regulation, a comprehensive ban prohibiting smoking in most enclosed public spaces. This association strongly provides support for the benefits of implementing smoke-free legislation in the prevention of pregnancy complications and brings to the forefront the importance of developing comprehensive regulations preventing or minimizing maternal and fetal exposure to this key environmental risk factor.

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ABBREVIATIONS

CI: confidence interval
SGA: small for gestational age
SHS: secondhand smoke

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