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ABSTRACT

Objective: This study aimed to analyse the impact of comprehensive smoke-free legislation on the prevalence and incidence of adult smoking in Primary Health Care patients from three Spanish regions, overall and stratified by sex.

Design: Longitudinal observational study conducted between 2008 and 2013.

Setting: 66 Primary Health Care teams in Catalonia, Navarre and the Balearic Islands (Spain).

Participants: Population over 15 years of age assigned to Primary Health Care teams.

Primary and secondary outcomes measures: Quarterly age-standardized prevalence of non-smoker, smoker and ex-smoker and incidence of new smoker, new ex-smoker and ex-smoker relapse rates were estimated with data retrieved from PHC electronic health records. Joinpoint analysis was used to analyse the trends of age-standardized prevalence and incidence rates**.** Trends were expressed as annual percentage change and average annual percent change.

Results: The overall standardized smoker prevalence rate showed a significant downward trend (higher in men than women) and the overall standardized ex-smoker prevalence rate showed a significant increased trend (higher in women than men) in the three regions. Standardized smoker and ex-smoker prevalence rates were higher for men than women in all regions. With regard to overall trends of incidence rates, new smokers decreased significantly in Catalonia and Navarre and similarly in men and women, new ex-smokers decreased significantly and more in men in Catalonia and the Balearic Islands**,** and ex-smoker relapse increased in Catalonia, particularly in women, and decreased in Navarre.

Conclusions: Trends on smoking behaviour in Primary Health Care patients remain unchanged after the comprehensive smoke-free legislation.

Keywords: Electronic health records; Joinpoint analysis; Primary Health Care; Smoke-Free Policy; Smoking.

Strengths and limitations of this study

- To our knowledge, no studies have been published on the impact of the Spanish comprehensive smoke-free legislation in all adult Primary Health Care patients
- The use of Primary Health Care records with a large number of participants and centres as data source to study time trends for smoking avoids the memory bias associated with surveys
- The results of quarterly data by joinpoint analysis provides more precise information than an analysis before-after the implementation of the Law
- This study only considered age and sex since other variables were not available for the adjusted analysis.
- The study period started later (short follow-up) in Balearic Islands to ensure reliability of data

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INTRODUCTION

Smoking is the leading worldwide cause of preventable death.[1] According to the World Health Organization (WHO), it is estimated that at least 30 million people may die prematurely from tobacco-related diseases.[2] Legislative measures have been adopted to protect people's health in public areas and workplaces. These include increasing the price of cigarettes, banning advertising, sponsorship and smoking in workplaces and public spaces, displaying warnings on tobacco packets and implementing prevention programs.[3]

Some studies show a decrease in smoking prevalence since the introduction of smoke-free legislation (SFL).[4–9] A metanalysis of 26 studies on the effect of the smoke-free workplace in various countries concluded in 2002 that smoke-free workplaces protect not only non-smokers from the dangers of passive smoking, but they also encourage smokers to reduce tobacco consumption. The authors concluded that SFL is associated with a 3% to 4% reduction in tobacco consumption.[10] In contrast, a Cochrane review published in 2016 which included 24 studies on smoking behaviour showed inconsistencies regarding the impact of smoking bans on smoking prevalence and tobacco consumption.[11]

In January 1, 2006, the Spanish government introduced a partial SFL (Law 28/2005),[12] which included regulations on the sale, supply, consumption and advertising of tobacco products. Smoking was banned in all indoor public and private workplaces with the exception of the hospitality sector, where partial restrictions were established depending on the size of the establishment, i.e., in bars or restaurants smaller than 100 m2 the managers could decide whether to allow smoking in the premises (Law 28/2005). The mean concentration of nicotine subsequently decreased by 60% in public administration offices and by 97.4% in private workplaces, but in areas where smoking was permitted, including bars and nightclubs, no changes were found.[13–15] This prompted the enactment of a comprehensive SFL (Law 42/2010),[16] which came into force in January 2011. This comprehensive law expanded smoking restriction to all hospitality venues of any size and, as a result, smoking was forbidden in all enclosed public places, including bars, restaurants and nightclubs, and in some open-air public places such as playgrounds.

Some studies have analysed the impact of these two Spanish laws on smoking prevalence. However, most have been based on health surveys[13,17–20] and surveys of hospitality workers.[21,22] Moreover, some studies evaluate only the partial law,[13,17,18] whereas others analyse the compound impact of both laws.[19,20,23] The results of these studies are often conflicting; while some conclude that the partial SFL does not have any effect on the downward trend in the prevalence of smokers,[13,19,23] other studies show differences in the smoking quit-ratio trends before/after SFL[18] and minor increases in the prevalence of active smoking.[20]

Only one study conducted in primary health care (PHC) patients evaluates the impact of the Spanish partial SFL, including smoking prevalence in active smoker workers that attended PHC visits; one month after the implementation

of the law, a 9.5% decline of smokers was observed.[24] To our knowledge, no studies have been published on the impact of the Spanish comprehensive SFL in all adult PHC patients. In view of the pivotal role of PHC services in smoking habits, we consider that the information registered in PHC records is a good proxy to generate up-to-date evidence and to evaluate the impact of comprehensive SFL in the general population.

The aim of this study was to examine the impact of the Spanish comprehensive SFL (Law 42/2010) on the prevalence and incidence of adult smoking in PHC patients in three regions (Catalonia, Navarre and Balearic Islands), during the 2008-2013 period, overall and stratified by sex.

METHODS

Design, study participants and information source

Longitudinal observational study of the adult population assigned to 66 Primary Health Care teams (PHCT) in three Spanish regions: Catalonia, Navarre and the Balearic Islands (22 PHCT per region). Inclusion criteria of the PHCT were: 1) computerization of electronic health records (EHR) by January 1, 2005 in Catalonia and Navarre, and 2008 in the Balearic Islands; and 2) agreement to participate in the study by over 80% health-care professionals working in each PHCT. Random cluster sampling was stratified by region, with the PHCT as randomization unit.[25] In each PHCT, General Practitioners (GP) with a patient list between 400 and 3000 were selected. GP with shorter patient lists were accepted if it was their first year in the PHCT.

The study period included from the first quarter of 2008 to the fourth quarter of 2013 in Catalonia and Navarre; and from the second quarter of 2010 to the fourth quarter of 2013 in the Balearic Islands. The study started in 2008 to obtain data from the 2 years prior analysis, a requirement to adequately construct the variable ex-smoker. In the case of the Balearic Islands, the study started later to ensure reliability of data.

Inclusion criteria for patients were: 1) Population allocated to the selected PHCT for the whole 2007-2013 period in Catalonia and Navarre; in the Balearic Islands, patients allocated to the selected PHCT in 2013 and evaluated retrospectively (no annual comprehensive register of patients was available). 2) Age ≥16 and ≤100 years in 2007 in Catalonia and Navarre, and 2010 in the Balearic Islands. 3) In order to have data in the EHR collected during the study period, a minimum of one visit to their PHCT during the 2007-2013 period in Catalonia and Navarre and 2010-2013 in the Balearic Islands; and 4) Information on smoking habit recorded in the EHR for the quarter prior to the onset of the study: last quarter of 2007 in Catalonia and Navarre and first quarter of 2010 in the Balearic Islands, to enable the adequate construction of the various variables. Thus, closed cohorts (with fixed membership, where nobody is added nor excluded after the study begins) were constituted in the three regions. Figure 1 shows the flowchart of the study.

Data were retrieved from the REGIPREV database,[25] which contains encrypted and anonymized clinical information recorded in the EHR by these 66 PHCT. An algorithm was applied to extract equivalent data from the health records software used in each region: “ECAP” in Catalonia, “Atenea” in Navarre and “e-siap” in the Balearic Islands. Codes of

the International Classification of Diseases, 9th revision in the Balearic Islands (ICD-9) and 10th in Catalonia (ICD 10th revision)[26] and the International Classification of Primary Care, Second edition, in Navarre (ICPC-2)[27] were used.

Variables

The dependent variables originate from clinical variables (number of cigarettes per day, history of smoking, history of advice for smoking cessation) and from diagnostic codes to classify diseases (codes F17.0 to F17.9 and Z72.0 of the ICD-10, 305.1 of the ICD-9 and P17 of the ICPC-2) recorded in the EHR. We calculated the following variables at the end of each quarter of the study period:

- Smoking status (three categories): 1) non-smoker: patient that has never been a tobacco consumer, 2) smoker: tobacco consumer or patient that has quit smoking for less than 12 months; and 3) ex-smoker: patient who used to smoke but has quit smoking for at least 12 continuous months. If the EHR did not register smoking status at some point in time, the last observation was carried forward.
- New smoker: patient non-smoker for the 12 months prior to the considered quarter that has started smoking during said quarter.
- New ex-smoker: patient was a smoker two years before the considered quarter and has continuously abstained from tobacco for at least 12 months.
- Ex-smoker relapse: patient ex-smoker during the 12 months prior to the considered quarter that has started smoking again during said quarter.

For higher accuracy in prevalence and incidence changes, quarterly estimates were calculated.

The following variables of each patient were collected at baseline (2008 in Catalonia and Navarre; 2010 in the Balearic Islands): age, sex (male/female), annual number of health problems and annual number of PHC visits. The number of health problems was used as a morbidity indicator; it was calculated as the sum of the number of different active health problems (chronic and acute, coded by ICPC-2).

Data analyses

Descriptive statistics were used to summarize overall information. Categorical variables were expressed as percentage, and continuous variables as mean (standard deviation) or median (interquartile range [IQR]).

Because they used different EHR systems (different standards and computer programs), different complementary measures to the SFL and also due to the shorter study period in the Balearic Islands, we performed a stratified analysis per region, overall and by sex. Age-standardized prevalence (non-smokers, smokers and ex-smokers) and incidence (new smokers, new ex-smokers and ex-smoker relapse) rates were calculated for each quarter using the direct method, and based on the European Standard Population (rates per 10,000 inhabitants).

Joinpoint analysis was used to analyse the trends of age-standardized prevalence (smokers and ex-smokers) and incidence rates (new smokers, new ex-smokers and ex-smoker relapse) and to identify the best-fitting points (the 'joinpoints', in calendar quarters) where the rate changes significantly overtime. Significant changes include changes in

direction or in the rate of increase or decrease[28]. Temporal trends were expressed as the annual percentage change (APC), computed over each specified time interval, and the average annual percent change (AAPC), computed to summarize and compare these trends over the entire time period. Ninety-five percent confidence intervals (95% CI) of APC and AAPC were calculated.

Analyses were performed using Stata/SE version 14.2 for Windows (Stata Corp. LP, College Station, Texas, US). The joinpoint regression analysis was carried out using the joinpoint software from the Surveillance Research Program of the US National Cancer Institute [ref. Joinpoint Regression Program, Version 4.3.1. April, 2016; Statistical Research and Applications Branch, National Cancer Institute] (National Cancer Institute. Statistical Research and Applications Branch) [On-line: https://surveillance.cancer.gov/branches/srab/].

RESULTS

The study population was 392,966 patients: 141,071 in Catalonia, 73,644 in Navarre and 178,251 in the Balearic Islands. At the onset of the study, the mean age was 50.4 years in Catalonia, 54.0 in Navarre and 47.7 in the Balearic Islands. In the three cohorts more than half were women (>51 %). Catalonia presented the highest median number of visits (9, IQR: 3 -16) and the Balearic Islands presented the highest number of recorded active health problems per patient (median 10, IQR: 6-16) (Table 1).

Table 1: Characteristics of the cohort study population by region at the onset of the study (2008 in Catalonia and Navarre, 2010 in the Balearic Islands).

	Catalonia N =141,071	**Navarre** N = 73,644	**Balearic Islands** N =178,251
Age (years), SD	50.37 (17.23)	54.04 (18.26)	47.65 (17.56)
Sex (female), number (%)	72340 (51.28)	37898 (51.46)	94164 (52.83)
Number of visits, mean (SD); median (IQR)	11.69 (12.19); 9.00 (3.00-16.00)	8.93 (9.30); 7.00 (3.00-12.00)	11.01 (13.25); 7.00 (3.00-15.00)
Number of health problems, mean (SD); median (IQR)	6.23 (4.58); 5.00 (3.00-8.00)	9.95 (5.39); 9.00 (6.00-13.00)	11.85 (7.74); 10.00 (6.00-16.00)

Abbreviations: SD, standard deviation; IQR, interquartile range.
Patients belonged to 22 Primary Health Care Teams in each region.

The **overall standardized smoker prevalence rates** were of similar magnitude in the three regions (ranges of 3579.2 - 4138.9 in Catalonia; 3719.8 - 4034.2 in Navarre; and 3787.4 - 4029.7 in the Balearic Islands). The prevalence rate decreased in Navarre during the whole study period, decreased in the Balearic Islands in most quarters, and also in Catalonia except for the last year. These rates were higher for men than for women in all regions (Supplementary File Tables S1-S6). A significant downward **overall trend of smoker prevalence rates** was found in Catalonia (AAPC=- 0.020), Navarre (AAPC= -0.014) and the Balearic Islands (AAPC= -0.018); this downward trend was higher for men than for

women in the three regions. In Catalonia, the most significant reduction occurred during the period 2010.3-2011.2 (APC= -0,092), similarly to the Balearic Islands (2010.2-2012.4; APC= -0.021), whereas in Navarre it occurred between 2008.1-2011.3 (APC= -0.017) (Tables 2, 3, 4).

For the whole period, the **overall standardized ex-smoker prevalence rates** increased in Navarre, in the Balearic Islands and in Catalonia except for the last year. The rates in Catalonia were higher (ranges of: 1168.5 - 1781.2 in Catalonia; 313.3 - 764.1 in Navarre; and 559.3 - 914.1 in the Balearic Islands). The standardized ex-smoker prevalence rates were higher for men than for women in all regions (Supplementary File Tables S1-S6). The **overall trend of ex-smoker prevalence rates** increased significantly in the three regions throughout the study period but was higher in Navarre (Navarre AAPC= 0.154; Catalonia AAPC= 0.069; Balearic Islands AAPC= 0.139). The increase in the prevalence rate of ex-smokers was higher for the 2008.1-2008.3 period in Catalonia and Navarre, and for 2010.2-2012.2 in the Balearic Islands, and higher in women in the three regions (women: Catalonia AAPC= 0.103; Navarre AAPC=0.160 and Balearic Islands AAPC= 0.176) (Tables 2, 3, 4).

The **overall new smoker standardized incidence rates** showed low values in the three regions (ranges of 7.9 - 26.8 in Catalonia; 9.5 - 30.9 in Navarre; 1.6 - 17.5 in the Balearic Islands) and higher for men than for women in Catalonia and Navarre (Supplementary File Tables S1-S6). The **overall trend of new smoker incidence rates** decreased significantly in Catalonia (AAPC= -0.113) and Navarre (AAPC= -0.099); additionally, the decline was similar for men and women. In contrast, the trend remained stable in the Balearic Islands (Tables 2, 3, 4).

The **overall standardized new ex-smoker incidence rates** showed higher values in Catalonia (range: 110.7 - 317.6) than in Navarre (range: 48.6 - 181.0) and the Balearic Islands (range: 93.7 - 188.1) (Supplementary File Tables S1-S6). The **overall trend of new ex-smoker incidence rates** showed a significant decrease in Catalonia (AAPC= -0.076) and especially in the Balearic Islands (AAPC= -0.125). This downward trend was higher for men than for women in Catalonia and the Balearic Islands (Tables 2, 3, 4).

The **overall standardized ex-smoker relapse incidence rates** presented higher values in the Balearic Islands (range: 103.9 - 576.6) than in Catalonia (range: 70.7 - 334.5) and Navarre (range: 58.6 - 230.3) (Supplementary File Tables S1-S6). The **overall trend of ex-smoker relapse incidence rates** showed significant increases in Catalonia (AAPC= 0.173), particularly in women (AAPC= 0.140). In contrast, Navarre showed significant decreases (AAPC= -0.121) (Tables 2, 3, 4).

Table 2. Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse. Joinpoints overall and by sex in CATALONIA. N=141,071 (2008-2013)

	Trend 1		Trend 2		Trend 3		Trend 4		Trend 5		AAPC (95% IC) 2008.1 - 2013.4
	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC(95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	
Smoker prevalence											
F	2008.1 - 2010.3	-0.005[d] (-0.010 ; 0.001)	2010.3 - 2011.2	-0.108[b] (-0.180 ; -0.036)	2011.2 - 2013.4	-0.006[c] (-0.011 ; -0.001)					-0.019[a] (-0.028 ; -0.010)
M	2008.1 - 2010.3	-0.020[a] (-0.022 ; -0.017)	2010.3 - 2011.2	-0.086[a] (-0.120 ; -0.052)	2011.2 - 2012.4	-0.031[a] (-0.038 ; -0.024)	2012.4 - 2013.4	0.027[a] (0.016; 0.037)			-0.023[a] (-0.028 ; -0.018)
G	**2008.1 - 2010.3**	-0.013[a] (-0.016 ; -0.010)	2010.3 - 2011.2	-0.092[a] (-0.133 ; -0.051)	2011.2 - 2011.4	-0.023[a] (-0.032 ; -0.015)	2012.4 - 2013.4	0.020[b] (0.007; 0.033)			-0.020[a] (-0.026 ; -0.015)
Ex-smoker prevalence											
F	2008.1 - 2008.4	0.160[a] (0.131 ; 0.188)	2008.4 - 2011.2	0.106[a] (0.102 ; 0.111)	2011.2 - 2012.1	0.147[a] (0.100 ; 0.193)	2012.1 - 2013.1	0.092[a] (0.069; 0.114)	2013.1 - 2013.4	0.005[d] (-0.017;0.027)	0.103[a] (0.095 ; 0.111)
M	2008.1 - 2008.3	0.138[b] (0.041 ; 0.235)	2008.3 - 2011.1	0.053[a] (0.045 ; 0.061)	2011.1 - 2012.4	0.073[a] (0.060 ; 0.086)	2012.4 - 2013.4	-0.050[a] (-0.074;-0.026)			0.049[a] (0.039 ; 0.058)
G	2008.1 - 2008.3	0.154[a] (0.081 ; 0.228)	2008.3 - 2011.1	0.074[a] (0.067 ; 0.080)	2011.1 - 2012.4	0.092[a] (0.082 ; 0.103)	2012.4 - 2013.4	-0.024[c] (-0.042;-0.005)			0.069[a] (0.062 ; 0.077)
New smokers incidence											
F	2008.1 - 2013.4	-0.116[b] (-0.188; -0.044)									-0.116[b] (-0.188 ; -0.044)
M	2008.1 - 2013.4	-0.113[a] (-0.173; -0.053)									-0.113[a] (-0.173 ; -0.053)
G	2008.1 - 2013.4	-0.113[a] (-0.168; -0.057)									-0.113[a] (-0.168 ; -0.057)
New ex-smokers incidence											
F	2008.1 - 2013.4	-0.053[d] (-0.109 ; 0.003)									-0.053[d] (-0.109 ; 0.003)
M	2008.1 - 2013.4	-0.082[b] (-0.142; -0.022)									-0.082[b] (-0.142 ; -0.022)
G	2008.1 - 2013.4	-0.076[b] (-0.133; -0.020)									-0.076[b] (-0.133 ; -0.020)
Ex-smoker relapse incidence											
F	2008.1 - 2012.3	-0.090[d] (-0.205 ; 0.025)	2012.3 - 2013.4	0.972[a] (0.524 ; 1.422)							0.140[c] (0.016 ; 0.264)
M	2008.1 - 2009.3	-0.649[d] (-1.552 ; 0.262)	2009.3 - 2010.2	0.787[d] (-5.329 ; 7.298)	2010.2 - 2012.2	-0.318[c] (-0.599; -0.037)	2012.3 - 2013.2	1.853[d] (-0.505; 4.266)	2013.2 - 2013.4	0.561[d] (-0.759;1.898)	0.096[d] (-0.709 ; 0.907)
G	2008.1 - 2012.3	-0.083[d] (-0.175 ; 0.010)	2012.3 - 2013.4	1.100[a] (0.803 ; 1.398)							0.173[a] (0.083 ; 0.264)

Note: 2008.*. represents the quarter * of the year 2008

APC, annual percentage change and AAPC, average annual percent change estimated by joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.
[a] p≤ 0.001; [b] p≤ 0.01; [c] p≤ 0.05; [d] p>0.05

Table 3. Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse. Joinpoints overall and by sex in NAVARRE. N=73,644 (2008-2013)

	Trend 1		Trend 2		Trend 3		Trend 4		Trend 5		AAPC (95% IC) 2008.1 - 2013.4
	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	
Smoker prevalence											
F	2008.1 - 2010.3	-0.010[a] (-0.012 ; -0.007)	2010.3 - 2011.2	-0.024[d] (-0.059 ; 0.010)	2011.2 - 2013.4	-0.002[d] (-0.005 ; 0.001)					-0.008[a] (-0.013 ; -0.004)
M	2008.1 - 2013.4	-0.020[a] (-0.021 ; -0.019)									-0.020[a] (-0.021 ; -0.019)
G	2008.1 - 2011.3	-0.017[a] (-0.019 ; -0.015)	2011.3 - 2013.4	-0.010[a] (-0.014 ; -0.005)							-0.014[a] (-0.016 ; -0.012)
Ex-smoker prevalence											
F	2008.1 -2008.3	0.347[a] (0.248 ; 0.445)	2008.3 - 2010.2	0.177[a] (0.163 ; 0.191)	2010.2 - 2011.3	0.123[a] (0.100; 0.147)	2011.3 - 2012.2	0.184[a] (0.114 ; 0.254)	2012.2 - 2013.4	0.098[a] (0,087 ; 0,109)	0.160[a] (0.148 ; 0.173)
M	2008.1 - 2008.3	0.294[a] (0.170 ; 0.419)	2008.3 - 2009.4	0.178[a] (0.143 ; 0.213)	2009.4 - 2012.4	0.128[a] (0.122 ; 0.134)	2012.4 - 2013.4	0.092[a] (0.067 ; 0.117)			0.147[a](0.134 ; 0.160)
G	2008.1 - 2008.3	0.312[a] (0.181 ; 0.442)	2008.3 - 2009.4	0.183 [a](0.146 ; 0.220)	2009.4 - 2012.4	0.137[a] (0.130 ; 0.143)	2012.4 - 2013.4	0.092[a] (0.065 ; 0.120)			0.154[a] (0.141 ; 0.168)
New smokers incidence											
F	2008.1 - 2013.4	-0.099[b] (-0.171 ; -0.027)									-0.099[b] (-0.171 ; -0.027)
M	2008.1 - 2013.4	-0.098[b] (-0.163 ; -0.034)									-0.098[b] (-0.163 ; -0.034)
G	2008.1 - 2013.4	-0.099[b] (-0.161 ; -0.038)									-0.099[b] (-0.161 ; -0.038)
New ex-smokers incidence											
F	2008.1 - 2013.4	-0.102 [b](-0.161 ; -0.042)									-0.102[b] (-0.161 ; -0.042)
M	2008.1 - 2013.4	-0.027[d] (-0.096 ; 0.041)									-0.027[d] (-0.096 ; 0.041)
G	2008.1 - 2013.4	-0.051[d] (-0.114 ; 0.011)									-0.051[d] (-0.114 ; 0.011)
Ex-smoker relapse incidence											
F	2008.1 - 2013.4	-0.149[a] (-0.220 ; -0.079)									-0.149[a] (-0.220 ; -0.079)
M	2008.1 - 2013.4	-0.128[c] (-0.225 ; -0.031)									-0.128[d] (-0.225 ; -0.031)
G	2008.1 - 2013.4	-0.121[a] (-0.189 ; -0.052)									-0.121[a] (-0.189 ; -0.052)

Note: 2008.*. represents the quarter * of the year 2008

APC, annual percentage change and AAPC, average annual percent change estimated by joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.

[a] p≤ 0.001; [b] p≤ 0.01; [c] p≤ 0.05; [d] p>0.05

Table 4. Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse. Joinpoints overall and by sex in THE BALEARIC ISLANDS. N=178,251 (2010-2013)

	Trend 1			Trend 2			Trend 3			AAPC (95% IC) 2010.2 - 2013.4	
	Time	APC (95% IC)		Time	APC (95% IC)		Time	APC (95% IC)			
Smoker prevalence											
F	2010.2 - 2013.4	-0.012[a]	(-0.014; -0.010)							-0.012[a]	(-0.014; -0.010)
M	2010.2 - 2011.1	-0.021[a]	(-0.026; -0.016)	2011.1 - 2012.3	-0.031[a]	(-0.033; -0.029)	2012.3 - 2013.4	-0.015[a]	(-0.018;-0.012)	-0.023[a]	(-0.025; -0.022)
G	2010.2 - 2012.4	-0.021[a]	(-0.023;-0.019)	2012.4 - 2013.4	-0.009[d]	(-0.019; 0.002)				-0.018[a]	(-0.021; -0.015)
Ex-smoker prevalence											
F	2010.2 - 2012.2	0.222[a]	(0.216; 0.229)	2012.2 - 2013.4	0.114[a]	(0.105; 0.122)				0.176[a]	(0.171; 0.180)
M	2010.2 - 2012.2	0.147[a]	(0.136; 0.159)	2012.2 - 2013.4	0.070[a]	(0.055; 0.085)				0.114[a]	(0.106; 0.122)
G	2010.2 - 2012.2	0.177[a]	(0.172; 0.182)	2012.2 - 2013.4	0.089[a]	(0.082; 0.095)				0.139[a]	(0.136; 0.143)
New smokers incidence											
F	2010.2 - 2012.4	-0.584[b]	(-0.963; -0.203)	2012.4 - 2013.4	2.627[c]	(0.686; 4.605)				0.323[d]	(-0.214; 0.863)
M	2010.2 - 2012.4	-0.611[b]	(-0.907; -0.314)	2012.4 - 2013.4	2.105[a]	(1.062; 3.158)				0.157[d]	(-0.162; 0.477)
G	2010.2 - 2012.4	-0.613[b]	(-0.927; -0.298)	2012.4 - 2013.4	2.460[b]	(1.130; 3.808)				0.255[d]	(-0.129; 0.641)
New ex-smokers incidence											
F	2010.2 - 2013.4	-0.119[c]	(-0.225; -0.012)							-0.119[c]	(-0.225; -0.012)
M	2010.2 - 2013.4	-0.128[b]	(-0.205; -0.051)							-0.128[b]	(-0.205; -0.051)
G	2010.2 - 2013.4	-0.125[b]	(-0.200; -0.049)							-0.125[b]	(-0.200; -0.049)
Ex-smoker relapse incidence											
F	2010.2 - 2013.1	-0.388[a]	(-0.531; -0.245)							-0.388[a]	(-0.531; -0.245)
M	2010.2 - 2013.1	-0.453[a]	(-0.595; -0.311)							-0.453[a]	(-0.595; -0.311)
G	2010.2 - 2013.1	-0.203[c]	(-0.360; -0.046)	2013.1 - 2013.4	-1.903[d]	(-5.201; 1.510)				-0.570[d]	(-1.218; 0.082)

Note: 2010.*. represents the quarter * of the year 2010

APC, annual percentage change and AAPC, average annual percent change estimated by joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.
[a] p≤ 0.001; [b] p≤ 0.01; [c] p≤ 0.05; [d] p>0.05

DISCUSSION

The previous implementation of the partial Spanish SFL could account for the low effectiveness of the comprehensive SFL observed in this study. A small significant downward trend of smoker prevalence rates, higher in men than in women, was found in the three regions throughout the study period. Correspondingly, the trend of ex-smoker prevalence rates increased in the three regions, particularly in Navarre and during the period 2008.1-2008.3 in Catalonia and Navarre, and the period 2010.2-2012.2 in the Balearic Islands. Even though the standardized ex-smoker prevalence rate was higher for men, the increase in the trend of ex-smoker prevalence rate was higher in women in the three regions. The overall trends of new smoker incidence rates decreased significantly in Catalonia and Navarre and were similar for men and women. Also, the overall trends of new ex-smokers decreased significantly in Catalonia and the Balearic Islands, particularly for men. In addition, the overall trends of ex-smoker relapse increased in Catalonia and decreased in Navarre, more for women than for men in both cases. For all outcomes, the magnitude of the trends (overall and by sex) was very small (range 0.01% - 0.4%).

The trends of smoker prevalence declined throughout the study and no changes were observed after the implementation of the comprehensive SFL. Indeed, the most significant decrease begins in 2010 in Catalonia and the Balearic Islands and in 2008 in Navarre, prior to the implementation of the comprehensive SFL (January 1, 2011). Comparisons are difficult due to the lack of studies on smoking prevalence and incidence from a PHC perspective and because some studies evaluate the impact of SFL on smoking prevalence with surveys that use different methodologies. Two studies that analysed data from surveys to the general population[19,20] did not find a significant decrease in the prevalence of smokers after the Spanish comprehensive law. In contrast, Lidon *et al.*[29] observed that after the implementation of both Spanish SFL, a significant decrease was observed in the smoking prevalence (from 34.5% to 26.1%, Prevalence Ratio = 0.76, $p < 0.001$) of people 16 years of age and older living in Barcelona surveyed in 2004–2005 and followed-up in 2013–2014. In addition, National Health Survey data from the 1987-2005 period revealed an annual average absolute decline of 1.0% in the prevalence of male smokers, whereas women showed an annual average absolute increase in prevalence of 0.2%. Between 2006 and 2014, the prevalence of smokers declined annually by 0.7% in men and 0.5% in women.[23] Although the values of the current study are lower the higher decline in the prevalence of smokers in men agree with these data.[23] Also, one study that estimated the effect of the Spanish SFL for the 2012-2025 period predicted a decrease in smoking prevalence in all age groups and for both sexes, except for women aged 40–64.[30]

Concomitantly with the decline in the prevalence trends in smokers, a constant increase of prevalence trends in ex-smokers was observed in the three regions. Other studies failed to note a significant change in the prevalence of ex-smokers after the comprehensive SFL: a difference of only 0.3 % between 2007 and 2011[20] and a non-significant increase of 3.3% between 2006 and 2011.[19] In agreement with a recent evidence review,[23] we observed a higher increase in the trend of ex-smokers prevalence in women. This review showed that the rate of smoking cessation in men increased 0.9% annually during the 1987-2014 period, and 1.5% in women after the Partial SFL came into force. The later incorporation of women to smoking might explain these gender differences.

We observed a gradual decline in the new smoker incidence trends in Catalonia and Navarre throughout the study period. A review by Wilson *et al.*[31] of two studies that evaluated smoking initiation reported mixed results, while Guerrero *et al.*(32) concluded that the Spanish partial SFL had no effect on new smokers in 2009 In contrast, Pinilla and Abásolo[33] observed a 6% decrease in the rate of smoking initiation among young people after the implementation of the same law, with a more positive impact in higher socioeconomic strata. We have not found studies that evaluate the impact of the comprehensive SFL on the incidence of new smokers. However, our data show a continuation in the trend observed in Pinilla's study[33] on the impact of the partial law, although the effect in two of the regions of our study is much smaller (<1%).

The incidence trend in new ex-smokers declined gradually throughout the study period in Catalonia and the Balearic Islands. While the literature to date lacks data on the effect of the SFL on the incidence of new ex-smokers, it provides some information on prevalence. In this respect, one study on the Spanish partial SFL observed an increase of 8% between 2006 and 2011 in the rate of cessation among adult smokers (age 21 years and older) according to data from the National Health Survey.[33] In Luxembourg, smoking cessation attributed to the SFL was higher among daily smokers with a higher socioeconomic status.[8] In our cohort, we observed apparently random increases and declines in the adjusted rates in the three regions throughout the study.

The incidence trend in ex-smoker relapses increased in Catalonia and declined in Navarre constantly throughout the whole period, particularly for women. However, the literature presents conflicting results regarding smoking relapse. One study on the partial Spanish SFL observed that most people who had succeeded in giving up smoking in 2006 had not relapsed by 2009.[32] On the other hand, a quasi-experimental study conducted in the United States observed that relapse was similar between employees in workplaces with SFL and employees where smoking was permitted.[34] In contrast, Shang found that a comprehensive SFL in bars significantly deters smoking relapse among people ages 21 and older.[35] According to Buczkowski *et al.*,[36] the main reasons for relapse are stress, missing the pleasure obtained from smoking and the smoking environment. Other factors not analysed in our study that might influence relapse rates could explain the variations between regions, for instance living with other smokers, being enrolled in work or clinics cessation programmes[37] or the region-specific complementary measures to the SFL (for instance, Foral Law 6/2003,(38) February 14, of smoking prevention, protection from secondhand tobacco smoke and promotion of health with regard to smoking in Navarre). In addition, we should consider the impact of the financial crisis during the study period and the subsequent increase of anxiety and depression in the population.[39] In this respect, Navarre was the region with the lowest unemployment rate in Spain according to the 2010 Economically Active Population Survey (unemployment of 11.6% in Navarre, versus 18.0% in Catalonia and 22.2% in the Balearic Islands). According to the 2009 European Health Survey in Spain, these unemployment figures correlate with the prevalence of chronic depression, which was of 3.4% in Navarre versus 5.4% in Catalonia and 7.0% in the Balearic Islands.

Limitations and strengths of the study

It is important to take into account that other than the Law, the pattern of tobacco consumption is influenced by factors such as health interventions, level of education, age, civil status, having children and being unemployed.[40]

However, this study only considered age and sex since other variables were not available. In addition, many patients were excluded from the study because data regarding smoking status at the onset were not recorded. Nevertheless, in order to avoid changes due to the improvement of the tobacco records during that period, we excluded those without information at the beginning of the study. Moreover, young people might be underrepresented due to their lower use of PHC services. On the other hand, 70% of the population attends PHC services at least once a year and smokers attend more frequently than no smokers.[41]

This study provides useful data on the impact of the Spanish comprehensive SFL on adult smoking behaviour in PHC patients. It is crucial to analyse the consequences of a public health law on PHC users. Primary health care has a pivotal role in smoking cessation because it is the gatekeeper of the health services, it is accessible and provides continuity of care to smokers.[42] We should also highlight that this study includes the evaluation of novel variables such as incidence of new smokers, new ex-smokers and ex-smoker relapse. The use of PHC records with a large number of participants and centres as data source to study time trends for smoking avoids the memory bias associated with surveys. The results should therefore be generalizable. To our knowledge, this study is amongst the first to show quarterly data from EHR.

CONCLUSIONS

The introduction of the Spanish comprehensive SFL (Law 42/2010) does not significantly modify incidence and prevalence trends of smoking behaviour in PHC adult patients in Catalonia, Navarre and the Balearic Islands. The impact of the comprehensive SFL might have been lessened by the effect of the previous implementation of the partial SFL (Law 28/2005). The current article provides baseline data for future research into the effectiveness of this Law. In addition to specific factors associated with smoking behaviour (such as the price of a pack of cigarettes or funding of smoking cessation services), future studies should consider socio-economic status and age groups.

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Contributors: BB, TRB, MPV, JBM, and CVF designed the study and wrote the protocol. YRM, MPV and JBM conducted literature searches and provided summaries of previous research studies. BB, JLL, JM, JR and MPV obtained the data. TRB conducted the statistical analysis. All authors contributed to the interpretation of the results. YRM and MPV wrote the first draft of the manuscript. All authors read, contributed and approved the final version of the manuscript.

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Competing interest: The authors declare no conflict of interest.

Ethical aspects: This study follows the tenets of the Helsinki Declaration and of Good Clinical Research Practice and has been approved by the Ethical and Clinical Research Committee of the IDIAP Jordi Gol. Confidentiality was guaranteed through data encryption and anonymization in agreement with the data confidentiality Law 15/1999.

Data sharing statement: No additional data are available.

Figure 1: Flow-chart of patients included in the study, by region.

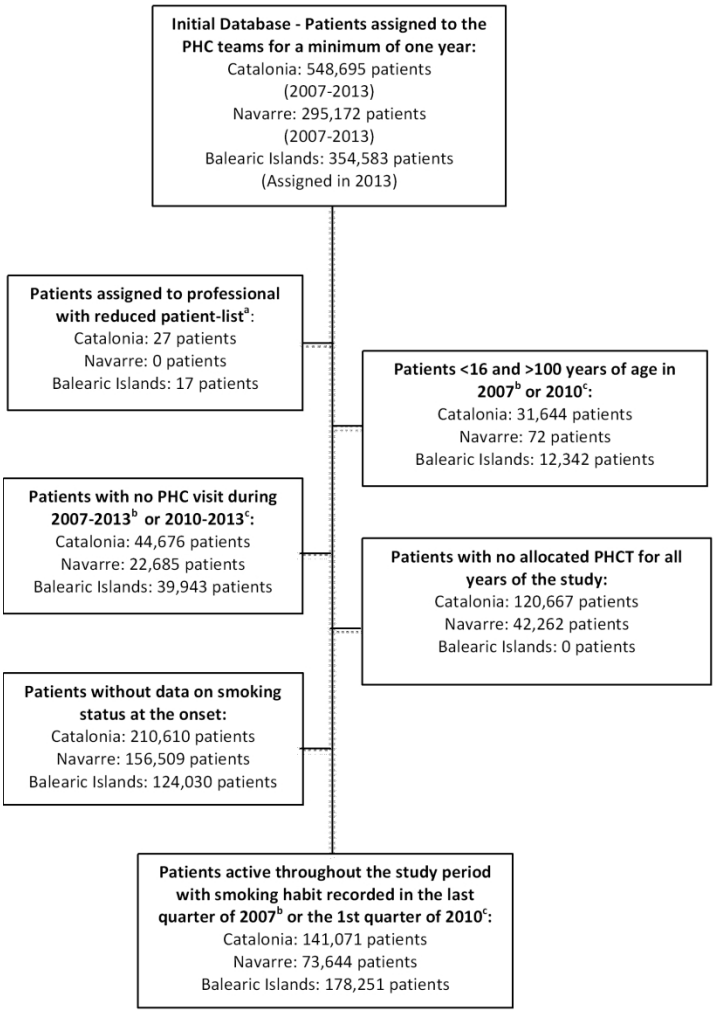
REFERENCES

1. Jha P. Avoidable global cancer deaths and total deaths from smoking. *Nat Rev Cancer* 2009;9:655–64.
2. Murray CJL, Lopez AD. Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. *Lancet* 2017;349:1498–504.
3. World Health Organization, and Tobacco Free Initiative. Building blocks to tobacco control: a hand-book. (Tools for advancing tobacco control in the 21st century). Geneva*: WHO;* 2004.
4. Federico B, Mackenbach JP, Eikemo TA, *et al*. Impact of the 2005 smoke-free policy in Italy on prevalence, cessation and intensity of smoking in the overall population and by educational group. *Addiction* 2012;107:1677–86.
5. Hahn EJ, Rayens MK, Butler KM, *et al*. Smoke-free laws and adult smoking prevalence. *Prev Med* 2008;47:206–9.
6. Nagelhout GE, Willemsen MC, de Vries H. The population impact of smoke-free workplace and hospitality industry legislation on smoking behaviour. Findings from a national population survey. *Addiction* 2011;106:816–23.
7. Hublet A, Schmid H, Clays E, *et al*. Association between tobacco control policies and smoking behaviour among adolescents in 29 European countries. *Addiction* 2009;104:1918–26.
8. Tchicaya A, Lorentz N, Demarest S. Socioeconomic inequalities in smoking and smoking cessation due to a smoking ban: General population-based cross-sectional study in Luxembourg. *PLoS One* 2016;11:1–15.
9. Ye X, Chen S, Yao Z, *et al*. Smoking behaviors before and after implementation of a smoke-free legislation in Guangzhou, China. *BMC Public Health* 2015;15:982.
10. Fichtenberg CM, Glantz SA. Effect of smoke-free workplace on smoking behaviour: systematic review. BMJ 2002;325:188.
11. Frazer K, Callinan JE, McHugh J, *et al.* Legislative smoking bans for reducing harms from secondhand smoke exposure, smoking prevalence and tobacco consumption. *Cochrane database Syst Rev* 2016;2:CD005992.
12. Ley de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro y la publicidad de los productos del tabaco. L. N. 28/2005 (27 diciembre 2005). Available at: https://www.boe.es/buscar/doc.php?id=BOE-A-2005-21261 . Accessed 6-3-2017.
13. Nebot M, Fernández E, (Coords) Evaluación del impacto de la ley de medidas sanitarias frente al tabaquismo. Grupo de Trabajo en Tabaquismo de la Sociedad Española de Epidemiología. Barcelona: Sociedad Española de Epidemiología y Ministerio de Sanidad y Política Social, 9-43. 2009. Available in: URL: http://www.seepidemiologia.es/documents/dummy/Monografia-Grupo%20Trabajo%20sobre%20tabaquismo.pdf)
14. Cordoba R, Villalbi JR, Salvador-Llivina T, *et al.* El proceso en España de la adopción de una legislación eficaz para la prevención del tabaquismo [Spain's process of passing effective smoking prevention legislation]. *Rev Esp Salud Publica* 2006;80:631–45.
15. Nebot M, López MJ, Ariza C, Pérez-Ríos M, *et al*. Impact of the Spanish smoking law on exposure to secondhand smoke in offices and hospitality venues: Before-and-after study. *Environ Health Perspect* 2009;117:344–7.
16. Ley de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro y la publicidad de los productos del tabaco (30 December 2010), por la que se modifica la Ley 28/2005, de 26 de diciembre, de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro, el consumo y la publicidad de los productos del tabaco. Boletín Oficial del Estado (Spanish Official State Bulletin). L. N. 42/2010.No. 318. Available at: https://www.boe.es/buscar/act.php?id=BOE-A-2010-20138 . Accessed 6-3-2017.
17. Regidor E, de Mateo S, Ronda E, *et al.* Heterogeneous trend in smoking prevalence by sex and age group following the implementation of a national smoke-free law. *J Epidemiol Community Health* 2011;65:702–8.
18. Regidor E, Pascual C, Giráldez-García C, *et al.* Impact of tobacco prices and smoke-free policy on smoking cessation, by gender and educational group: Spain, 1993-2012. *Int J Drug Policy* 2015;26:1215–21.
19. Perez-Rios M, Fernandez E, Schiaffino A, *et al*. Changes in the prevalence of tobacco consumption and the profile of Spanish smokers after a comprehensive smoke-free policy. *PLoS One* 2015;10:1–9.
20. Jiménez Ruiz CA, Riesco Miranda JA, Altet Gómez N, *et al*. Impact of legislation on passive smoking in Spain. *Respiration* 2014;87:190–5.
21. Catalina Romero C, Gelpi Médez JA, Cortés Arcas MV, *et al.* Evolución en España del consumo de tabaco en población trabajadora desde la entrada en vigor de la Ley 28/2005 de medidas sanitarias frente al tabaquismo [Prevalence of Tobacco Consumption Among Working Population after the Law 42/2010, Spain]. *Rev Esp salud pública* 2010;84:223–7.
22. Catalina Romero C, Sainz Gutiérrez JC, Quevedo Aguado L*, et al.* Prevalencia de consumo de tabaco en población trabajadora tras la entrada en vigor de la Ley 42/2010 [Prevalence of tobacco consumption among working population after the law 42/2010, Spain]. *Rev Esp Salud Publica* 2012;86:177–88.
23. Pérez-Ríos M, Galán I(editors) Evaluación de las políticas de control del tabaquismo en España (Leyes 28/2005 y

42/2010) Revisión de la evidencia. Grupo de Trabajo en Tabaquismo de la Sociedad Española de Epidemiología. Barcelona: Sociedad Española de Epidemiología y Ministerio de Sanidad y Política Social, 2017;11-74. Available in: URL: http://www.seepidemiologia.es/documents/dummy/V9.0%2520-%2520Libro%2520Tabaquismo%25202017%2520-%2520Abierto%2520Final.pdf

24. de Lluc Bauzà-Amengual M, Blasco-González M, Sánchez-Vazquez E, *et al.* Impacto de la Ley del tabaco en el lugar de trabajo: estudio de seguimiento de una cohorte de trabajadores en España 2005--07 [Impact of the Tobacco Law on the workplace: a follow up study of a cohort of workers in Spain 2005–2007]. *Atención primaria* 2010;42:309–13.
25. Bolíbar B, Pareja C, Astier-Peña MP, *et al*. Variability in the performance of preventive services and in the degree of control of identified health problems: a primary care study protocol. *BMC Public Health* 2008;8:281.
26. The International Statistical Classification of Diseases and Related Health Problems (ICD-10th revision) classification of mental and behavioural disorders: clinical descriptions and diagnostic guidelines. Geneva: World Health Organization, 1992. Available at: http://www.who.int/classifications/icd/en/bluebook.pdf . Accessed 6-3-2017..
27. Okkes IM, Becker HW, Bernstein RM, *et al*.The March 2002 update of the electronic version of ICPC-2. A step forward to the use of ICD-10 as a nomenclature and a terminology for ICPC-2. *Fam Pract* 2002;19:543–6.
28. Kim H-J, Fay MP, Feuer EJ, *et al*. Permutation tests for joinpoint regression with applications to cancer rates. *Stat Med* 2000;19:335–51. Available at: http://onlinelibrary.wiley.com/doi/10.1002/(SICI)1097-0258(20000215)19:3%253C335::AID-SIM336%253E3.0.CO;2-Z/abstract. Accessed 8-3-2017.
29. Lidón-moyano C, Fu M, Ballbè M, *et al*. Addictive Behaviors Impact of the Spanish smoking laws on tobacco consumption and secondhand smoke exposure : A longitudinal population study. *Addict Behav* 2017;75:30–5.
30. Martín-Sánchez JC, Martinez-Sanchez JM, Bilal U, *et al*. Sex and Age Specific Projections of Smoking Prevalence in Spain: A Bayesian Approach. *Nicotine Tob Res* 2017; ntx120, https://doi.org/10.1093/ntr/ntx120.
31. Wilson LM, Avila Tang E, Chander G, *et al.* Impact of tobacco control interventions on smoking initiation, cessation, and prevalence: A systematic review. *J Environ Public Health* 2012; doi:10.1155/2012/961724
32. Guerrero F, Santonja F-J, Villanueva R-J. Analysing the Spanish smoke-free legislation of 2006: a new method to quantify its impact using a dynamic model. *Int J Drug Policy* 2011 Jul;22:247–51.
33. Pinilla J, Abásolo I. The effect of policies regulating tobacco consumption on smoking initiation and cessation in Spain: is it equal across socioeconomic groups? *Tob Induc Dis* 2017;15:8.
34. Longo DR, Johnson JC, Kruse RL, *et al.* A prospective investigation of the impact of smoking bans on tobacco cessation and relapse. *Tob Control* 2001;10:267–72.
35. Shang C. The effect of smoke-free air law in bars on smoking initiation and relapse among teenagers and young adults. *Int J Environ Res Public Health* 2015;12:504–20.
36. Buczkowski K, Marcinowicz L, Czachowski S, *et al.* Motivations toward smoking cessation, reasons for relapse, and modes of quitting: results from a qualitative study among former and current smokers. *Patient Prefer Adherence* 2014;8:1353–63.
37. Schillo BA, Keller PA, Betzner AE, *et al*. Minnesota's smokefree policies: Impact on cessation program participants. *Am J Prev Med* 2012;43:S171–8.
38. Ley foral 6/2003, de 14 de febrero, de prevención del consumo de tabaco, de protección del aire respirable y de la promoción de la salud en relación al tabaco (Navarra). Available at: http://www.lexnavarra.navarra.es/detalle.asp?r=3323. Accessed 31-7-2017
39. Gili M, Garcia Campayo J, Roca M. Crisis económica y salud mental. Informe SESPAS 2014 [Economic crisis and mental health. SESPAS report 2014]. *Gac Sanit* 2014;28 Suppl 1:104–8.
40. Buonanno P, Ranzani M. Thank you for not smoking: Evidence from the Italian smoking ban. *Health Policy* 2013;109:192–9.
41. Camarelles Guillem F, Dalmau González-Gallarza R, Clemente Jiménez L, *et al*. Documento de consenso para la atención clínica al tabaquismo en España [Consensus report for the clinical care of smoking cessation in Spain]. *Med Clin* 2013;140:272.e1-272.e12.
42. Córdoba R, Cabezas C, Camarelles F, *et al.* Recomendaciones sobre el estilo de vida. *Atención primaria* 2012;44:16–22.

Figure 1: Flow-chart of patients included in the study, by region.



Patients belonged to 22 Primary Health Care Teams in each region

[a] *atypical patient-list <400 o >3000; GP with shorter patient lists were accepted if it was their first year in the Primary Health Care Team*

[b] In Catalonia or Navarre

[c] In the Balearic Islands

PHC: Primary health care

Figure 1: Flow-chart of patients included in the study, by region

203x293mm (240 x 240 DPI)

SUPPLEMENTARY DATA FOR *EFFECT OF THE SPANISH COMPREHENSIVE SMOKE-FREE LAW ON TIME TRENDS IN SMOKING BEHAVIOUR IN PRIMARY HEALTH CARE PATIENTS*

Table S1: Age-adjusted rates by direct method per 10,000 inhabitants based on the European Standard Population. CATALONIA N=141,071 (2008-2013).

Quarter	Smoking status prevalence			New smokers incidence	New ex-smokers incidence	Ex-smoker relapses incidence
	Non smokers	Smokers	Ex-smokers			
2008.1	4692.6	4138.9	1168.5	20.8	254.3	226.9
2008.2	4679.3	4099.0	1221.7	21.4	212.9	151.4
2008.3	4668.8	4073.6	1257.6	16.6	267.5	218.5
2008.4	4650.2	4051.7	1298.1	26.1	317.6	100.4
2009.1	4638.8	4053.6	1307.6	25.2	260.1	128.6
2009.2	4628.2	4036.8	1335.1	15.8	228.5	78.3
2009.3	4618.4	4021.6	1360.0	12.7	161.3	113.7
2009.4	4604.4	3998.5	1397.2	19.6	212.7	165.6
2010.1	4590.0	4001.8	1408.2	19.0	160.9	123.1
2010.2	4573.5	3994.3	1432.2	26.4	135.8	148.8
2010.3	4560.0	3981.0	1459.0	20.8	139.0	100.5
2010.4	4539.7	3957.4	1503.0	26.8	188.1	112.5
2011.1	4077.0	3758.0	1510.3	15.1	171.9	103.2
2011.2	4068.6	3721.4	1555.3	12.4	213.0	90.0
2011.3	4061.6	3696.3	1587.3	13.0	145.9	81.4
2011.4	4050.8	3649.8	1644.7	15.8	255.4	91.3
2012.1	4012.6	3658.7	1673.9	13.4	222.7	111.1
2012.2	4004.9	3629.6	1710.7	11.3	171.3	91.9
2012.3	4000.4	3608.5	1736.3	7.9	118.8	70.7
2012.4	3990.2	3579.2	1775.8	11.8	201.3	103.9
2013.1	3963.0	3601.1	1781.2	16.5	184.9	141.7
2013.2	3956.3	3618.6	1770.3	15.2	136.7	247.6
2013.3	3952.8	3635.1	1757.3	9.3	110.7	248.6
2013.4	3946.5	3659.3	1739.5	14.7	172.8	334.5

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S2: Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population. NAVARRE N=73,644 (2008-2013).

Quarter	Smoking status prevalence			New smokers incidence	New ex-smokers incidence	Ex-smoker relapses incidence
	Non smokers	Smokers	Ex-smokers			
2008.1	5652.5	4034.2	313.3	25.3	175.3	227.0
2008.2	5642.5	4013.0	344.5	17.2	181.0	160.4
2008.3	5632.4	4003.3	364.3	16.5	109.1	129.4
2008.4	5620.0	3993.3	386.7	21.4	127.7	230.3
2009.1	5645.0	3951.4	403.7	30.9	136.4	225.4
2009.2	5630.8	3944.1	425.1	23.5	132.1	174.0
2009.3	5623.5	3934.7	441.8	12.5	100.3	100.7
2009.4	5614.7	3925.5	459.8	14.8	109.9	134.7
2010.1	5618.3	3905.9	475.8	27.2	111.2	209.4
2010.2	5605.5	3893.8	500.7	21.1	114.9	132.5
2010.3	5595.1	3889.1	515.8	16.4	82.2	98.7
2010.4	5581.9	3885.3	532.8	21.4	89.9	81.2
2011.1	4990.3	3806.9	548.1	16.0	136.8	141.3
2011.2	4979.2	3795.8	570.2	20.3	116.7	113.8
2011.3	4972.0	3791.7	581.6	12.7	48.6	60.2
2011.4	4964.3	3780.5	600.4	13.8	99.6	118.6
2012.1	4910.7	3804.6	630.0	18.6	127.3	87.6
2012.2	4902.9	3781.3	661.1	13.7	130.1	108.4
2012.3	4897.7	3773.3	674.3	9.8	75.2	58.6
2012.4	4888.9	3760.5	695.8	15.2	110.2	96.0
2013.1	4886.8	3746.7	711.8	15.1	121.0	116.4
2013.2	4876.8	3733.2	735.2	16.9	104.2	97.4
2013.3	4870.8	3727.9	746.6	9.5	60.7	119.1
2013.4	4861.3	3719.8	764.1	16.9	90.7	97.8

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S3: Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population. THE BALEARIC ISLANDS N=178,251 (2010-2013).

Quarter	Smoking status prevalence			New smokers incidence	New ex-smokers incidence	Ex-smoker relapses incidence
	Non smokers	Smokers	Ex-smokers			
2010.2	5411.0	4029.7	559.3	9.3	158.5	576.6
2010.3	5406.4	4007.3	586.2	9.0	151.6	527.0
2010.4	5401.6	3982.7	615.7	9.3	158.7	503.7
2011.1	5375.0	3987.9	637.1	6.6	149.9	545.7
2011.2	5372.4	3959.3	668.4	5.2	170.9	424.4
2011.3	5369.7	3929.5	700.9	5.2	160.1	383.9
2011.4	5367.4	3898.4	734.2	4.0	169.8	385.6
2012.1	5345.3	3888.3	766.4	4.3	188.1	351.8
2012.2	5344.0	3862.4	793.6	2.4	137.0	370.6
2012.3	5342.5	3841.0	816.6	2.9	113.5	372.6
2012.4	5341.7	3818.9	839.4	1.6	133.0	339.2
2013.1	5324.1	3825.3	850.7	2.1	130.5	480.5
2013.2	5317.8	3810.5	871.7	12.1	106.7	453.0
2013.3	5308.3	3800.6	891.1	17.5	93.7	103.9
2013.4	5298.6	3787.4	914.1	17.5	116.8	285.1

Note: 2010.*. represents the quarter * of the year 2010

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S4. Age-adjusted rates by the direct method for 10,000 inhabitants based on the European Standard Population in CATALONIA. N=72,340 (2008-2013).

Quarter	Smoking Status prevalence						New smokers incidence		New ex-smokers incidence		Ex-smoker relapse incidence	
	Non smokers		Smokers		Ex-smokers							
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
2008.1	5909.5	3349.2	3411.5	4910.7	679.0	1740.1	16.6	27.8	246.7	260.5	315.2	158.2
2008.2	5900.4	3331.6	3385.4	4856.2	714.2	1812.2	14.3	34.4	266.5	202.9	101.2	195.0
2008.3	5891.9	3318.8	3368.4	4822.1	739.7	1859.1	14.0	21.8	275.0	265.9	289.0	166.5
2008.4	5876.9	3296.1	3356.2	4789.4	766.9	1914.5	24.0	31.9	254.1	329.2	112.0	99.6
2009.1	5832.7	3323.5	3379.8	4769.9	787.5	1906.6	27.8	26.3	289.2	234.0	148.8	105.2
2009.2	5823.1	3311.7	3366.5	4749.0	810.4	1939.3	13.7	19.7	182.0	237.8	89.5	79.2
2009.3	5814.6	3300.6	3356.3	4728.4	829.2	1971.1	11.9	15.3	154.4	165.8	181.4	65.8
2009.4	5804.4	3282.4	3335.4	4702.6	860.2	2015.0	14.3	28.0	243.3	203.9	188.5	152.0
2010.1	5757.2	3312.5	3359.5	4679.7	883.3	2007.8	14.0	26.7	201.5	144.1	133.5	109.4
2010.2	5744.1	3292.3	3355.5	4668.2	900.4	2039.6	24.1	30.4	146.6	131.6	164.1	152.0
2010.3	5730.0	3279.4	3345.8	4650.5	924.2	2070.2	20.7	22.7	156.1	134.4	106.6	98.0
2010.4	5710.9	3256.8	3332.3	4616.4	956.8	2126.8	30.9	24.3	205.4	177.3	132.2	114.9
2011.1	5231.2	2821.0	3138.8	4408.8	975.2	2115.4	15.0	16.8	181.1	166.1	62.6	146.7
2011.2	5223.4	2811.7	3115.8	4356.5	1006.0	2177.1	12.2	14.3	231.6	203.8	118.9	65.4
2011.3	5216.7	2804.3	3095.4	4326.8	1033.2	2214.1	12.4	15.2	166.4	136.0	93.0	68.5
2011.4	5209.6	2789.1	3057.6	4270.9	1078.0	2285.2	12.1	21.2	308.9	241.6	111.0	78.8
2012.1	5142.2	2792.0	3082.8	4259.8	1120.2	2293.5	9.3	19.1	251.1	216.5	140.4	83.6
2012.2	5136.1	2782.4	3059.1	4225.1	1150.0	2337.7	10.4	12.4	215.6	162.3	107.4	75.8
2012.3	5132.0	2777.7	3041.8	4200.0	1171.4	2367.6	8.7	7.3	135.6	113.1	61.0	80.2
2012.4	5123.4	2765.4	3020.5	4161.9	1201.3	2417.9	10.2	16.2	192.8	203.5	128.5	89.1
2013.1	5063.9	2781.5	3055.9	4167.2	1225.4	2396.5	15.4	19.9	213.2	180.4	167.8	123.5
2013.2	5058.8	2773.4	3057.2	4202.9	1229.3	2368.9	10.3	21.9	146.9	131.3	216.4	251.9
2013.3	5055.0	2770.2	3060.2	4234.1	1230.0	2340.9	9.0	10.7	127.0	106.7	217.7	263.3
2013.4	5049.2	2763.3	3063.6	4281.9	1232.5	2300.1	11.8	21.1	202.8	159.2	325.6	315.6

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S5. Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population in NAVARRE. N=37,898 (2008-2013).

Quarter	Smoking Status prevalence						New smokers incidence		New ex-smokers incidence		Ex-smoker relapse incidence	
	Non smokers		Smokers		Ex-smokers							
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
2008.1	6224.8	5021.1	3542.5	4569.6	232.7	409.3	22.3	31.0	152.7	172.3	164.4	295.8
2008.2	6215.3	5010.6	3527.8	4539.7	256.9	449.7	15.2	20.3	168.7	187.7	136.9	173.7
2008.3	6207.4	4998.8	3518.5	4528.6	274.2	472.6	11.5	22.1	147.1	97.1	147.9	123.7
2008.4	6198.6	4982.4	3510.9	4515.4	290.4	502.2	14.8	30.0	157.9	125.6	296.5	98.8
2009.1	6209.7	5028.3	3485.7	4451.5	304.6	520.2	24.9	39.7	184.8	111.3	254.0	197.0
2009.2	6197.8	5011.6	3480.3	4441.1	321.9	547.3	17.4	32.6	177.2	127.7	152.7	171.7
2009.3	6191.6	5003.2	3475.5	4426.3	332.9	570.4	10.7	15.2	108.4	98.3	73.4	111.5
2009.4	6186.2	4990.0	3470.2	4413.1	343.6	596.9	8.4	24.0	97.2	115.8	126.6	134.7
2010.1	6175.4	5014.1	3464.6	4375.5	360.0	610.4	22.6	33.5	115.7	112.9	224.3	208.6
2010.2	6164.6	4999.4	3455.7	4359.8	379.7	640.8	16.4	27.9	119.1	114.5	106.4	129.5
2010.3	6154.5	4988.6	3456.0	4350.4	389.5	661.0	16.2	17.0	111.3	75.9	88.3	94.5
2010.4	6142.1	4974.6	3455.4	4343.4	402.5	682.1	17.8	26.3	126.9	80.9	71.3	85.7
2011.1	5541.4	4399.8	3388.4	4248.3	415.4	697.1	12.2	21.0	146.2	135.4	91.3	183.2
2011.2	5532.4	4386.6	3381.0	4233.8	431.9	724.9	15.5	26.8	151.1	110.6	117.2	103.9
2011.3	5524.7	4379.8	3377.8	4228.5	442.7	737.0	12.6	13.7	55.8	44.9	61.6	54.1
2011.4	5518.9	4370.0	3369.7	4213.6	456.6	761.7	9.6	19.5	118.2	95.4	70.0	160.8
2012.1	5452.1	4335.6	3408.9	4217.7	484.2	792.0	15.9	22.5	129.3	126.5	106.9	65.3
2012.2	5445.6	4326.1	3389.4	4190.1	510.2	829.0	11.7	17.2	125.1	131.6	95.3	114.5
2012.3	5442.6	4318.6	3385.2	4178.7	517.4	847.9	6.2	14.2	67.6	78.0	68.6	41.2
2012.4	5434.5	4308.9	3379.5	4159.1	531.2	877.2	12.5	19.6	130.8	110.0	66.7	126.7
2013.1	5420.0	4323.0	3380.9	4128.0	544.3	894.2	14.1	16.4	133.8	124.7	68.6	157.5
2013.2	5413.7	4309.1	3367.7	4114.5	563.9	921.6	10.1	25.2	103.2	104.7	87.0	98.4
2013.3	5408.6	4302.1	3363.6	4108.1	573.1	935.1	7.2	12.7	72.3	57.3	152.7	85.9
2013.4	5399.9	4291.6	3360.4	4094.8	584.9	958.8	13.9	21.7	65.6	102.8	72.2	116.0

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S6. Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population in THE BALEARIC ISLANDS. N= 94,164 (2010-2013).

Quarter	Smoking Status prevalence						New smokers incidence		New ex-smokers incidence		Ex-smoker relapse incidence	
	Non smokers		Smokers		Ex-smokers							
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
2010.2	6224.8	4484.3	3412.3	4723.7	362.9	792.0	8.9	9.9	106.8	169.6	631.1	560.7
2010.3	6220.5	4479.3	3395.5	4695.0	384.0	825.7	8.2	10.4	149.6	147.6	576.9	435.9
2010.4	6215.8	4474.3	3376.3	4664.4	408.0	861.2	8.8	10.1	179.3	150.7	484.7	571.6
2011.1	6171.2	4472.1	3395.3	4651.8	433.5	876.2	6.7	6.6	141.1	146.7	562.7	508.9
2011.2	6168.5	4469.8	3375.7	4612.8	455.9	917. 5	5.2	5.4	140.3	173.8	446.1	426.0
2011.3	6165.8	4467.0	3353.4	4574.6	480.8	958.4	4.9	6.0	162.5	154.9	400.9	391.6
2011.4	6163.2	4465.3	3330.1	4534.6	506.8	1000.1	4.6	3.4	149.3	170.9	296.8	540.3
2012.1	6118.6	4474.0	3337.9	4501.2	543.6	1024.8	3.7	5.1	179.3	182.1	306.5	461.7
2012.2	6117.0	4473.2	3318.1	4468.3	564.9	1058.5	2.8	1.9	109.0	139.6	359.8	348.7
2012.3	6115.2	4471.9	3302.0	4440.5	582.8	1087.6	3.2	2.5	103.4	112.8	376.5	363.9
2012.4	6114.3	4471.2	3285.7	4411.7	600.0	1117.0	1.7	1.6	122.8	132.9	414.0	213.4
2013.1	6077.2	4479.2	3302.2	4406.4	620.6	1114.4	0.9	4.1	137.9	122.6	492.0	470.3
2013.2	6070.8	4473.1	3291.1	4387.8	638.2	1139.1	11.9	12.7	91.0	105.4	410.8	532.6
2013.3	6056.9	4468.7	3288.0	4370.1	655.1	1161.2	23.4	10.4	94.4	90.1	110.4	87.5
2013.4	6046.1	4460.3	3280.8	4349.5	673.1	1190.2	18.2	16.9	100.0	121.4	342.4	116.1

Note: 2010.*. represents the quarter * of the year 2010

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6-7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	6 + Figure 1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7-8
		(*b*) Describe any methods used to examine subgroups and interactions	7-8
		(*c*) Explain how missing data were addressed	6 + 15
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6, 8. Figure 1
		(b) Give reasons for non-participation at each stage	6. Figure 1
		(c) Consider use of a flow diagram	6. Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8. Table 1.
		(b) Indicate number of participants with missing data for each variable of interest	8
Outcome data	15*	Report numbers of outcome events or summary measures	8-12. Tables 2-4
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-12. Tables 2-4
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14-15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	15-16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

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Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

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Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

ABSTRACT

Objective: This study aimed to analyse the impact of comprehensive smoke-free legislation on the prevalence and incidence of adult smoking in Primary Health Care patients from three Spanish regions, overall and stratified by sex.

Design: Longitudinal observational study conducted between 2008 and 2013.

Setting: 66 Primary Health Care teams in Catalonia, Navarre and the Balearic Islands (Spain).

Participants: Population over 15 years of age assigned to Primary Health Care teams.

Primary and secondary outcomes measures: Quarterly age-standardized prevalence of non-smoker, smoker and ex-smoker and incidence of new smoker, new ex-smoker and ex-smoker relapse rates were estimated with data retrieved from PHC electronic health records. Joinpoint analysis was used to analyse the trends of age-standardized prevalence and incidence rates**.** Trends were expressed as annual percentage change and average annual percent change.

Results: The overall standardized smoker prevalence rate showed a significant downward trend (higher in men than women) and the overall standardized ex-smoker prevalence rate showed a significant increased trend (higher in women than men) in the three regions. Standardized smoker and ex-smoker prevalence rates were higher for men than women in all regions. With regard to overall trends of incidence rates, new smokers decreased significantly in Catalonia and Navarre and similarly in men and women, new ex-smokers decreased significantly and more in men in Catalonia and the Balearic Islands**,** and ex-smoker relapse increased in Catalonia, particularly in women, and decreased in Navarre.

Conclusions: Trends on smoking behaviour in Primary Health Care patients remain unchanged after the implementation of comprehensive smoke-free legislation.

Keywords: Electronic health records; Joinpoint analysis; Primary Health Care; Smoke-Free Policy; Smoking.

Strengths and limitations of this study

- To our knowledge, no studies have been published on the impact of the Spanish comprehensive smoke-free legislation in all adult Primary Health Care patients
- Used as a research tool, electronic health records portray real-life conditions and provide comprehensive, long-term health histories from a large population sample
- The results of quarterly data by joinpoint analysis provides more precise information than an analysis before-after the implementation of the Law
- This study only considered age and sex since other variables were not available for the adjusted analysis.
- The study period started later (shorter follow-up) in the Balearic Islands to ensure reliability of data

Effect of the Spanish comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

INTRODUCTION

Smoking is the leading worldwide cause of preventable death.[1] According to the World Health Organization (WHO), it is estimated that at least 30 million people may die prematurely from tobacco-related diseases.[2] Legislative measures have been adopted to protect people's health in public areas and workplaces. These include increasing the price of cigarettes, banning advertising, sponsorship and smoking in workplaces and public spaces, displaying warnings on tobacco packets and implementing prevention programs.[3]

Some studies show a decrease in smoking prevalence since the introduction of smoke-free legislation (SFL).[4–9] A metanalysis of 26 studies on the effect of the smoke-free workplace in various countries concluded in 2002 that smoke-free workplaces protect not only non-smokers from the dangers of passive smoking, but they also encourage smokers to reduce tobacco consumption. The authors concluded that SFL is associated with a 3% to 4% reduction in tobacco consumption.[10] In contrast, a Cochrane review published in 2016 which included 24 studies on smoking behaviour showed inconsistencies regarding the impact of smoking bans on smoking prevalence and tobacco consumption.[11]

On January 1, 2006, the Spanish government introduced a partial SFL (Law 28/2005),[12] which included regulations on the sale, supply, consumption and advertising of tobacco products. Smoking was banned in all indoor public and private workplaces with the exception of the hospitality sector, where partial restrictions were established depending on the size of the establishment, i.e., in bars or restaurants smaller than 100 m2 the managers could decide whether to allow smoking in the premises (Law 28/2005). The mean concentration of nicotine subsequently decreased by 60% in public administration offices and by 97.4% in private workplaces, but in areas where smoking was permitted, including bars and nightclubs, no changes were found.[13–15] This prompted the enactment of a comprehensive SFL (Law 42/2010),[16] which came into force in January 2011. This comprehensive law expanded smoking restriction to all hospitality venues of any size and, as a result, smoking was forbidden in all enclosed public places, including bars, restaurants and nightclubs, and in some open-air public places such as playgrounds.

Some studies have analysed the impact of these two Spanish laws on smoking prevalence. However, most have been based on health surveys[13,17–20] and surveys of hospitality workers.[21,22] Moreover, some studies evaluate only the partial law,[13,17,18] whereas others analyse the compound impact of both laws.[19,20,23,24] The results of these studies are often conflicting; while some conclude that the partial SFL does not have any effect on the downward trend in the prevalence of smokers,[13,19,23] other studies show a reduction in smoking prevalence[24], an increase of the smoking quit-ratio in the short term[18] and minor increases in the prevalence of active smoking.[20]

Only one study conducted in primary health care (PHC) patients evaluates the impact of the Spanish partial SFL, including smoking prevalence in active smoker workers that attended PHC visits; one month after the implementation

of the law, a 9.5% decline of smokers was observed.[25] To our knowledge, no studies have been published on the impact of the Spanish comprehensive SFL in all adult PHC patients. In view of the pivotal role of PHC services in smoking habits, we consider that the information registered in PHC records is a good proxy to generate up-to-date evidence and to evaluate the impact of comprehensive SFL in the general population.

We hypothesized that Law 42/2010 does not only reduce exposure to environmental cigarette smoke and its harmful effects but crucially, it promotes smoking denormalisation in society, thus encouraging smokers to quit or reduce consumption and discouraging non-smokers from initiating this habit. Accordingly, the aim of this study was to examine the impact of the Spanish comprehensive SFL (Law 42/2010) on the prevalence and incidence of adult smoking in PHC patients in three regions (Catalonia, Navarre and Balearic Islands), during the 2008-2013 period, overall and stratified by sex.

METHODS

Design, study participants and information source

Longitudinal observational study of the adult population assigned to 66 Primary Health Care teams (PHCT) in three Spanish regions: Catalonia, Navarre and the Balearic Islands (22 PHCT per region). Inclusion criteria of the PHCT were: 1) computerization of electronic health records (EHR) by January 1, 2005 in Catalonia and Navarre, and 2008 in the Balearic Islands; and 2) agreement to participate in the study by over 80% health-care professionals working in each PHCT. Random cluster sampling was stratified by region, with the PHCT as randomization unit.[26] In each PHCT, General Practitioners (GP) with a patient list between 400 and 3000 were selected. GP with shorter patient lists were accepted if it was their first year in the PHCT.

The study period included from the first quarter of 2008 to the fourth quarter of 2013 in Catalonia and Navarre; and from the second quarter of 2010 to the fourth quarter of 2013 in the Balearic Islands. The study started in 2008 to obtain data from the 2 years prior analysis, a requirement to adequately construct the variable ex-smoker. In the case of the Balearic Islands, the study started later to ensure reliability of data.

Inclusion criteria for patients were: 1) Population allocated to the selected PHCT for the whole 2007-2013 period in Catalonia and Navarre; in the Balearic Islands, patients allocated to the selected PHCT in 2013 and evaluated retrospectively (no historical annual comprehensive register of allocation of patients was available). 2) Age ≥16 and ≤100 years in 2007 in Catalonia and Navarre, and 2010 in the Balearic Islands. 3) In order to have data in the EHR collected during the study period, a minimum of one visit to their PHCT during the 2007-2013 period in Catalonia and Navarre and 2010-2013 in the Balearic Islands; and 4) Information on smoking habit recorded in the EHR for the quarter prior to the onset of the study: last quarter of 2007 in Catalonia and Navarre and first quarter of 2010 in the Balearic Islands, to enable the adequate construction of the various variables. Thus, closed cohorts (with fixed membership, where nobody is added nor excluded after the study begins) were constituted in the three regions. Figure 1 shows the flowchart of the study.

Data were retrieved from the REGIPREV database,[25] which contains encrypted and anonymized clinical information recorded in the EHR by these 66 PHCT. An algorithm was applied to extract equivalent data from the health records software used in each region: "ECAP" in Catalonia, "Atenea" in Navarre and "e-siap" in the Balearic Islands. Codes of the International Classification of Diseases, 9th revision in the Balearic Islands (ICD-9) and 10th in Catalonia (ICD 10th revision)[27] and the International Classification of Primary Care, Second edition, in Navarre (ICPC-2)[28] were used.

Variables

The dependent variables originate from clinical variables (number of cigarettes per day, history of smoking, history of advice for smoking cessation) and from diagnostic codes to classify diseases (codes F17.0 to F17.9 and Z72.0 of the ICD-10, 305.1 of the ICD-9 and P17 of the ICPC-2) recorded in the EHR. We created the following variables at the end of each quarter of the study period:

- Smoking status (three categories): 1) non-smoker: patient that has never been a tobacco consumer, 2) smoker: tobacco consumer or patient that has quit smoking for less than 12 months; and 3) ex-smoker: patient who used to smoke but has quit smoking for at least 12 continuous months. If the EHR did not contain a new entry related to the smoking status, we assumed that no changes had taken place and thus the last observation was carried forward.
- New smoker: patient non-smoker for the 12 months prior to the considered quarter that has started smoking during said quarter.
- New ex-smoker: the patient was a smoker two years before the considered quarter and has continuously abstained from tobacco for at least 12 months.
- Ex-smoker relapse: patient ex-smoker during the 12 months prior to the considered quarter that has started smoking again during said quarter.

For higher accuracy in prevalence and incidence changes, quarterly estimates were calculated.

The following variables of each patient were collected at baseline (2008 in Catalonia and Navarre; 2010 in the Balearic Islands): age, sex (male/female), annual number of health problems and annual number of PHC visits. The number of health problems was used as a morbidity indicator; it was calculated as the sum of the number of different active health problems (chronic and acute, coded by ICPC-2).

Data analyses

Descriptive statistics were used to summarize overall information. Categorical variables were expressed as percentage, and continuous variables as mean (standard deviation) or median (interquartile range [IQR]).

Because the three regions used different EHR systems (different standards and computer programs), different complementary measures to the SFL and also due to the shorter study period in the Balearic Islands, we performed a stratified analysis per region, overall and by sex. Age-standardized prevalence (non-smokers, smokers and ex-smokers) and incidence (new smokers, new ex-smokers and ex-smoker relapse) rates were calculated for each quarter using the direct method, and based on the European Standard Population (rates per 10,000 inhabitants).

Joinpoint analysis was used to analyse the trends of age-standardized prevalence (smokers and ex-smokers) and incidence rates (new smokers, new ex-smokers and ex-smoker relapse) and to identify the best-fitting points (the 'joinpoints', in calendar quarters) where the rate changes significantly in the linear slope of the temporal trend. Significant changes include changes in direction or in the rate of increase or decrease[29]. Joinpoint analysis estimates the magnitude of the increase or the decrease observed in each specified time interval by estimating the annual percentage change (APC). In addition, temporal trends were expressed as the average annual percent change (AAPC), computed to summarize and compare these trends over the entire time period. Ninety-five percent confidence intervals (95% CI) of APC and AAPC were calculated.

Analyses were performed using Stata/SE version 14.2 for Windows (Stata Corp. LP, College Station, Texas, US). The joinpoint regression analysis was carried out using the joinpoint software from the Surveillance Research Program of the US National Cancer Institute [ref. Joinpoint Regression Program, Version 4.3.1. April, 2016; Statistical Research and Applications Branch, National Cancer Institute] (National Cancer Institute. Statistical Research and Applications Branch) [On-line: https://surveillance.cancer.gov/branches/srab/].

RESULTS

The study population was 392,966 patients: 141,071 in Catalonia, 73,644 in Navarre and 178,251 in the Balearic Islands (Figure 1). At the onset of the study, the mean age was 50.4 years in Catalonia, 54.0 in Navarre and 47.7 in the Balearic Islands. In the three cohorts more than half were women (>51 %). Catalonia presented the highest median number of visits (9, IQR: 3 -16) and the Balearic Islands presented the highest number of recorded active health problems per patient (median 10, IQR: 6-16) (Table 1).

Table 1: Characteristics of the cohort study population by region at the onset of the study (2008 in Catalonia and Navarre, 2010 in the Balearic Islands).

	Catalonia N =141,071	**Navarre** N = 73,644	**Balearic Islands** N =178,251
Age (years), SD	50.37 (17.23)	54.04 (18.26)	47.65 (17.56)
Sex (female), number (%)	72340 (51.28)	37898 (51.46)	94164 (52.83)
Number of visits, mean (SD); median (IQR)	11.69 (12.19); 9.00 (3.00-16.00)	8.93 (9.30); 7.00 (3.00-12.00)	11.01 (13.25); 7.00 (3.00-15.00)
Number of health problems, mean (SD); median (IQR)	6.23 (4.58); 5.00 (3.00-8.00)	9.95 (5.39); 9.00 (6.00-13.00)	11.85 (7.74); 10.00 (6.00-16.00)

Abbreviations: SD, standard deviation; IQR, interquartile range.
Patients belonged to 22 Primary Health Care Teams in each region.

The **overall standardized smoker prevalence rates** were of similar magnitude in the three regions (ranges of 3579.2 - 4138.9 in Catalonia; 3719.8 - 4034.2 in Navarre; and 3787.4 - 4029.7 in the Balearic Islands). The prevalence rate

decreased in Navarre during the whole study period, decreased in the Balearic Islands in most quarters, and also in Catalonia except for the last year. These rates were higher for men than for women in all regions (Supplementary File Tables S1-S6). A significant downward **overall trend of smoker prevalence rates** was found in Catalonia (AAPC=- 2.02), Navarre (AAPC= -1.40) and the Balearic Islands (AAPC= -1.75); this downward trend was higher for men than for women in the three regions. In Catalonia, the most significant reduction occurred during the period 2010.3-2011.2 (APC= -8,77), similarly to the Balearic Islands (2010.2-2012.4; APC= -2.11), whereas in Navarre it occurred between 2008.1-2011.3 (APC= -1.69) (Tables 2, 3, 4, Supplementary File Figure S1).

For the whole period, the **overall standardized ex-smoker prevalence rates** increased in Navarre, in the Balearic Islands and in Catalonia except for the last year. The rates in Catalonia were higher (ranges of: 1168.5 - 1781.2 in Catalonia; 313.3 - 764.1 in Navarre; and 559.3 - 914.1 in the Balearic Islands). The standardized ex-smoker prevalence rates were higher for men than for women in all regions (Supplementary File Tables S1-S6). The **overall trend of ex-smoker prevalence rates** increased significantly in the three regions throughout the study period but was higher in Navarre (Navarre AAPC= 16.67; Catalonia AAPC= 7.18; Balearic Islands AAPC= 14.92). The increase in the prevalence rate of ex-smokers was higher for the 2008.1-2008.3 period in Catalonia and Navarre, and for 2010.2-2012.2 in the Balearic Islands, and higher in women in the three regions (women: Catalonia AAPC= 10.83; Navarre AAPC=17.37 and Balearic Islands AAPC= 19.20) (Tables 2, 3, 4, Supplementary File Figure S1).

The **overall new smoker standardized incidence rates** showed low values in the three regions (ranges of 7.9 - 26.8 in Catalonia; 9.5 - 30.9 in Navarre; 1.6 - 17.5 in the Balearic Islands) and higher for men than for women in Catalonia and Navarre (Supplementary File Tables S1-S6). The **overall trend of new smoker incidence rates** decreased significantly in Catalonia (AAPC= -10.65) and Navarre (AAPC= -9.44); additionally, the decline was similar for men and women. In contrast, the trend remained stable in the Balearic Islands (Tables 2, 3, 4, Supplementary File Figure S2).

The **overall standardized new ex-smoker incidence rates** showed higher values in Catalonia (range: 110.7 - 317.6) than in Navarre (range: 48.6 - 181.0) and the Balearic Islands (range: 93.7 - 188.1) (Supplementary File Tables S1-S6). The **overall trend of new ex-smoker incidence rates** showed a significant decrease in Catalonia (AAPC= -7.37) and especially in the Balearic Islands (AAPC= -11.72). This downward trend was higher for men than for women in Catalonia and the Balearic Islands (Tables 2, 3, 4, Supplementary File Figure S2).

The **overall standardized ex-smoker relapse incidence rates** presented higher values in the Balearic Islands (range: 103.9 - 576.6) than in Catalonia (range: 70.7 - 334.5) and Navarre (range: 58.6 - 230.3) (Supplementary File Tables S1-S6). The **overall trend of ex-smoker relapse incidence rates** showed significant increases in Catalonia (AAPC= 18.91), particularly in women (AAPC= 14.99). In contrast, Navarre showed significant decreases (AAPC= -11.37) (Tables 2, 3, 4, Supplementary File Figure S2).

Table 2. Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse. Jointpoints overall and by sex in CATALONIA. N=141,071 (2008-2013)

	Trend 1		Trend 2		Trend 3		Trend 4		Trend 5		AAPC (95% IC) 2008.1 - 2013.4
	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC(95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	
Smoker prevalence											
F	2008.1 - 2010.3	-0.48[d] (-1.03 ; 0.08)	2010.3 - 2011.2	-10.27[c] (-17.96 ; -1.86)	2011.2 - 2013.4	-0.58[c] (-1.11 ; -0.04)					-1.86[a] (-2.95 ; -0.75)
M	2008.1 - 2010.3	-1.96[a] (-2.23 ; -1.70)	2010.3 - 2011.2	-8.26[a] (-12.11 ; -4.24)	2011.2 - 2012.4	-3.01[a] (-3.82 ; -2.18)	2012.4 - 2013.4	2.69[a] (1.48 ; 3.91)			-2.30[a] (-2.86 ; -1.73)
G	2008.1 - 2010.3	-1.33[a] (-1.65 ; -1.00)	2010.3 - 2011.2	-8.77[b] (-13.46 ; -3.83)	2011.2 - 2011.4	-2.30[a] (-3.29 ; -1.29)	2012.4 - 2013.4	2.02[c] (0.56 ; 3.50)			-2.02[a] (-2.71 ; -1.32)
Ex-smoker prevalence											
F	2008.1 - 2008.4	17.32[a] (13.34 ; 21.44)	2008.4 - 2011.2	11.23[a] (10.59 ; 11.87)	2011.2 - 2012.1	15.78[a] (8.71 ; 23.30)	2012.1 - 2013.1	9.61[a] (6.34 ; 12.98)	2013.1 - 2013.4	0.52[d] (-2.16 ; 3.28)	10.83[a] (9.74; 11.94)
M	2008.1 - 2008.3	14.77[c] (3.01 ; 27.86)	2008.3 - 2011.1	5.48[a] (4.55 ; 6.42)	2011.1 - 2012.4	7.54[a] (5.93 ; 9.17)	2012.4 - 2013.4	-4.85[a] (-7.29 ; -2.34)			4.99[a] (3.86 ; 6.13)
G	2008.1 - 2008.3	16.69[a] (7.59 ; 26.57)	2008.3 - 2011.1	7.63[a] (6.90 ; 8.37)	2011.1 - 2012.4	9.68[a] (8.40 ; 10.96)	2012.4 - 2013.4	-2.35[c] (-4.31 ; -0.35)			7.18[a] (6.31 ; 8.07)
New smokers incidence											
F	2008.1 - 2013.4	-11.00[b] (-17.19 ; -4.35)									-11.00[b] (-17.19 ; -4.35)
M	2008.1 - 2013.4	-10.68[a] (-15.90 ; -5.14)									-10.68[a] (-15.90 ; -5.14)
G	2008.1 - 2013.4	-10.65[a] (-15.45 ; 5.59)									-10.65[a] (-15.45 ; 5.59)
New ex-smokers incidence											
F	2008.1 - 2013.4	-5.17[d] (-10.33 ; 0.29)									-5.17[d] (-10.33 ; 0.29)
M	2008.1 - 2013.4	-7.89[b] (-13.23 ; -2.22)									-7.89[b] (-13.23 ; -2.22)
G	2008.1 - 2013.4	-7.37[b] (-12.47 ; -1.96)									-7.37[b] (-12.47 ; -1.96)
Ex-smokers relapse incidence											
F	2008.1 - 2012.3	-8.62[d] (-18.97 ; 3.05)	2012.3 - 2013.4	163.01[a] (60.46 ; 331.10)							14.99[c] (0.62 ; 31.41)
M	2008.1 - 2009.3	-47.87[d] (-82.66 ; 56.76)	2009.3 - 2010.2	118.99[d] (-100 ; 1329577)	2010.2 - 2012.3	-27.30[d] (-49.13 ; 3.88)	2012.3 - 2013.2	527.0[d] (-75.9 ; 16209.4)	2013.2 - 2013.4	74.88[d] (-70.67 ; 942.8)	10.03[d] (-62.75 ; 225.05)
G	2008.1 - 2012.3	-7.94[d] (-16.33 ; 1.30)	2012.3 - 2013.4	198.72[a] (116.0 ; 313.1)							18.91[a] (8.01 ; 30.90)

Note: 2008.*. represents the trimester * of the year 2008

APC, annual percentage change and AAPC, average annual percent change estimated by joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.
[a] p≤ 0.001; [b] p≤ 0.01; [c] p≤ 0.05; [d] p>0.05

Table 3. Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse. Jointpoints overall and by sex in NAVARRE. N=73,644 (2008-2013)

	Trend 1		Trend 2		Trend 3		Trend 4		Trend 5		AAPC (95% IC) 2008.1 - 2013.4
	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	
Smoker prevalence											
F	2008.1 - 2010.3	-0.95[a] (-1.23 ; -0.67)	2010.3 - 2011.2	-2.39[d] (-6.56 ; 1.96)	2011.2 - 2013.4	-0.22[d] (-0.51 ; 0.08)					-0.82[b] (-1.36 ; -0.28)
M	2008.1 - 2013.4	-1.95[a] (-2.06 ; -1.84)									-1.95[a] (-2.06 ; -1.84)
G	2008.1 - 2011.3	-1.69[a] (-1.90 ; -1.48)	2011.3 - 2013.4	-0.95[a] (-1.39 ; -0.52)							-1.40[a] (-1.60 ; -1.20)
Ex-smoker prevalence											
F	2008.1 -2008.3	41.34[a] (25.34 ; 59.38)	2008.3 - 2010.2	19.33[a] (17.20 ; 21.50)	2010.2 - 2011.3	13.11[a] (9.64 ; 16.70)	2011.3 - 2012.2	20.16[b] (9.28 ; 32.12)	2012.2 - 2013.4	10.28[a] (8.87 ; 11.72)	17.37[a] (15.50 ; 19.26)
M	2008.1 - 2008.3	34.19[a] (16.08 ; 55.11)	2008.3 - 2009.4	19.48[a] (14.38 ; 24.80)	2009.4 - 2012.4	13.63[a] (12.85 ; 14.41)	2012.4 - 2013.4	9.63[a] (6.53 ; 12.81)			15.82[a] (14.08 ; 17.60)
G	2008.1 - 2008.3	36.52[a] (17.15 ; 59.08)	2008.3 - 2009.4	20.06[a] (14.63 ; 25.75)	2009.4 - 2012.4	14.66[a] (13.80 ; 15.52)	2012.4 - 2013.4	9.66[a] (6.27 ; 13.16)			16.67[a] (14.81 ; 18.57)
New smokers incidence											
F	2008.1 - 2013.4	-9.43[b] (-15.71 ; -2.68)									-9.43[b] (-15.71 ; -2.68)
M	2008.1 - 2013.4	-9.38[b] (-15.04 ; -3.35)									-9.38[b] (-15.04 ; -3.35)
G	2008.1 - 2013.4	-9.44[b] (-14.84 ; -3.68)									-9.44[b] (-14.84 ; -3.68)
New ex-smokers incidence											
F	2008.1 - 2013.4	-9.66[b] (-14.86 ; -4.14)									-9.66[b] (-14.86 ; -4.14)
M	2008.1 - 2013.4	-2.68[d] (-9.12 ; 4.22)									-2.68[d] (-9.12 ; 4.22)
G	2008.1 - 2013.4	-5.00[d] (-10.75 ; 1.11)									-5.00[d] (-10.75 ; 1.11)
Ex-smoker relapse incidence											
F	2008.1 - 2013.4	-13.88[a] (-19.74 ; -7.61)									-13.88[a] (-19.74 ; -7.61)
M	2008.1 - 2013.4	-12.03[c] (-20.16 ; -3.06)									-12.03[c] (-20.16 ; -3.06)
G	2008.1 - 2013.4	-11.37[a] (-17.23 ; -5.09)									-11.37[a] (-17.23 ; -5.09)

Note: 2008.*. represents the trimester * of the year 2008

APC, annual percentage change and AAPC, average annual percent change estimated by joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.

[a] p≤ 0.001; [b] p≤ 0.01; [c] p≤ 0.05; [d] p>0.05

Table 4. Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse. Jointpoints overall and by sex in THE BALEARIC ISLANDS. N=178,251 (2010-2013)

	Trend 1		Trend 2		Trend 3		AAPC (95% IC) 2008.1 - 2013.4
	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	
Smoker prevalence							
F	2010.2 - 2013.4	-1.20[a] (-1.40 ; -1.01)					-1.20[a] (-1.40 ; -1.01)
M	2010.2 - 2011.1	-2.11[a] (-2.59 ; -1.63)	2011.1 - 2012.3	-3.06[a] (-3.29 ; -2.83)	2012.3 - 2013.4	-1.48[a] (-1.74 ; -1.22)	-2.29[a] (-2.43 ; -2.15)
G	2010.2 - 2012.4	-2.11[a] (-2.31 ; -1.91)	2012.4 - 2013.4	-0.86[d] (-1.87 ; 0.17)			-1.75[a] (-2.04 ; -1.47)
Exsmoker prevalence							
F	2010.2 - 2012.2	24.88[a] (24.10 ; 25.66)	2012.2 - 2013.4	12.03[a] (11.11 ; 12.95)			19.20[a] (18.67 ; 19.72)
M	2010.2 - 2012.2	15.87[a] (14.59 ; 17.17)	2012.2 - 2013.4	7.28[a] (5.69 ; 8.89)			12.11[a] (11.22 ; 13.00)
G	2010.2 - 2012.2	19.35[a] (18.76 ; 19.93)	2012.2 - 2013.4	9.27[a] (8.56 ; 9.99)			14.92[a] (14.52 ; 15.32)
New smokers incidence							
F	2010.2 - 2012.4	-44.30[b] (-61.99 ; -18.40)	2012.4 - 2013.4	1236.9[c] (98.1 ; 8922.6)			38.10[d] (-19.25 ; 136.16)
M	2010.2 - 2012.4	-45.84[a] (-59.81 ; -27.01)	2012.4 - 2013.4	702.68[a] (187.6 ; 2140.5)			17.00[d] (-14.94 ; 60.95)
G	2010.2 - 2012.4	-45.95[a] (-60.61 ; -25.84)	2012.4 - 2013.4	1036.5[b] (207.5 ; 4098.1)			29.03[d] (-12.11 ; 89.42)
New exsmokers incidence							
F	2010.2 - 2013.4	-11.19[c] (--20.15 ; -1.22)					-11.19[c] (-20.15 ; -1.22)
M	2010.2 - 2013.4	-12.06[c] (-18.59 ; -5.02)					-12.06[c] (-18.59 ; -5.02)
G	2010.2 - 2013.4	-11.72[b] (-18.15 ; -4.78)					-11.72[b] (-18.15 ; -4.78)
Ex-smokers relapse incidence							
F	2010.2 - 2013.1	-32.20[a] (-41.27 ; -21.73)					-32.20[a] (-41.27 ; -21.73)
M	2010.2 - 2013.1	-36.50[a] (-44.95 ; -26.75)					-36.50[a] (-44.95 ; -26.75)
G	2010.2 - 2013.1	-18.41[c] (-30.28 ; -4.52)	2013.1 - 2013.4	-85.36[d] (-99.52 ; 347.65)			-43.54[d] (-70.63 ; 8.57)

Note: 2010.*. represents the quarter * of the year 2010

APC, annual percentage change and AAPC, average annual percent change estimated by joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.
[a] p≤ 0.001; [b] p≤ 0.01; [c] p≤ 0.05; [d] p>0.05

DISCUSSION

The previous implementation of the partial Spanish SFL could account for the low effectiveness of the comprehensive SFL observed in this study. A significant downward trend of smoker prevalence rates, higher in men than in women, was found in the three regions throughout the study period. Correspondingly, the trend of ex-smoker prevalence rates increased in the three regions, particularly in Navarre and during the period 2008.1-2008.3 in Catalonia and Navarre, and the period 2010.2-2012.2 in the Balearic Islands. Even though the standardized ex-smoker prevalence rate was higher for men, the increase in the trend of ex-smoker prevalence rate was higher in women in the three regions. The overall trends of new smoker incidence rates decreased significantly in Catalonia and Navarre and were similar for men and women. Also, the overall trends of new ex-smokers decreased significantly in Catalonia and the Balearic Islands, particularly for men. In addition, the overall trends of ex-smoker relapse increased in Catalonia and decreased in Navarre, more for women than for men in both cases.

The trends of smoker prevalence declined throughout the study and no changes were observed after the implementation of the comprehensive SFL. Indeed, the most significant decrease begins in 2010 in Catalonia (3rd quarter) and the Balearic Islands and in 2008 in Navarre, prior to the implementation of the comprehensive SFL (January 1, 2011). However, the trend in Catalonia shows a drop in the prevalence rate of smokers around the time of the implementation of the Law. In contrast, trends in Navarre and the Balearic Islands show a more progressive decline. Comparisons are difficult due to the lack of studies on smoking prevalence and incidence from a PHC perspective and because some studies evaluate the impact of SFL on smoking prevalence with surveys that use different methodologies. Two studies that analysed data from surveys to the general population[19,20] did not find a significant decrease in the prevalence of smokers after the Spanish comprehensive law. In contrast, Lidon *et al.*[24] showed that after the implementation of both Spanish SFL, a significant decrease was observed in the smoking prevalence (from 34.5% to 26.1%, Prevalence Ratio = 0.76, $p < 0.001$) of people 16 years of age and older living in Barcelona surveyed in 2004–2005 and followed-up in 2013–2014. In addition, National Health Survey data from the 1987-2005 period revealed an annual average absolute decline of 1.0% in the prevalence of male smokers, whereas women showed an annual average absolute increase in prevalence of 0.2%. Between 2006 and 2014, the prevalence of smokers declined annually by 0.7% in men and 0.5% in women.[23] Although the values of the current study are higher, the steeper decline in the prevalence of smokers in men agree with these data.[23] Also, one study that estimated the effect of the Spanish SFL for the 2012-2025 period predicted a decrease in smoking prevalence in all age groups and for both sexes, except for women aged 40–64.[30]

Concomitantly with the decline in the prevalence trends in smokers, a constant increase of prevalence trends in ex-smokers was observed in the three regions. Other studies failed to note a significant change in the prevalence of ex-smokers after the comprehensive SFL: a difference of only 0.3 % between 2007 and 2011[20] and a non-significant increase of 3.3% between 2006 and 2011.[19] In agreement with a recent evidence review,[23] we observed a higher increase in the trend of ex-smokers prevalence in women. This review showed that the rate of smoking cessation in men increased 0.9% annually during the 1987-2014 period, and 1.5% in women after the Partial SFL came into force. The later incorporation of women to smoking might explain these gender differences.

We observed a gradual decline in the new smoker incidence trends in Catalonia and Navarre throughout the study period. A review by Wilson *et al.*[31] of two studies that evaluated smoking initiation reported mixed results, while Guerrero *et al*.[32] concluded that the Spanish partial SFL had no effect on new smokers in 2009. In contrast, Pinilla and Abásolo[33] observed a 6% decrease in the rate of smoking initiation among young people after the implementation of the same law, with a more positive impact in higher socioeconomic strata. We have not found studies that evaluate the impact of the comprehensive SFL on the incidence of new smokers. However, our data show a continuation in the trend observed in Pinilla's study[33] on the impact of the partial law.

The incidence trend in new ex-smokers declined gradually throughout the study period in Catalonia and the Balearic Islands. While the literature to date lacks data on the effect of the SFL on the incidence of new ex-smokers, it provides some information on prevalence. In this respect, one study on the Spanish partial SFL observed an increase of 8% between 2006 and 2011 in the rate of cessation among adult smokers (age 21 years and older) according to data from the National Health Survey.[33] In Luxembourg, smoking cessation attributed to the SFL was higher among daily smokers with a higher socioeconomic status.[8] In our cohort, we observed apparent random increases and declines in the adjusted rates in the three regions throughout the study.

The incidence trend in ex-smoker relapses increased in Catalonia and declined in Navarre constantly throughout the whole period, particularly for women. However, the literature presents conflicting results regarding smoking relapse. One study on the partial Spanish SFL observed that most people who had succeeded in giving up smoking in 2006 had not relapsed by 2009.[32] On the other hand, a quasi-experimental study conducted in the United States observed that relapse was similar between employees in workplaces with SFL and employees where smoking was permitted.[34] In contrast, Shang found that a comprehensive SFL in bars significantly deters smoking relapse among people ages 21 and older.[35] According to Buczkowski *et al.*,[36] the main reasons for relapse are stress, missing the pleasure obtained from smoking and the smoking environment. Other factors not analysed in our study that might influence relapse rates could explain the variations between regions, for instance living with other smokers, being enrolled in work or clinics cessation programmes[37] or the region-specific complementary measures to the SFL (for instance, Foral Law 6/2003,[38] February 14, of smoking prevention, protection from secondhand tobacco smoke and promotion of health with regard to smoking in Navarre). In addition, we should consider the impact of the financial crisis during the study period and the subsequent increase of anxiety and depression in the population.[39] In this respect, Navarre was the region with the lowest unemployment rate in Spain according to the 2010 Economically Active Population Survey (unemployment of 11.6% in Navarre, versus 18.0% in Catalonia and 22.2% in the Balearic Islands). According to the 2009 European Health Survey in Spain, these unemployment figures correlate with the prevalence of chronic depression, which was of 3.4% in Navarre versus 5.4% in Catalonia and 7.0% in the Balearic Islands.

The SFL is a keystone of the WHO Framework Convention on Tobacco Control (FCTC) and the MPOWER policy package (M=Monitor; P=Protect; O=Offer; W=Warm; E=Enforce; R= Raise).[40] The enforcement of Laws 28/2005 and 42/2010 have significantly advanced smoking control in Spain, in particular the "Protect people from tobacco" strategy.

However, the remaining MPOWER strategies have been patchily implemented and require further development.[23] On balance, a combination of specific, feasible, pragmatic, sufficiently funded policies and interventions aimed at populations and individuals is essential to achieve progress regarding smoking behaviour.

Limitations and strengths of the study

It is important to take into account that other than the Law, the pattern of tobacco consumption is influenced by factors such as health interventions, level of education, age, civil status, having children and being unemployed.[41] However, this study only considered age, sex, number of health problems and number of PHC visits since other variables were not available. In addition, many patients were excluded from the study because of lack of baseline data on smoking (missing data is a common problem in studies based on EHR). In order to prevent bias caused by improved smoking records, we excluded the cases with no information at the beginning of the study. The selection criteria and the longitudinal design aimed to maximize the internal validity of the study. Moreover, young people might be underrepresented due to their lower use of PHC services. On the other hand, 70% of the population attends PHC services at least once a year and smokers attend more frequently than no smokers.[42] In view of the limited length of the study period, particularly in the Balearic Islands, we consider these results a first approximation to be succeeded by follow-up research. We should underscore that rather than just comparing two different periods, joinpoint analysis evaluates longitudinal trends, thus producing a more accurate assessment. While other statistical models could have been used, we believe that joinpoint is a suitable method to achieve the study objectives, as shown in previous studies.[43-45]

This study provides useful data on the impact of the Spanish comprehensive SFL on adult smoking behaviour in PHC patients. It is crucial to analyse the consequences of a public health law on PHC users. Primary health care has a pivotal role in smoking cessation because it is the gatekeeper of the health services, it is accessible and provides continuity of care to smokers.[46] We should also highlight that this study includes the evaluation of novel variables such as incidence of new smokers, new ex-smokers and ex-smoker relapse, which we consider of great relevance in relation to PHC interventions for smoking cessation. Used as a research tool, EHR portray real-life conditions and provide comprehensive, long-term health histories from a large population sample, ensure high representativeness and external validity and minimize potential recall bias. The results are only generalizable to PHC users. To our knowledge, this study is amongst the first to show quarterly data from EHR.

CONCLUSIONS

The introduction of the Spanish comprehensive SFL (Law 42/2010) does not significantly modify incidence and prevalence trends of smoking behaviour in PHC adult patients in Catalonia, Navarre and the Balearic Islands. The impact of the comprehensive SFL might have been lessened by the effect of the previous implementation of the partial SFL (Law 28/2005). The current article provides baseline data for future research into the effectiveness of this Law. In addition to specific factors associated with smoking behaviour (such as the price of a pack of cigarettes or funding of smoking cessation services), future studies should consider socio-economic status and age groups.

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Contributors: BB, TRB, MPV, JBM, and CVF designed the study and wrote the protocol. YRM, MPV and JBM conducted literature searches and provided summaries of previous research studies. BB, JLL, JM, JR and MPV obtained the data. TRB and TLJ conducted the statistical analysis. All authors contributed to the interpretation of the results. YRM and MPV wrote the first draft of the manuscript. All authors read, contributed and approved the final version of the manuscript.

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Competing interest: The authors declare no conflict of interest.

Ethical aspects: This study follows the tenets of the Helsinki Declaration and of Good Clinical Research Practice and has been approved by the Ethical and Clinical Research Committee of the IDIAP Jordi Gol. Confidentiality was guaranteed through data encryption and anonymization in agreement with the data confidentiality Law 15/1999.

Data sharing statement: No additional data are available.

Figure 1: Flow-chart of patients included in the study, by region.

REFERENCES

1. Jha P. Avoidable global cancer deaths and total deaths from smoking. *Nat Rev Cancer* 2009;9:655–64.
2. Murray CJL, Lopez AD. Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. *Lancet* 2017;349:1498–504.
3. World Health Organization, and Tobacco Free Initiative. Building blocks to tobacco control: a hand-book. (Tools for advancing tobacco control in the 21st century). Geneva*: WHO;* 2004.
4. Federico B, Mackenbach JP, Eikemo TA, *et al*. Impact of the 2005 smoke-free policy in Italy on prevalence, cessation and intensity of smoking in the overall population and by educational group. *Addiction* 2012;107:1677–86.
5. Hahn EJ, Rayens MK, Butler KM, *et al*. Smoke-free laws and adult smoking prevalence. *Prev Med* 2008;47:206–9.
6. Nagelhout GE, Willemsen MC, de Vries H. The population impact of smoke-free workplace and hospitality industry legislation on smoking behaviour. Findings from a national population survey. *Addiction* 2011;106:816–23.
7. Hublet A, Schmid H, Clays E, *et al*. Association between tobacco control policies and smoking behaviour among adolescents in 29 European countries. *Addiction* 2009;104:1918–26.
8. Tchicaya A, Lorentz N, Demarest S. Socioeconomic inequalities in smoking and smoking cessation due to a smoking ban: General population-based cross-sectional study in Luxembourg. *PLoS One* 2016;11:1–15.
9. Ye X, Chen S, Yao Z, *et al*. Smoking behaviors before and after implementation of a smoke-free legislation in Guangzhou, China. *BMC Public Health* 2015;15:982.
10. Fichtenberg CM, Glantz SA. Effect of smoke-free workplace on smoking behaviour: systematic review. BMJ 2002;325:188.
11. Frazer K, Callinan JE, McHugh J, *et al.* Legislative smoking bans for reducing harms from secondhand smoke exposure, smoking prevalence and tobacco consumption. *Cochrane database Syst Rev* 2016;2:CD005992.
12. Ley de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro y la publicidad de los productos del tabaco. L. N. 28/2005 (27 diciembre 2005). Available at: https://www.boe.es/buscar/doc.php?id=BOE-A-2005-21261 . Accessed 6-3-2017.
13. Nebot M, Fernández E, (Coords) Evaluación del impacto de la ley de medidas sanitarias frente al tabaquismo. Grupo de Trabajo en Tabaquismo de la Sociedad Española de Epidemiología. Barcelona: Sociedad Española de Epidemiología y Ministerio de Sanidad y Política Social, 9-43. 2009. Available in: URL: http://www.seepidemiologia.es/documents/dummy/Monografia-Grupo%20Trabajo%20sobre%20tabaquismo.pdf)
14. Cordoba R, Villalbi JR, Salvador-Llivina T, *et al.* El proceso en España de la adopción de una legislación eficaz para la prevención del tabaquismo [Spain's process of passing effective smoking prevention legislation]. *Rev Esp Salud Publica* 2006;80:631–45.
15. Nebot M, López MJ, Ariza C, Pérez-Ríos M, *et al*. Impact of the Spanish smoking law on exposure to secondhand smoke in offices and hospitality venues: Before-and-after study. *Environ Health Perspect* 2009;117:344–7.
16. Ley de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro y la publicidad de los productos del tabaco (30 December 2010), por la que se modifica la Ley 28/2005, de 26 de diciembre, de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro, el consumo y la publicidad de los productos del tabaco. Boletín Oficial del Estado (Spanish Official State Bulletin). L. N. 42/2010.No. 318. Available at: https://www.boe.es/buscar/act.php?id=BOE-A-2010-20138 . Accessed 6-3-2017.
17. Regidor E, de Mateo S, Ronda E, *et al.* Heterogeneous trend in smoking prevalence by sex and age group following the implementation of a national smoke-free law. *J Epidemiol Community Health* 2011;65:702–8.
18. Regidor E, Pascual C, Giráldez-García C, *et al.* Impact of tobacco prices and smoke-free policy on smoking cessation, by gender and educational group: Spain, 1993-2012. *Int J Drug Policy* 2015;26:1215–21.
19. Perez-Rios M, Fernandez E, Schiaffino A, *et al*. Changes in the prevalence of tobacco consumption and the profile of Spanish smokers after a comprehensive smoke-free policy. *PLoS One* 2015;10:1–9.
20. Jiménez Ruiz CA, Riesco Miranda JA, Altet Gómez N, *et al*. Impact of legislation on passive smoking in Spain. *Respiration* 2014;87:190–5.
21. Catalina Romero C, Gelpi Médez JA, Cortés Arcas MV, *et al.* Evolución en España del consumo de tabaco en población trabajadora desde la entrada en vigor de la Ley 28/2005 de medidas sanitarias frente al tabaquismo [Prevalence of Tobacco Consumption Among Working Population after the Law 42/2010, Spain]. *Rev Esp salud pública* 2010;84:223–7.
22. Catalina Romero C, Sainz Gutiérrez JC, Quevedo Aguado L*, et al.* Prevalencia de consumo de tabaco en población trabajadora tras la entrada en vigor de la Ley 42/2010 [Prevalence of tobacco consumption among working population after the law 42/2010, Spain]. *Rev Esp Salud Publica* 2012;86:177–88.
23. Pérez-Ríos M, Galán I(editors) Evaluación de las políticas de control del tabaquismo en España (Leyes 28/2005 y

42/2010) Revisión de la evidencia. Grupo de Trabajo en Tabaquismo de la Sociedad Española de Epidemiología. Barcelona: Sociedad Española de Epidemiología y Ministerio de Sanidad y Política Social, 2017;11-74. Available in: URL: http://www.seepidemiologia.es/documents/dummy/V9.0%2520-%2520Libro%2520Tabaquismo%25202017%2520-%2520Abierto%2520Final.pdf

24. Lidón-moyano C, Fu M, Ballbè M, *et al*. Addictive Behaviors Impact of the Spanish smoking laws on tobacco consumption and secondhand smoke exposure : A longitudinal population study. *Addict Behav* 2017;75:30–5.
25. Bauzà-Amengual M, Blasco-González M, Sánchez-Vazquez E, *et al.* Impacto de la Ley del tabaco en el lugar de trabajo: estudio de seguimiento de una cohorte de trabajadores en España 2005--07 [Impact of the Tobacco Law on the workplace: a follow up study of a cohort of workers in Spain 2005–2007]. *Atención primaria* 2010;42:309–13.
26. Bolíbar B, Pareja C, Astier-Peña MP, *et al*. Variability in the performance of preventive services and in the degree of control of identified health problems: a primary care study protocol. *BMC Public Health* 2008;8:281.
27. The International Statistical Classification of Diseases and Related Health Problems (ICD-10th revision) classification of mental and behavioural disorders: clinical descriptions and diagnostic guidelines. Geneva: World Health Organization, 1992. Available at: http://www.who.int/classifications/icd/en/bluebook.pdf . Accessed 6-3-2017..
28. Okkes IM, Becker HW, Bernstein RM, *et al*.The March 2002 update of the electronic version of ICPC-2. A step forward to the use of ICD-10 as a nomenclature and a terminology for ICPC-2. *Fam Pract* 2002;19:543–6.
29. Kim H-J, Fay MP, Feuer EJ, *et al*. Permutation tests for joinpoint regression with applications to cancer rates. *Stat Med* 2000;19:335–51. Available at: http://onlinelibrary.wiley.com/doi/10.1002/(SICI)1097-0258(20000215)19:3%253C335::AID-SIM336%253E3.0.CO;2-Z/abstract. Accessed 8-3-2017.
30. Martín-Sánchez JC, Martinez-Sanchez JM, Bilal U, *et al*. Sex and Age Specific Projections of Smoking Prevalence in Spain: A Bayesian Approach. *Nicotine Tob Res* 2017; ntx120, https://doi.org/10.1093/ntr/ntx120.
31. Wilson LM, Avila Tang E, Chander G, *et al.* Impact of tobacco control interventions on smoking initiation, cessation, and prevalence: A systematic review. *J Environ Public Health* 2012; doi:10.1155/2012/961724
32. Guerrero F, Santonja F-J, Villanueva R-J. Analysing the Spanish smoke-free legislation of 2006: a new method to quantify its impact using a dynamic model. *Int J Drug Policy* 2011 Jul;22:247–51.
33. Pinilla J, Abásolo I. The effect of policies regulating tobacco consumption on smoking initiation and cessation in Spain: is it equal across socioeconomic groups? *Tob Induc Dis* 2017;15:8.
34. Longo DR, Johnson JC, Kruse RL, *et al.* A prospective investigation of the impact of smoking bans on tobacco cessation and relapse. *Tob Control* 2001;10:267–72.
35. Shang C. The effect of smoke-free air law in bars on smoking initiation and relapse among teenagers and young adults. *Int J Environ Res Public Health* 2015;12:504–20.
36. Buczkowski K, Marcinowicz L, Czachowski S, *et al.* Motivations toward smoking cessation, reasons for relapse, and modes of quitting: results from a qualitative study among former and current smokers. *Patient Prefer Adherence* 2014;8:1353–63.
37. Schillo BA, Keller PA, Betzner AE, *et al*. Minnesota's smokefree policies: Impact on cessation program participants. *Am J Prev Med* 2012;43:S171–8.
38. Ley foral 6/2003, de 14 de febrero, de prevención del consumo de tabaco, de protección del aire respirable y de la promoción de la salud en relación al tabaco (Navarra). Available at: http://www.lexnavarra.navarra.es/detalle.asp?r=3323. Accessed 31-7-2017
39. Gili M, Garcia Campayo J, Roca M. Crisis económica y salud mental. Informe SESPAS 2014 [Economic crisis and mental health. SESPAS report 2014]. *Gac Sanit* 2014;28 Suppl 1:104–8.
40 World Health Organization. WHO report on the global tobacco epidemic, 2009: implementing smoke-free environments. Geneva: World Health Organization; 2009.
41. Buonanno P, Ranzani M. Thank you for not smoking: Evidence from the Italian smoking ban. *Health Policy* 2013;109:192–9.
42. Camarelles Guillem F, Dalmau González-Gallarza R, Clemente Jiménez L, *et al*. Documento de consenso para la atención clínica al tabaquismo en España [Consensus report for the clinical care of smoking cessation in Spain]. *Med Clin* 2013;140:272.e1-272.e12.
43. Lopez-Campos JL, Ruiz-Ramos M, Fernandez E, *et al.* Recent lung cancer mortality trends in Europe: effect of national smoke-free legislation strengthening. *Eur J Cancer Prev*. 2017 Apr 4. doi: 10.1097/CEJ.0000000000000354.
44. Jan C, Lee M, Roa R, *et al*. The association of tobacco control policies and the risk of acute myocardial infarction using hospital admissions data. *PLoS One*. 2014;9(2). doi: 10.1371/journal.pone.0088784
45. Rando-Matos Y, Pons-Vigués M, Rodriguez-Blanco T, *et al*. Effect of comprehensive smoke-free legislation on asthma and coronary disease trends in Spanish primary care patients. *Eur J Public Health* [Internet].

2018;cky010. doi: 10.1093/eurpub/cky010.
46. Córdoba R, Cabezas C, Camarelles F, *et al.* Recomendaciones sobre el estilo de vida. *Atención primaria* 2012;44:16–22.

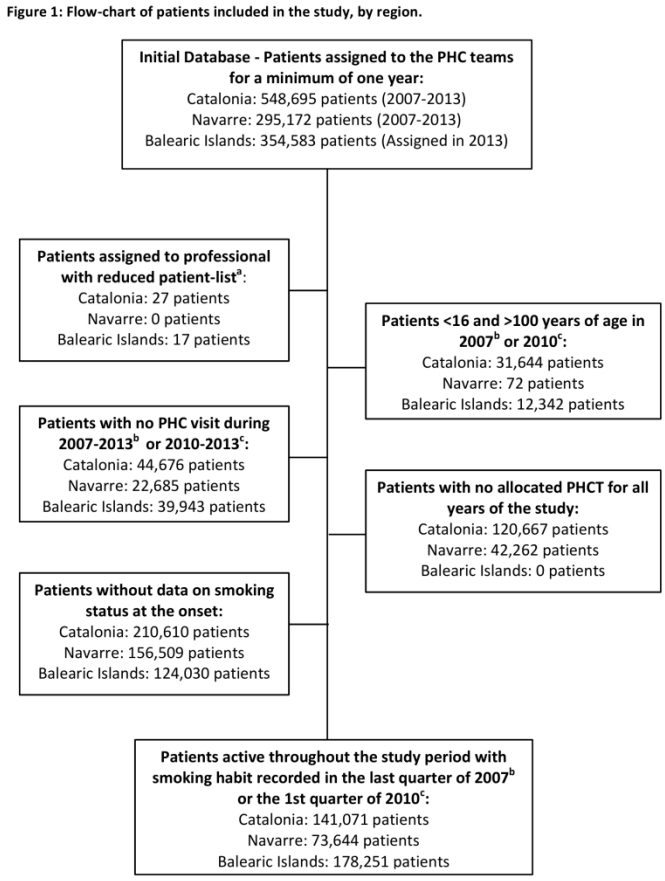

Figure 1: Flow-chart of patients included in the study, by region.

209x297mm (300 x 300 DPI)

SUPPLEMENTARY DATA FOR *Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study*

Table S1: Age-adjusted rates by direct method per 10,000 inhabitants based on the European Standard Population. CATALONIA N=141,071 (2008-2013).

Quarter	Smoking status prevalence			New smokers incidence	New ex-smokers incidence	Ex-smoker relapses incidence
	Non smokers	Smokers	Ex-smokers			
2008.1	4692.6	4138.9	1168.5	20.8	254.3	226.9
2008.2	4679.3	4099.0	1221.7	21.4	212.9	151.4
2008.3	4668.8	4073.6	1257.6	16.6	267.5	218.5
2008.4	4650.2	4051.7	1298.1	26.1	317.6	100.4
2009.1	4638.8	4053.6	1307.6	25.2	260.1	128.6
2009.2	4628.1	4036.8	1335.1	15.8	228.5	78.3
2009.3	4618.4	4021.6	1360.0	12.7	161.3	113.7
2009.4	4604.4	3998.5	1397.2	19.6	212.7	165.6
2010.1	4590.0	4001.8	1408.2	19.0	160.9	123.1
2010.2	4573.5	3994.3	1432.2	26.4	135.8	148.8
2010.3	4560.0	3981.0	1459.0	20.8	139.0	100.5
2010.4	4539.7	3957.4	1503.0	26.8	188.1	112.5
2011.1	4077.0	3758.0	1510.3	15.1	171.9	103.2
2011.2	4068.6	3721.4	1555.3	12.4	213.0	90.0
2011.3	4061.6	3696.3	1587.3	13.0	145.9	81.4
2011.4	4050.8	3649.8	1644.7	15.8	255.4	91.3
2012.1	4012.6	3658.7	1673.9	13.4	222.7	111.1
2012.2	4004.9	3629.6	1710.7	11.3	171.3	91.9
2012.3	4000.4	3608.5	1736.3	7.9	118.8	70.7
2012.4	3990.2	3579.2	1775.8	11.8	201.3	103.9
2013.1	3963.0	3601.1	1781.2	16.5	184.9	141.7
2013.2	3956.3	3618.6	1770.3	15.2	136.7	247.6
2013.3	3952.8	3635.1	1757.3	9.3	110.7	248.6
2013.4	3946.5	3659.3	1739.5	14.7	172.8	334.5

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S2: Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population. NAVARRE N=73,644 (2008-2013).

Quarter	Smoking status prevalence			New smokers incidence	New ex-smokers incidence	Ex-smoker relapses incidence
	Non smokers	Smokers	Ex-smokers			
2008.1	5652.5	4034.2	313.3	25.3	175.3	227.0
2008.2	5642.5	4013.0	344.5	17.2	181.0	160.4
2008.3	5632.4	4003.3	364.3	16.5	109.1	129.4
2008.4	5620.0	3993.3	386.7	21.4	127.7	230.3
2009.1	5645.0	3951.4	403.7	30.9	136.4	225.4
2009.2	5630.8	3944.1	425.1	23.5	132.1	174.0
2009.3	5623.5	3934.7	441.8	12.5	100.3	100.7
2009.4	5614.7	3925.5	459.8	14.8	109.9	134.7
2010.1	5618.3	3905.9	475.8	27.2	111.2	209.4
2010.2	5605.5	3893.8	500.7	21.1	114.9	132.5
2010.3	5595.1	3889.1	515.8	16.4	82.2	98.7
2010.4	5581.9	3885.3	532.8	21.4	89.9	81.2
2011.1	4990.3	3806.9	548.1	16.0	136.8	141.3
2011.2	4979.2	3795.8	570.2	20.3	116.7	113.8
2011.3	4972.0	3791.6	581.6	12.7	48.6	60.2
2011.4	4964.3	3780.5	600.4	13.8	99.6	118.6
2012.1	4910.7	3804.6	630.0	18.6	127.3	87.6
2012.2	4902.9	3781.3	661.1	13.7	130.1	108.4
2012.3	4897.7	3773.3	674.3	9.8	75.2	58.6
2012.4	4888.9	3760.5	695.8	15.2	110.2	96.0
2013.1	4886.8	3746.7	711.8	15.1	121.0	116.4
2013.2	4876.8	3733.2	735.2	16.9	104.2	97.4
2013.3	4870.8	3727.9	746.6	9.5	60.7	119.1
2013.4	4861.3	3719.8	764.1	16.9	90.7	97.8

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S3: Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population. THE BALEARIC ISLANDS N=178,251 (2010-2013).

Quarter	Smoking status prevalence			New smokers incidence	New ex-smokers incidence	Ex-smoker relapses incidence
	Non smokers	Smokers	Ex-smokers			
2010.2	5411.0	4029.7	559.3	9.3	158.5	576.6
2010.3	5406.4	4007.3	586.2	9.0	151.6	527.0
2010.4	5401.6	3982.7	615.7	9.3	158.7	503.7
2011.1	5374.9	3987.9	637.1	6.6	149.9	545.7
2011.2	5372.4	3959.3	668.3	5.2	170.9	424.4
2011.3	5369.7	3929.5	700.8	5.2	160.1	383.9
2011.4	5367.4	3898.4	734.2	4.0	169.8	385.6
2012.1	5345.3	3888.3	766.4	4.3	188.1	351.8
2012.2	5344.0	3862.4	793.6	2.4	137.0	370.6
2012.3	5342.5	3841.0	816.6	2.9	113.5	372.6
2012.4	5341.7	3818.9	839.4	1.6	133.0	339.2
2013.1	5324.1	3825.3	850.7	2.1	130.5	480.5
2013.2	5317.8	3810.5	871.7	12.1	106.7	453.0
2013.3	5308.3	3800.6	891.1	17.5	93.7	103.9
2013.4	5298.6	3787.4	914.1	17.5	116.8	285.1

Note: 2010.*. represents the quarter * of the year 2010

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S4. Age-adjusted rates by the direct method for 10,000 inhabitants based on the European Standard Population in CATALONIA. N=72,340 (2008-2013).

Quarter	Smoking Status prevalence						New smokers incidence		New ex-smokers incidence		Ex-smoker relapse incidence	
	Non smokers		Smokers		Ex-smokers							
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
2008.1	5909.5	3349.2	3411.5	4910.7	679.0	1740.1	16.6	27.8	246.7	260.5	315.2	158.2
2008.2	5900.4	3331.6	3385.4	4856.2	714.2	1812.2	14.3	34.4	266.5	202.9	101.2	195.0
2008.3	5891.9	3318.8	3368.4	4822.1	739.7	1859.1	14.0	21.8	275.0	265.9	289.0	166.5
2008.4	5876.9	3296.1	3356.2	4789.4	766.9	1914.5	24.0	31.9	254.1	329.2	112.0	99.6
2009.1	5832.7	3323.5	3379.8	4769.9	787.5	1906.6	27.8	26.3	289.2	234.0	148.8	105.2
2009.2	5823.1	3311.7	3366.5	4749.0	810.4	1939.3	13.7	19.7	182.0	237.8	89.5	79.2
2009.3	5814.6	3300.6	3356.2	4728.4	829.2	1971.1	11.9	15.3	154.4	165.7	181.4	65.8
2009.4	5804.4	3282.4	3335.4	4702.6	860.2	2015.0	14.3	28.0	243.3	203.9	188.5	152.0
2010.1	5757.2	3312.5	3359.5	4679.7	883.3	2007.8	14.0	26.7	201.5	144.1	133.5	109.4
2010.2	5744.1	3292.3	3355.5	4668.2	900.4	2039.6	24.1	30.4	146.6	131.6	164.1	152.0
2010.3	5730.0	3279.4	3345.8	4650.5	924.2	2070.2	20.7	22.7	156.1	134.4	106.6	98.0
2010.4	5710.9	3256.8	3332.3	4616.4	956.8	2126.8	30.9	24.3	205.4	177.3	132.2	114.9
2011.1	5231.2	2821.0	3138.8	4408.8	975.2	2115.4	15.0	16.8	181.1	166.1	62.6	146.7
2011.2	5223.4	2811.7	3115.8	4356.5	1006.0	2177.1	12.2	14.3	231.6	203.8	118.9	65.4
2011.3	5216.7	2804.3	3095.4	4326.8	1033.2	2214.1	12.4	15.2	166.4	136.0	93.0	68.5
2011.4	5209.6	2789.1	3057.6	4270.9	1078.0	2285.2	12.1	21.2	308.9	241.6	111.0	78.8
2012.1	5142.2	2792.0	3082.8	4259.8	1120.2	2293.5	9.3	19.1	251.1	216.5	140.4	83.6
2012.2	5136.1	2782.4	3059.1	4225.1	1150.0	2337.7	10.4	12.4	215.6	162.3	107.4	75.8
2012.3	5132.0	2777.7	3041.8	4200.0	1171.4	2367.6	8.7	7.3	135.6	113.1	61.0	80.2
2012.4	5123.4	2765.4	3020.5	4161.9	1201.3	2417.9	10.2	16.2	192.8	203.5	128.5	89.1
2013.1	5063.9	2781.5	3055.9	4167.2	1225.4	2396.5	15.4	19.9	213.2	180.4	167.8	123.5
2013.2	5058.8	2773.4	3057.2	4202.9	1229.3	2368.9	10.2	21.9	146.9	131.3	216.4	251.9
2013.3	5055.0	2770.2	3060.2	4234.1	1230.0	2340.9	9.0	10.7	127.0	106.7	217.7	263.3
2013.4	5049.2	2763.3	3063.6	4281.9	1232.5	2300.1	11.8	21.1	202.8	159.2	325.6	315.6

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S5. Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population in NAVARRE. N=37,898 (2008-2013).

Quarter	Smoking Status prevalence						New smokers incidence		New ex-smokers incidence		Ex-smoker relapse incidence	
	Non smokers		Smokers		Ex-smokers							
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
2008.1	6224.8	5021.1	3542.5	4569.6	232.7	409.3	22.3	31.0	152.7	172.3	164.4	295.8
2008.2	6215.3	5010.6	3527.8	4539.7	256.9	449.7	15.2	20.3	168.7	187.7	136.9	173.7
2008.3	6207.4	4998.8	3518.5	4528.6	274.2	472.6	11.5	22.1	147.1	97.1	147.9	123.7
2008.4	6198.6	4982.4	3510.9	4515.4	290.4	502.2	14.8	30.0	157.9	125.6	296.5	98.8
2009.1	6209.7	5028.3	3485.7	4451.5	304.6	520.2	24.9	39.7	184.8	111.3	254.0	197.0
2009.2	6197.8	5011.6	3480.3	4441.1	321.9	547.3	17.4	32.6	177.2	127.7	152.7	171.7
2009.3	6191.6	5003.2	3475.5	4426.3	332.9	570.4	10.7	15.2	108.4	98.3	73.4	111.5
2009.4	6186.2	4990.0	3470.2	4413.1	343.6	596.9	8.4	24.0	97.2	115.8	126.6	134.7
2010.1	6175.4	5014.1	3464.6	4375.5	360.0	610.4	22.6	33.5	115.7	112.9	224.3	208.6
2010.2	6164.6	4999.4	3455.7	4359.8	379.7	640.8	16.4	27.9	119.1	114.5	106.4	129.5
2010.3	6154.5	4988.6	3456.0	4350.4	389.5	661.0	16.2	17.0	111.3	75.9	88.3	94.5
2010.4	6142.1	4974.6	3455.4	4343.4	402.5	682.1	17.8	26.3	126.9	80.9	71.3	85.7
2011.1	5541.4	4399.8	3388.4	4248.3	415.4	697.1	12.2	21.0	146.2	135.4	91.3	183.2
2011.2	5532.4	4386.6	3381.0	4233.7	431.9	724.9	15.5	26.8	151.1	110.6	117.2	103.9
2011.3	5524.7	4379.8	3377.8	4228.5	442.7	737.0	12.6	13.7	55.8	44.9	61.6	54.1
2011.4	5518.9	4370.0	3369.7	4213.6	456.6	761.7	9.6	19.5	118.2	95.4	70.0	160.8
2012.1	5452.1	4335.6	3408.9	4217.7	484.2	792.0	15.9	22.5	129.3	126.5	106.9	65.3
2012.2	5445.6	4326.1	3389.4	4190.1	510.2	829.0	11.7	17.2	125.1	131.6	95.3	114.5
2012.3	5442.6	4318.6	3385.2	4178.7	517.4	847.9	6.2	14.2	67.6	78.0	68.6	41.2
2012.4	5434.5	4308.9	3379.5	4159.1	531.2	877.2	12.5	19.6	130.7	110.0	66.7	126.7
2013.1	5420.0	4323.0	3380.9	4128.0	544.3	894.1	14.1	16.4	133.8	124.7	68.6	157.5
2013.2	5413.7	4309.1	3367.7	4114.5	563.9	921.6	10.1	25.2	103.2	104.7	87.0	98.4
2013.3	5408.6	4302.1	3363.6	4108.1	573.1	935.1	7.2	12.7	72.3	57.3	152.7	85.9
2013.4	5399.9	4291.6	3360.4	4094.8	584.9	958.8	13.9	21.7	65.6	102.8	72.2	116.0

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S6. Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population in THE BALEARIC ISLANDS. N= 94,164 (2010-2013).

Quarter	Smoking Status prevalence						New smokers incidence		New ex-smokers incidence		Ex-smoker relapse incidence	
	Non smokers		Smokers		Ex-smokers							
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
2010.2	6224.8	4484.3	3412.3	4723.7	362.9	792.0	8.9	9.9	106.8	169.6	631.1	560.7
2010.3	6220.5	4479.3	3395.5	4695.0	384.0	825.7	8.2	10.4	149.6	147.6	576.9	435.9
2010.4	6215.8	4474.3	3376.3	4664.4	408.0	861.2	8.8	10.1	179.2	150.7	484.7	571.5
2011.1	6171.2	4472.1	3395.3	4651.7	433.5	876.2	6.7	6.6	141.1	146.7	562.7	508.9
2011.2	6168.5	4469.8	3375.7	4612.8	455.9	917.5	5.2	5.4	140.3	173.8	446.1	426.0
2011.3	6165.8	4467.0	3353.4	4574.6	480.8	958.4	4.9	6.0	162.5	154.9	400.9	391.6
2011.4	6163.1	4465.3	3330.1	4534.6	506.8	1000.1	4.6	3.4	149.3	170.9	296.7	540.3
2012.1	6118.6	4474.0	3337.9	4501.2	543.6	1024.8	3.7	5.1	179.2	182.1	306.5	461.7
2012.2	6117.0	4473.2	3318.1	4468.3	564.9	1058.5	2.8	1.9	109.0	139.6	359.8	348.6
2012.3	6115.2	4471.9	3302.0	4440.5	582.8	1087.7	3.1	2.5	103.4	112.8	376.5	363.9
2012.4	6114.3	4471.2	3285.7	4411.7	600.0	1117.0	1.7	1.6	122.7	132.9	414.0	213.4
2013.1	6077.2	4479.2	3302.2	4406.4	620.6	1114.4	0.9	4.1	137.9	122.6	492.0	470.3
2013.2	6070.8	4473.1	3291.1	4387.8	638.2	1139.1	11.9	12.7	91.0	105.4	410.8	532.6
2013.3	6056.9	4468.7	3287.9	4370.1	655.1	1161.2	23.4	10.4	94.4	90.1	110.4	87.5
2013.4	6046.1	4460.3	3280.8	4349.5	673.1	1190.2	18.2	16.9	100.0	121.4	342.4	116.1

Note: 2010.*. represents the quarter * of the year 2010

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

SUPPLEMENTARY DATA FOR Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

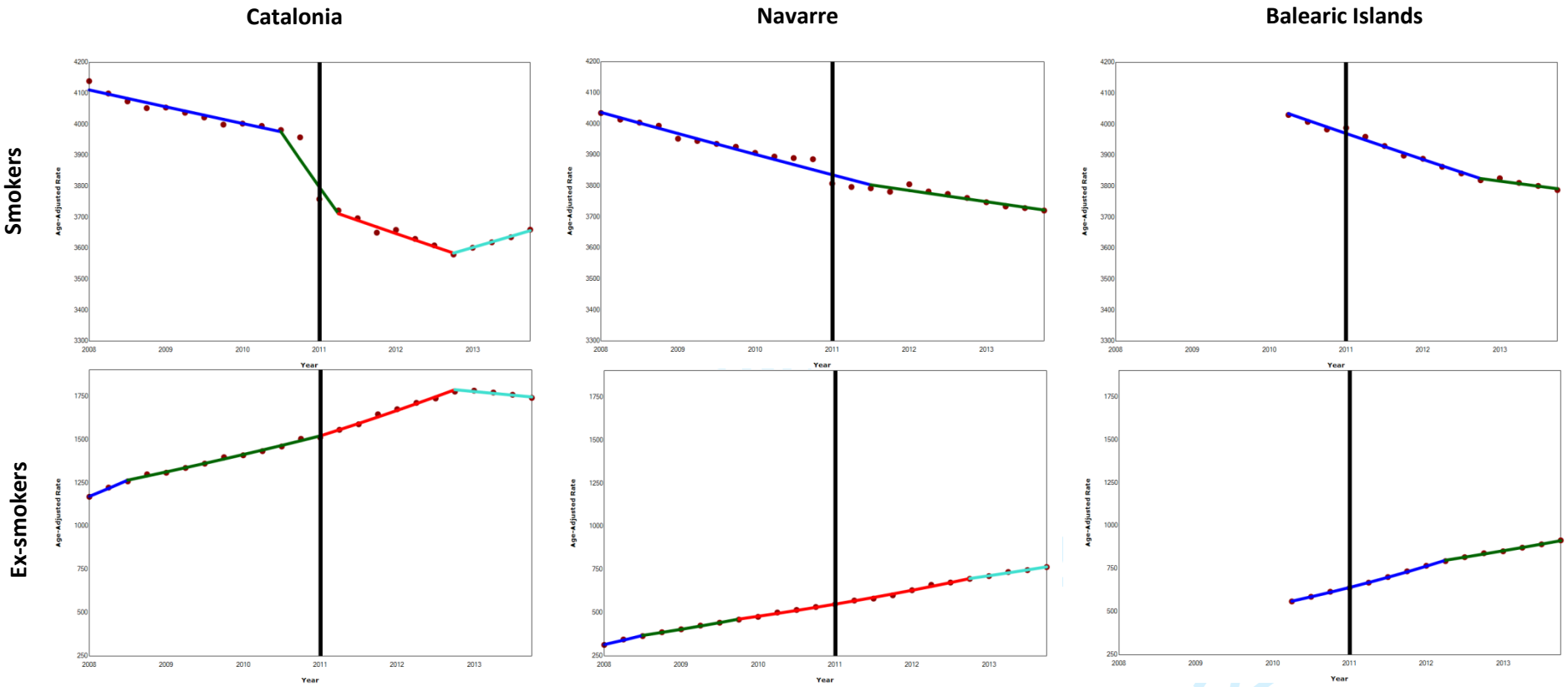

Figure S1: Overall trends of age-standardized prevalence rates of smoking status in Catalonia, Navarre and the Balearic Islands.
Solid lines represent the Joinpoint regression lines (each colour is a different trend); circle red points represent the age-adjusted prevalence rates. Black vertical lines represent the year when the Spanish comprehensive smoke-free law was introduced (2011).

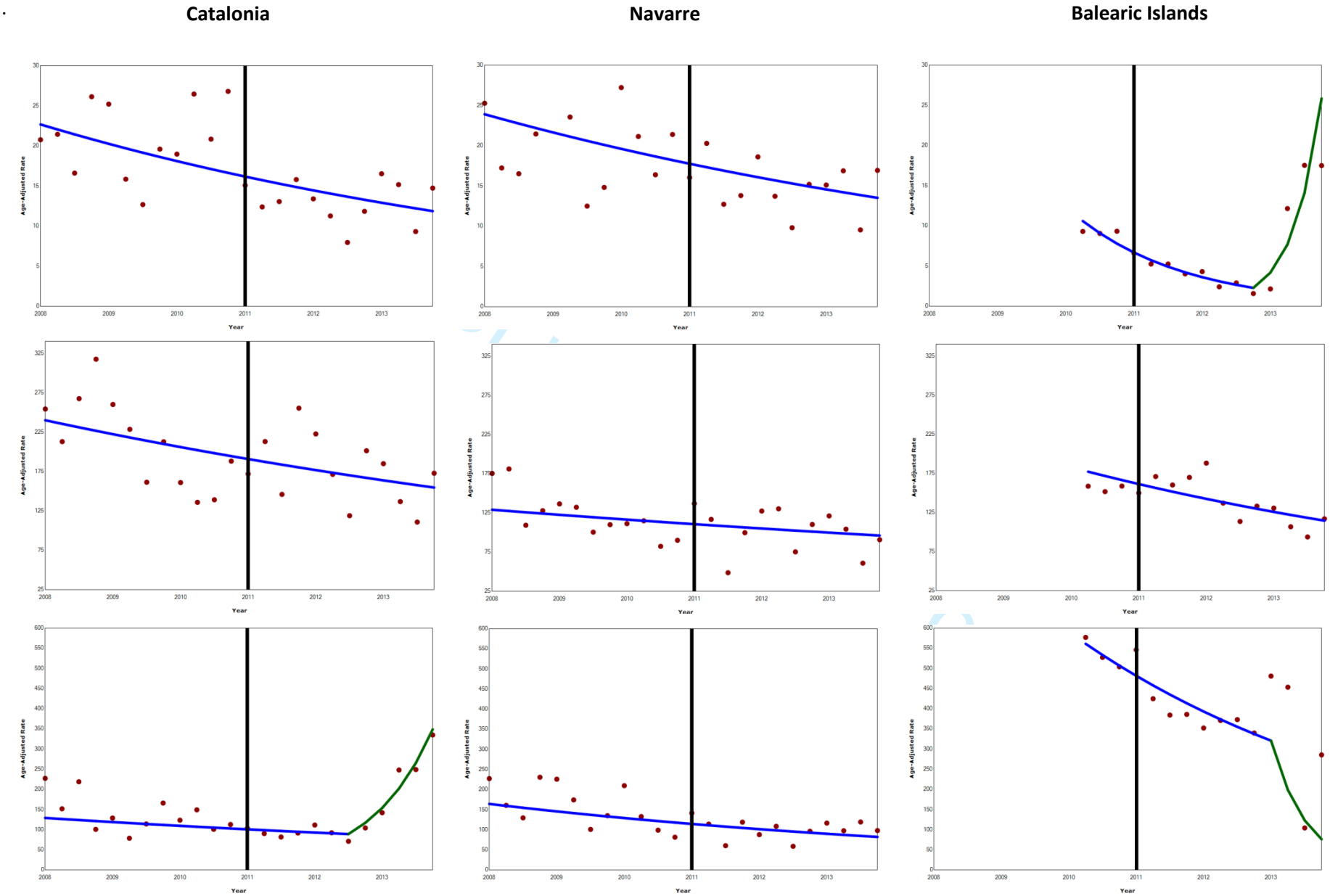

Figure S2: Overall trends of age-standardized incidence rates of new smokers, ex-smokers and ex-smoker relapse in Catalonia, Navarre and the Balearic Islands. Solid lines represent the Joinpoint regression lines (each colour is a different trend); circle red points represent the age-adjusted incidence rates. Black vertical lines represent the year when the Spanish comprehensive smoke-free law was introduced (2011).

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6-7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	6 + Figure 1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7-8
		(*b*) Describe any methods used to examine subgroups and interactions	7-8
		(*c*) Explain how missing data were addressed	6 + 15
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6, 8. Figure 1
		(b) Give reasons for non-participation at each stage	6. Figure 1
		(c) Consider use of a flow diagram	6. Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8. Table 1.
		(b) Indicate number of participants with missing data for each variable of interest	8
Outcome data	15*	Report numbers of outcome events or summary measures	8-12. Tables 2-4
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-12. Tables 2-4
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14-15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	15-16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

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Keywords:	Electronic health records, Joinpoint analysis, Primary Health Care, Smoke-Free Policy, Smoking

Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

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Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

ABSTRACT

Objective: This study aimed to analyse the impact of comprehensive smoke-free legislation on the prevalence and incidence of adult smoking in Primary Health Care patients from three Spanish regions, overall and stratified by sex.

Design: Longitudinal observational study conducted between 2008 and 2013.

Setting: 66 Primary Health Care teams in Catalonia, Navarre and the Balearic Islands (Spain).

Participants: Population over 15 years of age assigned to Primary Health Care teams.

Primary and secondary outcomes measures: Quarterly age-standardized prevalence of non-smoker, smoker and ex-smoker and incidence of new smoker, new ex-smoker and ex-smoker relapse rates were estimated with data retrieved from PHC electronic health records. Joinpoint analysis was used to analyse the trends of age-standardized prevalence and incidence rates**.** Trends were expressed as annual percentage change and average annual percent change.

Results: The overall standardized smoker prevalence rate showed a significant downward trend (higher in men than women) and the overall standardized ex-smoker prevalence rate showed a significant increased trend (higher in women than men) in the three regions. Standardized smoker and ex-smoker prevalence rates were higher for men than women in all regions. With regard to overall trends of incidence rates, new smokers decreased significantly in Catalonia and Navarre and similarly in men and women, new ex-smokers decreased significantly and more in men in Catalonia and the Balearic Islands**,** and ex-smoker relapse increased in Catalonia, particularly in women, and decreased in Navarre.

Conclusions: Trends on smoking behaviour in Primary Health Care patients remain unchanged after the implementation of comprehensive smoke-free legislation.

Keywords: Electronic health records; Joinpoint analysis; Primary Health Care; Smoke-Free Policy; Smoking.

Strengths and limitations of this study

- To our knowledge, no studies have been published on the impact of the Spanish comprehensive smoke-free legislation in all adult Primary Health Care patients
- Used as a research tool, electronic health records portray real-life conditions and provide comprehensive, long-term health histories from a large population sample
- The results of quarterly data by joinpoint analysis provides more precise information than an analysis before-after the implementation of the Law
- This study only considered age and sex since other variables were not available for the adjusted analysis.
- The study period started later (shorter follow-up) in the Balearic Islands to ensure reliability of data

Effect of the Spanish comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

INTRODUCTION

Smoking is the leading worldwide cause of preventable death.[1] According to the World Health Organization (WHO), it is estimated that at least 30 million people may die prematurely from tobacco-related diseases.[2] Legislative measures have been adopted to protect people's health in public areas and workplaces. These include increasing the price of cigarettes, banning advertising, sponsorship and smoking in workplaces and public spaces, displaying warnings on tobacco packets and implementing prevention programs.[3]

Some studies show a decrease in smoking prevalence since the introduction of smoke-free legislation (SFL).[4–9] A metanalysis of 26 studies on the effect of the smoke-free workplace in various countries concluded in 2002 that smoke-free workplaces protect not only non-smokers from the dangers of passive smoking, but they also encourage smokers to reduce tobacco consumption. The authors concluded that SFL is associated with a 3% to 4% reduction in tobacco consumption.[10] In contrast, a Cochrane review published in 2016 which included 24 studies on smoking behaviour showed inconsistencies regarding the impact of smoking bans on smoking prevalence and tobacco consumption.[11]

On January 1, 2006, the Spanish government introduced a partial SFL (Law 28/2005),[12] which included regulations on the sale, supply, consumption and advertising of tobacco products. Smoking was banned in all indoor public and private workplaces with the exception of the hospitality sector, where partial restrictions were established depending on the size of the establishment, i.e., in bars or restaurants smaller than 100 m2 the managers could decide whether to allow smoking in the premises (Law 28/2005). The mean concentration of nicotine subsequently decreased by 60% in public administration offices and by 97.4% in private workplaces, but in areas where smoking was permitted, including bars and nightclubs, no changes were found.[13–15] This prompted the enactment of a comprehensive SFL (Law 42/2010),[16] which came into force in January 2011. This comprehensive law expanded smoking restriction to all hospitality venues of any size and, as a result, smoking was forbidden in all enclosed public places, including bars, restaurants and nightclubs, and in some open-air public places such as playgrounds.

Some studies have analysed the impact of these two Spanish laws on smoking prevalence. However, most have been based on health surveys[13,17–20] and surveys of hospitality workers.[21,22] Moreover, some studies evaluate only the partial law,[13,17,18] whereas others analyse the compound impact of both laws.[19,20,23,24] The results of these studies are often conflicting; while some conclude that the partial SFL does not have any effect on the downward trend in the prevalence of smokers,[13,19,23] other studies show a reduction in smoking prevalence[24], an increase of the smoking quit-ratio in the short term[18] and minor increases in the prevalence of active smoking.[20]

Only one study conducted in primary health care (PHC) patients evaluates the impact of the Spanish partial SFL, including smoking prevalence in active smoker workers that attended PHC visits; one month after the implementation

of the law, a 9.5% decline of smokers was observed.[25] To our knowledge, no studies have been published on the impact of the Spanish comprehensive SFL in all adult PHC patients. In view of the pivotal role of PHC services in smoking habits, we consider that the information registered in PHC records is a good proxy to generate up-to-date evidence and to evaluate the impact of comprehensive SFL in the general population.

We hypothesized that Law 42/2010 does not only reduce exposure to environmental cigarette smoke and its harmful effects but crucially, it promotes smoking denormalisation in society, thus encouraging smokers to quit or reduce consumption and discouraging non-smokers from initiating this habit. Accordingly, the aim of this study was to examine the impact of the Spanish comprehensive SFL (Law 42/2010) on the prevalence and incidence of adult smoking in PHC patients in three regions (Catalonia, Navarre and Balearic Islands), during the 2008-2013 period, overall and stratified by sex.

METHODS

Design, study participants and information source

Longitudinal observational study of the adult population assigned to 66 Primary Health Care teams (PHCT) in three Spanish regions: Catalonia, Navarre and the Balearic Islands (22 PHCT per region). Inclusion criteria of the PHCT were: 1) computerization of electronic health records (EHR) by January 1, 2005 in Catalonia and Navarre, and 2008 in the Balearic Islands; and 2) agreement to participate in the study by over 80% health-care professionals working in each PHCT. Random cluster sampling was stratified by region, with the PHCT as randomization unit.[26] In each PHCT, General Practitioners (GP) with a patient list between 400 and 3000 were selected. GP with shorter patient lists were accepted if it was their first year in the PHCT.

The study period included from the first quarter of 2008 to the fourth quarter of 2013 in Catalonia and Navarre; and from the second quarter of 2010 to the fourth quarter of 2013 in the Balearic Islands. The study started in 2008 to obtain data from the 2 years prior analysis, a requirement to adequately construct the variable ex-smoker. In the case of the Balearic Islands, the study started later to ensure reliability of data.

Inclusion criteria for patients were: 1) Population allocated to the selected PHCT for the whole 2007-2013 period in Catalonia and Navarre; in the Balearic Islands, patients allocated to the selected PHCT in 2013 and evaluated retrospectively (no historical annual comprehensive register of allocation of patients was available). 2) Age ≥16 and ≤100 years in 2007 in Catalonia and Navarre, and 2010 in the Balearic Islands. 3) In order to have data in the EHR collected during the study period, a minimum of one visit to their PHCT during the 2007-2013 period in Catalonia and Navarre and 2010-2013 in the Balearic Islands; and 4) Information on smoking habit recorded in the EHR for the quarter prior to the onset of the study: last quarter of 2007 in Catalonia and Navarre and first quarter of 2010 in the Balearic Islands, to enable the adequate construction of the various variables. Thus, closed cohorts (with fixed membership, where nobody is added nor excluded after the study begins) were constituted in the three regions. Figure 1 shows the flowchart of the study.

Data were retrieved from the REGIPREV database,[26] which contains encrypted and anonymized clinical information recorded in the EHR by these 66 PHCT. An algorithm was applied to extract equivalent data from the health records software used in each region: “ECAP” in Catalonia, “Atenea” in Navarre and “e-siap” in the Balearic Islands. Codes of the International Classification of Diseases, 9th revision in the Balearic Islands (ICD-9) and 10th in Catalonia (ICD 10th revision)[27] and the International Classification of Primary Care, Second edition, in Navarre (ICPC-2)[28] were used.

Variables

Information on smoking is registered in the electronic health records using diagnostic codes to classify diseases (codes F17.0 to F17.9 and Z72.0 of the ICD-10, 305.1 of the ICD-9 and P17 of the ICPC-2), and also clinical variables (number of cigarettes per day, history of smoking, history of advice for smoking cessation). This information is stored with the entry date (Supplementary File Table S1). With the information on smoking status and entry date we created the following dependent variables at the end of each quarter of the study period:

- Smoking status (three categories): 1) non-smoker: patient that has never been a tobacco consumer, 2) smoker: tobacco consumer or patient that has quit smoking for less than 12 months; and 3) ex-smoker: patient who used to smoke but has quit smoking for at least 12 continuous months. When the EHR did not contain a new entry related to smoking status (diagnostic codes or clinical variables), we considered that no changes in smoking status had taken place and thus that the last observation was still valid.
- New smoker: patient non-smoker for the 12 months prior to the considered quarter that has started smoking during said quarter.
- New ex-smoker: the patient was a smoker two years before the considered quarter and has continuously abstained from tobacco for at least 12 months.
- Ex-smoker relapse: patient ex-smoker during the 12 months prior to the considered quarter that has started smoking again during said quarter.

For higher accuracy in prevalence and incidence changes, quarterly estimates were calculated.

The following variables of each patient were collected at baseline (2008 in Catalonia and Navarre; 2010 in the Balearic Islands): age, sex (male/female), annual number of health problems and annual number of PHC visits. The number of health problems was used as a morbidity indicator; it was calculated as the sum of the number of different active health problems (chronic and acute, coded by ICPC-2).

Data analyses

Descriptive statistics were used to summarize overall information. Categorical variables were expressed as percentage, and continuous variables as mean (standard deviation) or median (interquartile range [IQR]).

Because the three regions used different EHR systems (different standards and computer programs), have different socioeconomic characteristics, different complementary measures to the SFL and also due to the shorter study period in the Balearic Islands, we performed a stratified analysis per region, overall and by sex. Age-standardized prevalence (non-smokers, smokers and ex-smokers) and incidence (new smokers, new ex-smokers and ex-smoker relapse) rates were calculated for each quarter using the direct method, and based on the European Standard Population (rates per 10,000 inhabitants).

Joinpoint analysis was used to analyse the trends of age-standardized prevalence (smokers and ex-smokers) and incidence rates (new smokers, new ex-smokers and ex-smoker relapse) and to identify the best-fitting points (the 'joinpoints', in calendar quarters) where the rate changes significantly in the linear slope of the temporal trend. Significant changes include changes in direction or in the rate of increase or decrease[29]. Joinpoint analysis estimates the magnitude of the increase or the decrease observed in each specified time interval by estimating the annual percentage change (APC). In addition, temporal trends were expressed as the average annual percent change (AAPC), computed to summarize and compare these trends over the entire time period. Ninety-five percent confidence intervals (95% CI) of APC and AAPC were calculated. The trend of non-smoker prevalence rates was not calculated because the study

consisted of a closed cohort where no new participants are recruited, and thus the prevalence of non-smokers can either remain the same or decrease, but never increase.

Analyses were performed using Stata/SE version 14.2 for Windows (Stata Corp. LP, College Station, Texas, US). The joinpoint regression analysis was carried out using the joinpoint software from the Surveillance Research Program of the US National Cancer Institute [ref. Joinpoint Regression Program, Version 4.3.1. April, 2016; Statistical Research and Applications Branch, National Cancer Institute] (National Cancer Institute. Statistical Research and Applications Branch) [On-line: https://surveillance.cancer.gov/branches/srab/].

Patient and public involvement

Study population were not involved in the development of the research question or the outcome measures nor the design of the study. The results will be presented to citizens through informative activities and the media.

RESULTS

The study population was 392,966 patients: 141,071 in Catalonia, 73,644 in Navarre and 178,251 in the Balearic Islands (Figure 1). At the onset of the study, the mean age was 50.4 years in Catalonia, 54.0 in Navarre and 47.7 in the Balearic Islands. In the three cohorts more than half were women (>51 %). Catalonia presented the highest median number of visits (9, IQR: 3 -16) and the Balearic Islands presented the highest number of recorded active health problems per patient (median 10, IQR: 6-16) (Table 1).

Table 1: Characteristics of the cohort study population by region at the onset of the study (2008 in Catalonia and Navarre, 2010 in the Balearic Islands).

	Catalonia N =141,071	**Navarre** N = 73,644	**Balearic Islands** N =178,251
Age (years), SD	50.37 (17.23)	54.04 (18.26)	47.65 (17.56)
Sex (female), number (%)	72340 (51.28)	37898 (51.46)	94164 (52.83)
Number of visits, mean (SD); median (IQR)	11.69 (12.19); 9.00 (3.00-16.00)	8.93 (9.30); 7.00 (3.00-12.00)	11.01 (13.25); 7.00 (3.00-15.00)
Number of health problems, mean (SD); median (IQR)	6.23 (4.58); 5.00 (3.00-8.00)	9.95 (5.39); 9.00 (6.00-13.00)	11.85 (7.74); 10.00 (6.00-16.00)

Abbreviations: SD, standard deviation; IQR, interquartile range.
Patients belonged to 22 Primary Health Care Teams in each region.

The **overall standardized smoker prevalence rates** were of similar magnitude in the three regions (ranges of 3579.2 - 4138.9 in Catalonia; 3719.8 - 4034.2 in Navarre; and 3787.4 - 4029.7 in the Balearic Islands). The prevalence rate decreased in Navarre during the whole study period, decreased in the Balearic Islands in most quarters, and also in Catalonia except for the last year. These rates were higher for men than for women in all regions (Supplementary File Tables S2-S7). A significant downward **overall trend of smoker prevalence rates** was found in Catalonia (AAPC=- 2.02), Navarre (AAPC= -1.40) and the Balearic Islands (AAPC= -1.75); this downward trend was higher for men than for women in the three regions. In Catalonia, the most significant reduction occurred during the period 2010.3-2011.2 (APC= -8,77), similarly to the Balearic Islands (2010.2-2012.4; APC= -2.11), whereas in Navarre it occurred between 2008.1-2011.3 (APC= -1.69) (Tables 2, 3, 4, Supplementary File Figure S1).

For the whole period, the **overall standardized ex-smoker prevalence rates** increased in Navarre, in the Balearic Islands and in Catalonia except for the last year. The rates in Catalonia were higher (ranges of: 1168.5 - 1781.2 in Catalonia; 313.3 - 764.1 in Navarre; and 559.3 - 914.1 in the Balearic Islands). The standardized ex-smoker prevalence rates were higher for men than for women in all regions (Supplementary File Tables S2-S7). The **overall trend of ex-smoker prevalence rates** increased significantly in the three regions throughout the study period but was higher in Navarre (Navarre AAPC= 16.67; Catalonia AAPC= 7.18; Balearic Islands AAPC= 14.92). The increase in the prevalence rate of ex-smokers was higher for the 2008.1-2008.3 period in Catalonia and Navarre, and for 2010.2-2012.2 in the Balearic

Islands, and higher in women in the three regions (women: Catalonia AAPC= 10.83; Navarre AAPC=17.37 and Balearic Islands AAPC= 19.20) (Tables 2, 3, 4, Supplementary File Figure S1).

The **overall new smoker standardized incidence rates** showed low values in the three regions (ranges of 7.9 - 26.8 in Catalonia; 9.5 - 30.9 in Navarre; 1.6 - 17.5 in the Balearic Islands) and higher for men than for women in Catalonia and Navarre (Supplementary File Tables S2-S7). The **overall trend of new smoker incidence rates** decreased significantly in Catalonia (AAPC= -10.65) and Navarre (AAPC= -9.44); additionally, the decline was similar for men and women. In contrast, the trend remained stable in the Balearic Islands (Tables 2, 3, 4, Supplementary File Figure S2).

The **overall standardized new ex-smoker incidence rates** showed higher values in Catalonia (range: 110.7 - 317.6) than in Navarre (range: 48.6 - 181.0) and the Balearic Islands (range: 93.7 - 188.1) (Supplementary File Tables S2-S7). The **overall trend of new ex-smoker incidence rates** showed a significant decrease in Catalonia (AAPC= -7.37) and especially in the Balearic Islands (AAPC= -11.72). This downward trend was higher for men than for women in Catalonia and the Balearic Islands (Tables 2, 3, 4, Supplementary File Figure S2).

The **overall standardized ex-smoker relapse incidence rates** presented higher values in the Balearic Islands (range: 103.9 - 576.6) than in Catalonia (range: 70.7 - 334.5) and Navarre (range: 58.6 - 230.3) (Supplementary File Tables S2-S7). The **overall trend of ex-smoker relapse incidence rates** showed significant increases in Catalonia (AAPC= 18.91), particularly in women (AAPC= 14.99). In contrast, Navarre showed significant decreases (AAPC= -11.37) (Tables 2, 3, 4, Supplementary File Figure S2).

Table 2. Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse. Jointpoints overall and by sex in CATALONIA. N=141,071 (2008-2013)

	Trend 1		Trend 2		Trend 3		Trend 4		Trend 5		AAPC (95% IC) 2008.1 - 2013.4
	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC(95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	
Smoker prevalence											
F	2008.1 - 2010.3	-0.48[d] (-1.03 ; 0.08)	2010.3 - 2011.2	-10.27[c] (-17.96 ; -1.86)	2011.2 - 2013.4	-0.58[c] (-1.11 ; -0.04)					-1.86[a] (-2.95 ; -0.75)
M	2008.1 - 2010.3	-1.96[a] (-2.23 ; -1.70)	2010.3 - 2011.2	-8.26[a] (-12.11 ; -4.24)	2011.2 - 2012.4	-3.01[a] (-3.82 ; -2.18)	2012.4 - 2013.4	2.69[a] (1.48 ; 3.91)			-2.30[a] (-2.86 ; -1.73)
G	2008.1 - 2010.3	-1.33[a] (-1.65 ; -1.00)	2010.3 - 2011.2	-8.77[b] (-13.46 ; -3.83)	2011.2 - 2011.4	-2.30[a] (-3.29 ; -1.29)	2012.4 - 2013.4	2.02[c] (0.56 ; 3.50)			-2.02[a] (-2.71 ; -1.32)
Ex-smoker prevalence											
F	2008.1 - 2008.4	17.32[a] (13.34 ; 21.44)	2008.4 - 2011.2	11.23[a] (10.59 ; 11.87)	2011.2 - 2012.1	15.78[a] (8.71 ; 23.30)	2012.1 - 2013.1	9.61[a] (6.34 ; 12.98)	2013.1 - 2013.4	0.52[d] (-2.16 ; 3.28)	10.83[a] (9.74; 11.94)
M	2008.1 - 2008.3	14.77[c] (3.01 ; 27.86)	2008.3 - 2011.1	5.48[a] (4.55 ; 6.42)	2011.1 - 2012.4	7.54[a] (5.93 ; 9.17)	2012.4 - 2013.4	-4.85[a] (-7.29 ; -2.34)			4.99[a] (3.86 ; 6.13)
G	2008.1 - 2008.3	16.69[a] (7.59 ; 26.57)	2008.3 - 2011.1	7.63[a] (6.90 ; 8.37)	2011.1 - 2012.4	9.68[a] (8.40 ; 10.96)	2012.4 - 2013.4	-2.35[c] (-4.31 ; -0.35)			7.18[a] (6.31 ; 8.07)
New smokers incidence											
F	2008.1 - 2013.4	-11.00[b] (-17.19 ; -4.35)									-11.00[b] (-17.19 ; -4.35)
M	2008.1 - 2013.4	-10.68[a] (-15.90 ; -5.14)									-10.68[a] (-15.90 ; -5.14)
G	2008.1 - 2013.4	-10.65[a] (-15.45 ; 5.59)									-10.65[a] (-15.45 ; -5.59)
New ex-smokers incidence											
F	2008.1 - 2013.4	-5.17[d] (-10.33 ; 0.29)									-5.17[d] (-10.33 ; 0.29)
M	2008.1 - 2013.4	-7.89[b] (-13.23 ; -2.22)									-7.89[b] (-13.23 ; -2.22)
G	2008.1 - 2013.4	-7.37[b] (-12.47 ; -1.96)									-7.37[b] (-12.47 ; -1.96)
Ex-smokers relapse incidence											
F	2008.1 - 2012.3	-8.62[d] (-18.97 ; 3.05)	2012.3 - 2013.4	163.01[a] (60.46 ; 331.10)							14.99[c] (0.62 ; 31.41)
M	2008.1 - 2009.3	-47.87[d] (-82.66 ; 56.76)	2009.3 - 2010.2	118.99[d] (-100 ; 1329577)	2010.2 - 2012.3	-27.30[d] (-49.13 ; 3.88)	2012.3 - 2013.2	527.0[d] (-75.9 ; 16209.4)	2013.2 - 2013.4	74.88[d] (-70.67 ; 942.8)	10.03[d] (-62.75 ; 225.05)
G	2008.1 - 2012.3	-7.94[d] (-16.33 ; 1.30)	2012.3 - 2013.4	198.72[a] (116.0 ; 313.1)							18.91[a] (8.01 ; 30.90)

Note: 2008.*. represents the trimester * of the year 2008

APC, annual percentage change and AAPC, average annual percent change estimated by joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.
[a] p≤ 0.001; [b] p≤ 0.01; [c] p≤ 0.05; [d] p>0.05

Table 3. Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse. Jointpoints overall and by sex in NAVARRE. N=73,644 (2008-2013)

	Trend 1		Trend 2		Trend 3		Trend 4		Trend 5		AAPC (95% IC) 2008.1 - 2013.4
	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	
Smoker prevalence											
F	2008.1 - 2010.3	-0.95[a] (-1.23 ; -0.67)	2010.3 - 2011.2	-2.39[d] (-6.56 ; 1.96)	2011.2 - 2013.4	-0.22[d] (-0.51 ; 0.08)					-0.82[b] (-1.36 ; -0.28)
M	2008.1 - 2013.4	-1.95[a] (-2.06 ; -1.84)									-1.95[a] (-2.06 ; -1.84)
G	2008.1 - 2011.3	-1.69[a] (-1.90 ; -1.48)	2011.3 - 2013.4	-0.95[a] (-1.39 ; -0.52)							-1.40[a] (-1.60 ; -1.20)
Ex-smoker prevalence											
F	2008.1 -2008.3	41.34[a] (25.34 ; 59.38)	2008.3 - 2010.2	19.33[a] (17.20 ; 21.50)	2010.2 - 2011.3	13.11[a] (9.64 ; 16.70)	2011.3 - 2012.2	20.16[b] (9.28 ; 32.12)	2012.2 - 2013.4	10.28[a] (8.87 ; 11.72)	17.37[a] (15.50 ; 19.26)
M	2008.1 - 2008.3	34.19[a] (16.08 ; 55.11)	2008.3 - 2009.4	19.48[a] (14.38 ; 24.80)	2009.4 - 2012.4	13.63[a] (12.85 ; 14.41)	2012.4 - 2013.4	9.63[a] (6.53 ; 12.81)			15.82[a] (14.08 ; 17.60)
G	2008.1 - 2008.3	36.52[a] (17.15 ; 59.08)	2008.3 - 2009.4	20.06[a] (14.63 ; 25.75)	2009.4 - 2012.4	14.66[a] (13.80 ; 15.52)	2012.4 - 2013.4	9.66[a] (6.27 ; 13.16)			16.67[a] (14.81 ; 18.57)
New smokers incidence											
F	2008.1 - 2013.4	-9.43[b] (-15.71 ; -2.68)									-9.43[b] (-15.71 ; -2.68)
M	2008.1 - 2013.4	-9.38[b] (-15.04 ; -3.35)									-9.38[b] (-15.04 ; -3.35)
G	2008.1 - 2013.4	-9.44[b] (-14.84 ; -3.68)									-9.44[b] (-14.84 ; -3.68)
New ex-smokers incidence											
F	2008.1 - 2013.4	-9.66[b] (-14.86 ; -4.14)									-9.66[b] (-14.86 ; -4.14)
M	2008.1 - 2013.4	-2.68[d] (-9.12 ; 4.22)									-2.68[d] (-9.12 ; 4.22)
G	2008.1 - 2013.4	-5.00[d] (-10.75 ; 1.11)									-5.00[d] (-10.75 ; 1.11)
Ex-smoker relapse incidence											
F	2008.1 - 2013.4	-13.88[a] (-19.74 ; -7.61)									-13.88[a] (-19.74 ; -7.61)
M	2008.1 - 2013.4	-12.03[c] (-20.16 ; -3.06)									-12.03[c] (-20.16 ; -3.06)
G	2008.1 - 2013.4	-11.37[a] (-17.23 ; -5.09)									-11.37[a] (-17.23 ; -5.09)

Note: 2008.*. represents the trimester * of the year 2008

APC, annual percentage change and AAPC, average annual percent change estimated by joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.

[a] p≤ 0.001; [b] p≤ 0.01; [c] p≤ 0.05; [d] p>0.05

Table 4. Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse. Jointpoints overall and by sex in THE BALEARIC ISLANDS. N=178,251 (2010-2013)

	Trend 1		Trend 2		Trend 3		AAPC (95% IC)
	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	2008.1 - 2013.4
Smoker prevalence							
F	2010.2 - 2013.4	-1.20[a] (-1.40 ; -1.01)					-1.20[a] (-1.40 ; -1.01)
M	2010.2 - 2011.1	-2.11[a] (-2.59 ; -1.63)	2011.1 - 2012.3	-3.06[a] (-3.29 ; -2.83)	2012.3 - 2013.4	-1.48[a] (-1.74 ; -1.22)	-2.29[a] (-2.43 ; -2.15)
G	2010.2 - 2012.4	-2.11[a] (-2.31 ; -1.91)	2012.4 - 2013.4	-0.86[d] (-1.87 ; 0.17)			-1.75[a] (-2.04 ; -1.47)
Exsmoker prevalence							
F	2010.2 - 2012.2	24.88[a] (24.10 ; 25.66)	2012.2 - 2013.4	12.03[a] (11.11 ; 12.95)			19.20[a] (18.67 ; 19.72)
M	2010.2 - 2012.2	15.87[a] (14.59 ; 17.17)	2012.2 - 2013.4	7.28[a] (5.69 ; 8.89)			12.11[a] (11.22 ; 13.00)
G	2010.2 - 2012.2	19.35[a] (18.76 ; 19.93)	2012.2 - 2013.4	9.27[a] (8.56 ; 9.99)			14.92[a] (14.52 ; 15.32)
New smokers incidence							
F	2010.2 - 2012.4	-44.30[b] (-61.99 ; -18.40)	2012.4 - 2013.4	1236.9[c] (98.1 ; 8922.6)			38.10[d] (-19.25 ; 136.16)
M	2010.2 - 2012.4	-45.84[a] (-59.81 ; -27.01)	2012.4 - 2013.4	702.68[a] (187.6 ; 2140.5)			17.00[d] (-14.94 ; 60.95)
G	2010.2 - 2012.4	-45.95[a] (-60.61 ; -25.84)	2012.4 - 2013.4	1036.5[b] (207.5 ; 4098.1)			29.03[d] (-12.11 ; 89.42)
New exsmokers incidence							
F	2010.2 - 2013.4	-11.19[c] (--20.15 ; -1.22)					-11.19[c] (-20.15 ; -1.22)
M	2010.2 - 2013.4	-12.06[c] (-18.59 ; -5.02)					-12.06[c] (-18.59 ; -5.02)
G	2010.2 - 2013.4	-11.72[b] (-18.15 ; -4.78)					-11.72[b] (-18.15 ; -4.78)
Ex-smokers relapse incidence							
F	2010.2 - 2013.4	-32.20[a] (-41.27 ; -21.73)					-32.20[a] (-41.27 ; -21.73)
M	2010.2 - 2013.4	-36.50[a] (-44.95 ; -26.75)					-36.50[a] (-44.95 ; -26.75)
G	2010.2 - 2013.1	-18.41[c] (-30.28 ; -4.52)	2013.1 - 2013.4	-85.36[d] (-99.52 ; 347.65)			-43.54[d] (-70.63 ; 8.57)

Note: 2010.*. represents the quarter * of the year 2010

APC, annual percentage change and AAPC, average annual percent change estimated by joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.
[a] p≤ 0.001; [b] p≤ 0.01; [c] p≤ 0.05; [d] p>0.05

DISCUSSION

The previous implementation of the partial Spanish SFL could account for the low effectiveness of the comprehensive SFL observed in this study. A significant downward trend of smoker prevalence rates, higher in men than in women, was found in the three regions throughout the study period. Correspondingly, the trend of ex-smoker prevalence rates increased in the three regions, particularly in Navarre and during the period 2008.1-2008.3 in Catalonia and Navarre, and the period 2010.2-2012.2 in the Balearic Islands. Even though the standardized ex-smoker prevalence rate was higher for men, the increase in the trend of ex-smoker prevalence rate was higher in women in the three regions. The overall trends of new smoker incidence rates decreased significantly in Catalonia and Navarre and were similar for men and women. Also, the overall trends of new ex-smokers decreased significantly in Catalonia and the Balearic Islands, particularly for men. In addition, the overall trends of ex-smoker relapse increased in Catalonia and decreased in Navarre, more for women than for men in both cases.

The trends of smoker prevalence declined throughout the study and no changes were observed after the implementation of the comprehensive SFL. Indeed, the most significant decrease begins in 2010 in Catalonia (3rd quarter) and the Balearic Islands and in 2008 in Navarre, prior to the implementation of the comprehensive SFL (January 1, 2011). However, the trend in Catalonia shows a drop in the prevalence rate of smokers around the time of the implementation of the Law. In contrast, trends in Navarre and the Balearic Islands show a more progressive decline. Comparisons are difficult due to the lack of studies on smoking prevalence and incidence from a PHC perspective and because some studies evaluate the impact of SFL on smoking prevalence with surveys that use different methodologies. Two studies that analysed data from surveys to the general population[19,20] did not find a significant decrease in the prevalence of smokers after the Spanish comprehensive law. In contrast, Lidón *et al.*[24] showed that after the implementation of both Spanish SFL, a significant decrease was observed in the smoking prevalence (from 34.5% to 26.1%, Prevalence Ratio = 0.76, $p < 0.001$) of people 16 years of age and older living in Barcelona surveyed in 2004–2005 and followed-up in 2013–2014. In addition, National Health Survey data from the 1987-2005 period revealed an annual average absolute decline of 1.0% in the prevalence of male smokers, whereas women showed an annual average absolute increase in prevalence of 0.2%. Between 2006 and 2014, the prevalence of smokers declined annually by 0.7% in men and 0.5% in women.[23] Although the values of the current study are higher, the steeper decline in the prevalence of smokers in men agree with these data.[23] Also, one study that estimated the effect of the Spanish SFL for the 2012-2025 period predicted a decrease in smoking prevalence in all age groups and for both sexes, except for women aged 40–64.[30]

Concomitantly with the decline in the prevalence trends in smokers, a constant increase of prevalence trends in ex-smokers was observed in the three regions. Other studies failed to note a significant change in the prevalence of ex-smokers after the comprehensive SFL: a difference of only 0.3 % between 2007 and 2011[20] and a non-significant increase of 3.3% between 2006 and 2011.[19] In agreement with a recent evidence review,[23] we observed a higher increase in the trend of ex-smokers prevalence in women. This review showed that the rate of smoking cessation in men increased 0.9% annually during the 1987-2014 period, and 1.5% in women after the Partial SFL came into force. The later incorporation of women to smoking might explain these gender differences. We should underscore that other

studies that use health surveys as information source have a higher prevalence of ex-smokers than the prevalence we obtained in this study, especially for Navarre and the Balearic Islands.[31] This discrepancy could be explained by the misclassification of long-term ex-smokers as non-smokers during the process of computerization of medical records in the cases where the smoking habit was not sufficiently investigated.[32]

We observed a gradual decline in the new smoker incidence trends in Catalonia and Navarre throughout the study period, whereas incidence trends remained stable in the Balearic Islands (possibly due to the shorter study period or lower rates). A review by Wilson *et al.*[33] of two studies that evaluated smoking initiation reported mixed results, while Guerrero *et al*.[34] concluded that the Spanish partial SFL had no effect on new smokers in 2009. In contrast, Pinilla and Abásolo[35] observed a 6% decrease in the rate of smoking initiation among young people after the implementation of the same law, with a more positive impact in higher socioeconomic strata. We have not found studies that evaluate the impact of the comprehensive SFL on the incidence of new smokers. However, our data show a continuation in the trend observed in Pinilla's study[35] on the impact of the partial law.

The incidence trend in new ex-smokers declined gradually throughout the study period in Catalonia and the Balearic Islands. While the literature to date lacks data on the effect of the SFL on the incidence of new ex-smokers, it provides some information on prevalence. In this respect, one study on the Spanish partial SFL observed an increase of 8% between 2006 and 2011 in the rate of cessation among adult smokers (age 21 years and older) according to data from the National Health Survey.[35] In Luxembourg, smoking cessation attributed to the SFL was higher among daily smokers with a higher socioeconomic status.[8] In our cohort, we observed apparent random increases and declines in the adjusted rates in the three regions throughout the study.

The incidence trend in ex-smoker relapses increased in Catalonia and declined in Navarre constantly throughout the whole period, particularly for women, but the overall trend remained stable in the Balearic islands (most likely because of the shorter study period). However, the literature presents conflicting results regarding smoking relapse. One study on the partial Spanish SFL observed that most people who had succeeded in giving up smoking in 2006 had not relapsed by 2009.[34] On the other hand, a quasi-experimental study conducted in the United States observed that relapse was similar between employees in workplaces with SFL and employees where smoking was permitted.[36] In contrast, Shang found that a comprehensive SFL in bars significantly deters smoking relapse among people ages 21 and older.[37] According to Buczkowski *et al.*,[38] the main reasons for relapse are stress, missing the pleasure obtained from smoking and the smoking environment. Other factors not analysed in our study that might influence relapse rates could explain the variations between regions, for instance living with other smokers, being enrolled in work or clinics cessation programmes[39] or the region-specific complementary measures to the SFL (for instance, Foral Law 6/2003,[40] February 14, of smoking prevention, protection from secondhand tobacco smoke and promotion of health with regard to smoking in Navarre). In addition, we should consider the impact of the financial crisis during the study period and the subsequent increase of anxiety and depression in the population.[41] In this respect, Navarre was the region with the lowest unemployment rate in Spain according to the 2010 Economically Active Population Survey (unemployment of 11.6% in Navarre, versus 18.0% in Catalonia and 22.2% in the Balearic Islands). According to the 2009 European Health

Survey in Spain, these unemployment figures correlate with the prevalence of chronic depression, which was of 3.4% in Navarre versus 5.4% in Catalonia and 7.0% in the Balearic Islands.

The SFL is a keystone of the WHO Framework Convention on Tobacco Control (FCTC) and the MPOWER policy package (M=Monitor; P=Protect; O=Offer; W=Warm; E=Enforce; R= Raise).[42] The enforcement of Laws 28/2005 and 42/2010 have significantly advanced smoking control in Spain, in particular the "Protect people from tobacco" strategy. However, the remaining MPOWER strategies have been patchily implemented and require further development.[23] On balance, a combination of specific, feasible, pragmatic, sufficiently funded policies and interventions aimed at populations and individuals is essential to achieve progress regarding smoking behaviour.

Limitations and strengths of the study

It is important to take into account that other than the Law, the pattern of tobacco consumption is influenced by factors such as health interventions, level of education, age, civil status, having children and being unemployed.[43] However, this study only considered age, sex, number of health problems and number of PHC visits since other variables were not available. In addition, many patients were excluded from the study because of lack of baseline data on smoking (missing data is a common problem in studies based on EHR). In order to prevent bias caused by improved smoking records, we excluded the cases with no information at the beginning of the study. The selection criteria and the longitudinal design aimed to maximize the internal validity of the study. Moreover, young people might be underrepresented due to their lower use of PHC services. On the other hand, 70% of the population attends PHC services at least once a year and smokers attend more frequently than no smokers.[44] In view of the limited length of the study period, particularly in the Balearic Islands, we consider these results a first approximation to be succeeded by follow-up research. We should underscore that rather than just comparing two different periods, joinpoint analysis evaluates longitudinal trends, thus producing a more accurate assessment. The following characteristics of the study were taken into consideration: scarcity of data prior to the implementation of the SFL; delayed changes in smoking status; possibility of detecting more than one change in smoking trends; and influence of unanticipated factors. While other statistical models could have been used, we believe that joinpoint is a suitable method to achieve the study objectives, as shown in previous studies.[45-47]

This study provides useful data on the impact of the Spanish comprehensive SFL on adult smoking behaviour in PHC patients. It is crucial to analyse the consequences of a public health law on PHC users. Primary health care has a pivotal role in smoking cessation because it is the gatekeeper of the health services, it is accessible and provides continuity of care to smokers.[48] We should also highlight that this study includes the evaluation of novel variables such as incidence of new smokers, new ex-smokers and ex-smoker relapse, which we consider of great relevance in relation to PHC interventions for smoking cessation. Used as a research tool, EHR portray real-life conditions and provide comprehensive, long-term health histories from a large population sample, ensure high representativeness and external validity and minimize potential recall bias. The results are only generalizable to PHC users. To our knowledge, this study is amongst the first to show quarterly data from EHR.

CONCLUSIONS

The introduction of the Spanish comprehensive SFL (Law 42/2010) does not significantly modify incidence and prevalence trends of smoking behaviour in PHC adult patients in Catalonia, Navarre and the Balearic Islands. The impact of the comprehensive SFL might have been lessened by the effect of the previous implementation of the partial SFL (Law 28/2005). The current article provides baseline data for future research into the effectiveness of this Law. In addition to specific factors associated with smoking behaviour (such as the price of a pack of cigarettes or funding of smoking cessation services), future studies should consider socio-economic status and age groups.

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Contributors: BB, TRB, MPV, JBM, and CVF designed the study and wrote the protocol. YRM, MPV and JBM conducted literature searches and provided summaries of previous research studies. BB, JLL, JM, JR and MPV obtained the data. TRB and TLJ conducted the statistical analysis. All authors contributed to the interpretation of the results. YRM and MPV wrote the first draft of the manuscript. All authors read, contributed and approved the final version of the manuscript.

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Competing interest: The authors declare no conflict of interest.

Ethical aspects: This study follows the tenets of the Helsinki Declaration and of Good Clinical Research Practice and has been approved by the Ethical and Clinical Research Committee of the IDIAP Jordi Gol. Confidentiality was guaranteed through data encryption and anonymization in agreement with the data confidentiality Law 15/1999.

Data sharing statement: No additional data are available.

Figure 1: Flow-chart of patients included in the study, by region.

REFERENCES

1. Jha P. Avoidable global cancer deaths and total deaths from smoking. *Nat Rev Cancer* 2009;9:655–64.
2. Murray CJL, Lopez AD. Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. *Lancet* 2017;349:1498–504.
3. World Health Organization, and Tobacco Free Initiative. Building blocks to tobacco control: a hand-book. (Tools for advancing tobacco control in the 21st century). Geneva*: WHO;* 2004.
4. Federico B, Mackenbach JP, Eikemo TA, *et al*. Impact of the 2005 smoke-free policy in Italy on prevalence, cessation and intensity of smoking in the overall population and by educational group. *Addiction* 2012;107:1677–86.
5. Hahn EJ, Rayens MK, Butler KM, *et al*. Smoke-free laws and adult smoking prevalence. *Prev Med* 2008;47:206–9.
6. Nagelhout GE, Willemsen MC, de Vries H. The population impact of smoke-free workplace and hospitality industry legislation on smoking behaviour. Findings from a national population survey. *Addiction* 2011;106:816–23.
7. Hublet A, Schmid H, Clays E, *et al*. Association between tobacco control policies and smoking behaviour among adolescents in 29 European countries. *Addiction* 2009;104:1918–26.
8. Tchicaya A, Lorentz N, Demarest S. Socioeconomic inequalities in smoking and smoking cessation due to a smoking ban: General population-based cross-sectional study in Luxembourg. *PLoS One* 2016;11:1–15.
9. Ye X, Chen S, Yao Z, *et al*. Smoking behaviors before and after implementation of a smoke-free legislation in Guangzhou, China. *BMC Public Health* 2015;15:982.
10. Fichtenberg CM, Glantz SA. Effect of smoke-free workplace on smoking behaviour: systematic review. BMJ 2002;325:188.
11. Frazer K, Callinan JE, McHugh J, *et al.* Legislative smoking bans for reducing harms from secondhand smoke exposure, smoking prevalence and tobacco consumption. *Cochrane database Syst Rev* 2016;2:CD005992.
12. Ley de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro y la publicidad de los productos del tabaco. L. N. 28/2005 (27 diciembre 2005). Available at: https://www.boe.es/buscar/doc.php?id=BOE-A-2005-21261 . Accessed 6-3-2017.
13. Nebot M, Fernández E, (Coords) Evaluación del impacto de la ley de medidas sanitarias frente al tabaquismo. Grupo de Trabajo en Tabaquismo de la Sociedad Española de Epidemiología. Barcelona: Sociedad Española de Epidemiología y Ministerio de Sanidad y Política Social, 9-43. 2009. Available in: URL: http://www.seepidemiologia.es/documents/dummy/Monografia-Grupo%20Trabajo%20sobre%20tabaquismo.pdf)
14. Cordoba R, Villalbi JR, Salvador-Llivina T, *et al.* El proceso en España de la adopción de una legislación eficaz para la prevención del tabaquismo [Spain's process of passing effective smoking prevention legislation]. *Rev Esp Salud Publica* 2006;80:631–45.
15. Nebot M, López MJ, Ariza C, Pérez-Ríos M, *et al*. Impact of the Spanish smoking law on exposure to secondhand smoke in offices and hospitality venues: Before-and-after study. *Environ Health Perspect* 2009;117:344–7.
16. Ley de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro y la publicidad de los productos del tabaco (30 December 2010), por la que se modifica la Ley 28/2005, de 26 de diciembre, de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro, el consumo y la publicidad de los productos del tabaco. Boletín Oficial del Estado (Spanish Official State Bulletin). L. N. 42/2010.No. 318. Available at: https://www.boe.es/buscar/act.php?id=BOE-A-2010-20138 . Accessed 6-3-2017.
17. Regidor E, de Mateo S, Ronda E, *et al.* Heterogeneous trend in smoking prevalence by sex and age group following the implementation of a national smoke-free law. *J Epidemiol Community Health* 2011;65:702–8.
18. Regidor E, Pascual C, Giráldez-García C, *et al.* Impact of tobacco prices and smoke-free policy on smoking cessation, by gender and educational group: Spain, 1993-2012. *Int J Drug Policy* 2015;26:1215–21.
19. Perez-Rios M, Fernandez E, Schiaffino A, *et al*. Changes in the prevalence of tobacco consumption and the profile of Spanish smokers after a comprehensive smoke-free policy. *PLoS One* 2015;10:1–9.
20. Jiménez Ruiz CA, Riesco Miranda JA, Altet Gómez N, *et al*. Impact of legislation on passive smoking in Spain. *Respiration* 2014;87:190–5.
21. Catalina Romero C, Gelpi Médez JA, Cortés Arcas MV, *et al.* Evolución en España del consumo de tabaco en población trabajadora desde la entrada en vigor de la Ley 28/2005 de medidas sanitarias frente al tabaquismo [Prevalence of Tobacco Consumption Among Working Population after the Law 42/2010, Spain]. *Rev Esp salud pública* 2010;84:223–7.
22. Catalina Romero C, Sainz Gutiérrez JC, Quevedo Aguado L*, et al.* Prevalencia de consumo de tabaco en población trabajadora tras la entrada en vigor de la Ley 42/2010 [Prevalence of tobacco consumption among working population after the law 42/2010, Spain]. *Rev Esp Salud Publica* 2012;86:177–88.
23. Pérez-Ríos M, Galán I(editors) Evaluación de las políticas de control del tabaquismo en España (Leyes 28/2005 y

42/2010) Revisión de la evidencia. Grupo de Trabajo en Tabaquismo de la Sociedad Española de Epidemiología. Barcelona: Sociedad Española de Epidemiología y Ministerio de Sanidad y Política Social, 2017;11-74. Available in: URL: http://www.seepidemiologia.es/documents/dummy/V9.0%2520-%2520Libro%2520Tabaquismo%25202017%2520-%2520Abierto%2520Final.pdf

24. Lidón-moyano C, Fu M, Ballbè M, *et al*. Addictive Behaviors Impact of the Spanish smoking laws on tobacco consumption and secondhand smoke exposure : A longitudinal population study. *Addict Behav* 2017;75:30–5.
25. Bauzà-Amengual M, Blasco-González M, Sánchez-Vazquez E, *et al.* Impacto de la Ley del tabaco en el lugar de trabajo: estudio de seguimiento de una cohorte de trabajadores en España 2005--07 [Impact of the Tobacco Law on the workplace: a follow up study of a cohort of workers in Spain 2005–2007]. *Atención primaria* 2010;42:309–13.
26. Bolíbar B, Pareja C, Astier-Peña MP, *et al*. Variability in the performance of preventive services and in the degree of control of identified health problems: a primary care study protocol. *BMC Public Health* 2008;8:281.
27. The International Statistical Classification of Diseases and Related Health Problems (ICD-10th revision) classification of mental and behavioural disorders: clinical descriptions and diagnostic guidelines. Geneva: World Health Organization, 1992. Available at: http://www.who.int/classifications/icd/en/bluebook.pdf . Accessed 6-3-2017..
28. Okkes IM, Becker HW, Bernstein RM, *et al*.The March 2002 update of the electronic version of ICPC-2. A step forward to the use of ICD-10 as a nomenclature and a terminology for ICPC-2. *Fam Pract* 2002;19:543–6.
29. Kim H-J, Fay MP, Feuer EJ, *et al*. Permutation tests for joinpoint regression with applications to cancer rates. *Stat Med* 2000;19:335–51. Available at: http://onlinelibrary.wiley.com/doi/10.1002/(SICI)1097-0258(20000215)19:3%253C335::AID-SIM336%253E3.0.CO;2-Z/abstract. Accessed 8-3-2017.
30. Martín-Sánchez JC, Martinez-Sanchez JM, Bilal U, *et al*. Sex and Age Specific Projections of Smoking Prevalence in Spain: A Bayesian Approach. *Nicotine Tob Res* 2017; ntx120, https://doi.org/10.1093/ntr/ntx120.
31. Ministerio de Sanidad Servicios Sociales e Igualdad. Encuesta Europea de Salud en España: Determinantes de salud [Internet]. 2014. Available from: http://www.msssi.gob.es/estadEstudios/estadisticas/EncuestaEuropea/pdf/MODULO3RELATIVOweb.pdf
32. Ramos R, Balló E, Marrugat J, *et al.* Validity for Use in Research on Vascular Diseases of the SIDIAP (Information System for the Development of Research in Primary Care): the EMMA Study. *Rev Española Cardiol* (English Ed [Internet]. 2012;65:29–37. Available from: http://www.revespcardiol.org/en/validity-for-use-in-research/articulo/90072112/ Accessed 25-5-2018.
33. Wilson LM, Avila Tang E, Chander G, *et al.* Impact of tobacco control interventions on smoking initiation, cessation, and prevalence: A systematic review. *J Environ Public Health* 2012; doi:10.1155/2012/961724
34. Guerrero F, Santonja F-J, Villanueva R-J. Analysing the Spanish smoke-free legislation of 2006: a new method to quantify its impact using a dynamic model. *Int J Drug Policy* 2011 Jul;22:247–51.
35. Pinilla J, Abásolo I. The effect of policies regulating tobacco consumption on smoking initiation and cessation in Spain: is it equal across socioeconomic groups? *Tob Induc Dis* 2017;15:8.
36. Longo DR, Johnson JC, Kruse RL, *et al.* A prospective investigation of the impact of smoking bans on tobacco cessation and relapse. *Tob Control* 2001;10:267–72.
37. Shang C. The effect of smoke-free air law in bars on smoking initiation and relapse among teenagers and young adults. *Int J Environ Res Public Health* 2015;12:504–20.
38. Buczkowski K, Marcinowicz L, Czachowski S, *et al.* Motivations toward smoking cessation, reasons for relapse, and modes of quitting: results from a qualitative study among former and current smokers. *Patient Prefer Adherence* 2014;8:1353–63.
39. Schillo BA, Keller PA, Betzner AE, *et al*. Minnesota's smokefree policies: Impact on cessation program participants. *Am J Prev Med* 2012;43:S171–8.
40. Ley foral 6/2003, de 14 de febrero, de prevención del consumo de tabaco, de protección del aire respirable y de la promoción de la salud en relación al tabaco (Navarra). Available at: http://www.lexnavarra.navarra.es/detalle.asp?r=3323. Accessed 31-7-2017
41. Gili M, Garcia Campayo J, Roca M. Crisis económica y salud mental. Informe SESPAS 2014 [Economic crisis and mental health. SESPAS report 2014]. *Gac Sanit* 2014;28 Suppl 1:104–8.
42 World Health Organization. WHO report on the global tobacco epidemic, 2009: implementing smoke-free environments. Geneva: World Health Organization; 2009.
43. Buonanno P, Ranzani M. Thank you for not smoking: Evidence from the Italian smoking ban. *Health Policy* 2013;109:192–9.
44. Camarelles Guillem F, Dalmau González-Gallarza R, Clemente Jiménez L, *et al*. Documento de consenso para la atención clínica al tabaquismo en España [Consensus report for the clinical care of smoking cessation in Spain]. *Med Clin* 2013;140:272.e1-272.e12.

45. Lopez-Campos JL, Ruiz-Ramos M, Fernandez E, *et al.* Recent lung cancer mortality trends in Europe: effect of national smoke-free legislation strengthening. *Eur J Cancer Prev*. 2017 Apr 4. doi: 10.1097/CEJ.0000000000000354.
46. Jan C, Lee M, Roa R, *et al*. The association of tobacco control policies and the risk of acute myocardial infarction using hospital admissions data. *PLoS One*. 2014;9(2). doi: 10.1371/journal.pone.0088784
47. Rando-Matos Y, Pons-Vigués M, Rodriguez-Blanco T, *et al*. Effect of comprehensive smoke-free legislation on asthma and coronary disease trends in Spanish primary care patients. *Eur J Public Health* [Internet]. 2018;cky010. doi: 10.1093/eurpub/cky010.
48. Córdoba R, Cabezas C, Camarelles F, *et al.* Recomendaciones sobre el estilo de vida. *Atención primaria* 2012;44:16–22.

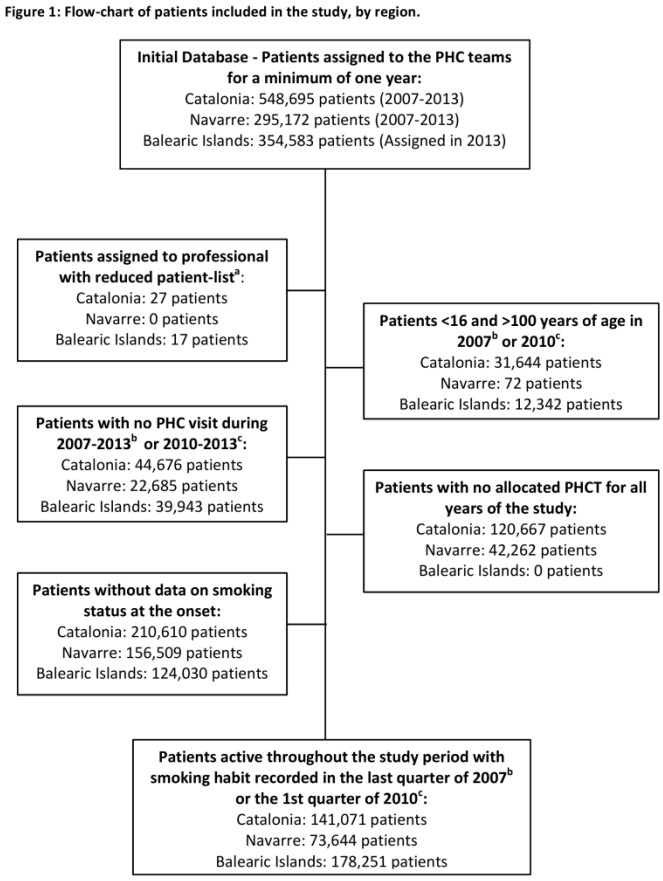

Figure 1: Flow-chart of patients included in the study, by region.

209x297mm (300 x 300 DPI)

SUPPLEMENTARY DATA FOR Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

Table S1: Information concerning smoking status in the electronic health records by region

<table>
<tr><th>Information from electronic health records</th><th>Catalonia</th><th>Navarre</th><th>Balearic Islands</th></tr>
<tr><td rowspan="2">Diagnostic codes related to smoking
(with entry date)</td><td>Smoker: F17, F17.0, F17.1 F17.2, F17.5, F17.6, F17.7, F17.8, F17.9 in ICD-10</td><td rowspan="2">Smoker: code P17 in ICPC-2</td><td rowspan="2">Smoker: 305.1 in ICD-9</td></tr>
<tr><td>Ex-smoker: Z72.0</td></tr>
<tr><td rowspan="3">Clinical variables related to smoking in the medical history
(with entry date)</td><td colspan="3">Smoking habit:
0: non-smoker.
1: smoker.
2: ex-smoker</td></tr>
<tr><td colspan="3">Number of cigarettes per day:
0 to 300</td></tr>
<tr><td colspan="3">Smoking cessation advice:
1: yes
0: no</td></tr>
</table>

Abbreviations: ICPC-2, International Classification of Primary Care, second edition; ICD-9 and 10, International Classification of Diseases, 9th and 10th revision.

Table S2: Age-adjusted rates by direct method per 10,000 inhabitants based on the European Standard Population. CATALONIA N=141,071 (2008-2013).

Quarter	Smoking status prevalence			New smokers incidence	New ex-smokers incidence	Ex-smoker relapses incidence
	Non smokers	Smokers	Ex-smokers			
2008.1	4692.6	4138.9	1168.5	20.8	254.3	226.9
2008.2	4679.3	4099.0	1221.7	21.4	212.9	151.4
2008.3	4668.8	4073.6	1257.6	16.6	267.5	218.5
2008.4	4650.2	4051.7	1298.1	26.1	317.6	100.4
2009.1	4638.8	4053.6	1307.6	25.2	260.1	128.6
2009.2	4628.1	4036.8	1335.1	15.8	228.5	78.3
2009.3	4618.4	4021.6	1360.0	12.7	161.3	113.7
2009.4	4604.4	3998.5	1397.2	19.6	212.7	165.6
2010.1	4590.0	4001.8	1408.2	19.0	160.9	123.1
2010.2	4573.5	3994.3	1432.2	26.4	135.8	148.8
2010.3	4560.0	3981.0	1459.0	20.8	139.0	100.5
2010.4	4539.7	3957.4	1503.0	26.8	188.1	112.5
2011.1	4077.0	3758.0	1510.3	15.1	171.9	103.2
2011.2	4068.6	3721.4	1555.3	12.4	213.0	90.0
2011.3	4061.6	3696.3	1587.3	13.0	145.9	81.4
2011.4	4050.8	3649.8	1644.7	15.8	255.4	91.3
2012.1	4012.6	3658.7	1673.9	13.4	222.7	111.1
2012.2	4004.9	3629.6	1710.7	11.3	171.3	91.9
2012.3	4000.4	3608.5	1736.3	7.9	118.8	70.7
2012.4	3990.2	3579.2	1775.8	11.8	201.3	103.9
2013.1	3963.0	3601.1	1781.2	16.5	184.9	141.7
2013.2	3956.3	3618.6	1770.3	15.2	136.7	247.6
2013.3	3952.8	3635.1	1757.3	9.3	110.7	248.6
2013.4	3946.5	3659.3	1739.5	14.7	172.8	334.5

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S3: Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population. NAVARRE N=73,644 (2008-2013).

Quarter	Smoking status prevalence			New smokers incidence	New ex-smokers incidence	Ex-smoker relapses incidence
	Non smokers	Smokers	Ex-smokers			
2008.1	5652.5	4034.2	313.3	25.3	175.3	227.0
2008.2	5642.5	4013.0	344.5	17.2	181.0	160.4
2008.3	5632.4	4003.3	364.3	16.5	109.1	129.4
2008.4	5620.0	3993.3	386.7	21.4	127.7	230.3
2009.1	5645.0	3951.4	403.7	30.9	136.4	225.4
2009.2	5630.8	3944.1	425.1	23.5	132.1	174.0
2009.3	5623.5	3934.7	441.8	12.5	100.3	100.7
2009.4	5614.7	3925.5	459.8	14.8	109.9	134.7
2010.1	5618.3	3905.9	475.8	27.2	111.2	209.4
2010.2	5605.5	3893.8	500.7	21.1	114.9	132.5
2010.3	5595.1	3889.1	515.8	16.4	82.2	98.7
2010.4	5581.9	3885.3	532.8	21.4	89.9	81.2
2011.1	4990.3	3806.9	548.1	16.0	136.8	141.3
2011.2	4979.2	3795.8	570.2	20.3	116.7	113.8
2011.3	4972.0	3791.6	581.6	12.7	48.6	60.2
2011.4	4964.3	3780.5	600.4	13.8	99.6	118.6
2012.1	4910.7	3804.6	630.0	18.6	127.3	87.6
2012.2	4902.9	3781.3	661.1	13.7	130.1	108.4
2012.3	4897.7	3773.3	674.3	9.8	75.2	58.6
2012.4	4888.9	3760.5	695.8	15.2	110.2	96.0
2013.1	4886.8	3746.7	711.8	15.1	121.0	116.4
2013.2	4876.8	3733.2	735.2	16.9	104.2	97.4
2013.3	4870.8	3727.9	746.6	9.5	60.7	119.1
2013.4	4861.3	3719.8	764.1	16.9	90.7	97.8

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S4: Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population. THE BALEARIC ISLANDS N=178,251 (2010-2013).

Quarter	Smoking status prevalence			New smokers incidence	New ex-smokers incidence	Ex-smoker relapses incidence
	Non smokers	Smokers	Ex-smokers			
2010.2	5411.0	4029.7	559.3	9.3	158.5	576.6
2010.3	5406.4	4007.3	586.2	9.0	151.6	527.0
2010.4	5401.6	3982.7	615.7	9.3	158.7	503.7
2011.1	5374.9	3987.9	637.1	6.6	149.9	545.7
2011.2	5372.4	3959.3	668.3	5.2	170.9	424.4
2011.3	5369.7	3929.5	700.8	5.2	160.1	383.9
2011.4	5367.4	3898.4	734.2	4.0	169.8	385.6
2012.1	5345.3	3888.3	766.4	4.3	188.1	351.8
2012.2	5344.0	3862.4	793.6	2.4	137.0	370.6
2012.3	5342.5	3841.0	816.6	2.9	113.5	372.6
2012.4	5341.7	3818.9	839.4	1.6	133.0	339.2
2013.1	5324.1	3825.3	850.7	2.1	130.5	480.5
2013.2	5317.8	3810.5	871.7	12.1	106.7	453.0
2013.3	5308.3	3800.6	891.1	17.5	93.7	103.9
2013.4	5298.6	3787.4	914.1	17.5	116.8	285.1

Note: 2010.*. represents the quarter * of the year 2010

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S5. Age-adjusted rates by the direct method for 10,000 inhabitants based on the European Standard Population in CATALONIA. N=72,340 (2008-2013).

Quarter	Smoking Status prevalence						New smokers incidence		New ex-smokers incidence		Ex-smoker relapse incidence	
	Non smokers		Smokers		Ex-smokers							
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
2008.1	5909.5	3349.2	3411.5	4910.7	679.0	1740.1	16.6	27.8	246.7	260.5	315.2	158.2
2008.2	5900.4	3331.6	3385.4	4856.2	714.2	1812.2	14.3	34.4	266.5	202.9	101.2	195.0
2008.3	5891.9	3318.8	3368.4	4822.1	739.7	1859.1	14.0	21.8	275.0	265.9	289.0	166.5
2008.4	5876.9	3296.1	3356.2	4789.4	766.9	1914.5	24.0	31.9	254.1	329.2	112.0	99.6
2009.1	5832.7	3323.5	3379.8	4769.9	787.5	1906.6	27.8	26.3	289.2	234.0	148.8	105.2
2009.2	5823.1	3311.7	3366.5	4749.0	810.4	1939.3	13.7	19.7	182.0	237.8	89.5	79.2
2009.3	5814.6	3300.6	3356.2	4728.4	829.2	1971.1	11.9	15.3	154.4	165.7	181.4	65.8
2009.4	5804.4	3282.4	3335.4	4702.6	860.2	2015.0	14.3	28.0	243.3	203.9	188.5	152.0
2010.1	5757.2	3312.5	3359.5	4679.7	883.3	2007.8	14.0	26.7	201.5	144.1	133.5	109.4
2010.2	5744.1	3292.3	3355.5	4668.2	900.4	2039.6	24.1	30.4	146.6	131.6	164.1	152.0
2010.3	5730.0	3279.4	3345.8	4650.5	924.2	2070.2	20.7	22.7	156.1	134.4	106.6	98.0
2010.4	5710.9	3256.8	3332.3	4616.4	956.8	2126.8	30.9	24.3	205.4	177.3	132.2	114.9
2011.1	5231.2	2821.0	3138.8	4408.8	975.2	2115.4	15.0	16.8	181.1	166.1	62.6	146.7
2011.2	5223.4	2811.7	3115.8	4356.5	1006.0	2177.1	12.2	14.3	231.6	203.8	118.9	65.4
2011.3	5216.7	2804.3	3095.4	4326.8	1033.2	2214.1	12.4	15.2	166.4	136.0	93.0	68.5
2011.4	5209.6	2789.1	3057.6	4270.9	1078.0	2285.2	12.1	21.2	308.9	241.6	111.0	78.8
2012.1	5142.2	2792.0	3082.8	4259.8	1120.2	2293.5	9.3	19.1	251.1	216.5	140.4	83.6
2012.2	5136.1	2782.4	3059.1	4225.1	1150.0	2337.7	10.4	12.4	215.6	162.3	107.4	75.8
2012.3	5132.0	2777.7	3041.8	4200.0	1171.4	2367.6	8.7	7.3	135.6	113.1	61.0	80.2
2012.4	5123.4	2765.4	3020.5	4161.9	1201.3	2417.9	10.2	16.2	192.8	203.5	128.5	89.1
2013.1	5063.9	2781.5	3055.9	4167.2	1225.4	2396.5	15.4	19.9	213.2	180.4	167.8	123.5
2013.2	5058.8	2773.4	3057.2	4202.9	1229.3	2368.9	10.2	21.9	146.9	131.3	216.4	251.9
2013.3	5055.0	2770.2	3060.2	4234.1	1230.0	2340.9	9.0	10.7	127.0	106.7	217.7	263.3
2013.4	5049.2	2763.3	3063.6	4281.9	1232.5	2300.1	11.8	21.1	202.8	159.2	325.6	315.6

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S6. Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population in NAVARRE. N=37,898 (2008-2013).

Quarter	Smoking Status prevalence						New smokers incidence		New ex-smokers incidence		Ex-smoker relapse incidence	
	Non smokers		Smokers		Ex-smokers							
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
2008.1	6224.8	5021.1	3542.5	4569.6	232.7	409.3	22.3	31.0	152.7	172.3	164.4	295.8
2008.2	6215.3	5010.6	3527.8	4539.7	256.9	449.7	15.2	20.3	168.7	187.7	136.9	173.7
2008.3	6207.4	4998.8	3518.5	4528.6	274.2	472.6	11.5	22.1	147.1	97.1	147.9	123.7
2008.4	6198.6	4982.4	3510.9	4515.4	290.4	502.2	14.8	30.0	157.9	125.6	296.5	98.8
2009.1	6209.7	5028.3	3485.7	4451.5	304.6	520.2	24.9	39.7	184.8	111.3	254.0	197.0
2009.2	6197.8	5011.6	3480.3	4441.1	321.9	547.3	17.4	32.6	177.2	127.7	152.7	171.7
2009.3	6191.6	5003.2	3475.5	4426.3	332.9	570.4	10.7	15.2	108.4	98.3	73.4	111.5
2009.4	6186.2	4990.0	3470.2	4413.1	343.6	596.9	8.4	24.0	97.2	115.8	126.6	134.7
2010.1	6175.4	5014.1	3464.6	4375.5	360.0	610.4	22.6	33.5	115.7	112.9	224.3	208.6
2010.2	6164.6	4999.4	3455.7	4359.8	379.7	640.8	16.4	27.9	119.1	114.5	106.4	129.5
2010.3	6154.5	4988.6	3456.0	4350.4	389.5	661.0	16.2	17.0	111.3	75.9	88.3	94.5
2010.4	6142.1	4974.6	3455.4	4343.4	402.5	682.1	17.8	26.3	126.9	80.9	71.3	85.7
2011.1	5541.4	4399.8	3388.4	4248.3	415.4	697.1	12.2	21.0	146.2	135.4	91.3	183.2
2011.2	5532.4	4386.6	3381.0	4233.7	431.9	724.9	15.5	26.8	151.1	110.6	117.2	103.9
2011.3	5524.7	4379.8	3377.8	4228.5	442.7	737.0	12.6	13.7	55.8	44.9	61.6	54.1
2011.4	5518.9	4370.0	3369.7	4213.6	456.6	761.7	9.6	19.5	118.2	95.4	70.0	160.8
2012.1	5452.1	4335.6	3408.9	4217.7	484.2	792.0	15.9	22.5	129.3	126.5	106.9	65.3
2012.2	5445.6	4326.1	3389.4	4190.1	510.2	829.0	11.7	17.2	125.1	131.6	95.3	114.5
2012.3	5442.6	4318.6	3385.2	4178.7	517.4	847.9	6.2	14.2	67.6	78.0	68.6	41.2
2012.4	5434.5	4308.9	3379.5	4159.1	531.2	877.2	12.5	19.6	130.7	110.0	66.7	126.7
2013.1	5420.0	4323.0	3380.9	4128.0	544.3	894.1	14.1	16.4	133.8	124.7	68.6	157.5
2013.2	5413.7	4309.1	3367.7	4114.5	563.9	921.6	10.1	25.2	103.2	104.7	87.0	98.4
2013.3	5408.6	4302.1	3363.6	4108.1	573.1	935.1	7.2	12.7	72.3	57.3	152.7	85.9
2013.4	5399.9	4291.6	3360.4	4094.8	584.9	958.8	13.9	21.7	65.6	102.8	72.2	116.0

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S7. Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population in THE BALEARIC ISLANDS. N= 94,164 (2010-2013).

Quarter	Smoking Status prevalence						New smokers incidence		New ex-smokers incidence		Ex-smoker relapse incidence	
	Non smokers		Smokers		Ex-smokers							
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
2010.2	6224.8	4484.3	3412.3	4723.7	362.9	792.0	8.9	9.9	106.8	169.6	631.1	560.7
2010.3	6220.5	4479.3	3395.5	4695.0	384.0	825.7	8.2	10.4	149.6	147.6	576.9	435.9
2010.4	6215.8	4474.3	3376.3	4664.4	408.0	861.2	8.8	10.1	179.2	150.7	484.7	571.5
2011.1	6171.2	4472.1	3395.3	4651.7	433.5	876.2	6.7	6.6	141.1	146.7	562.7	508.9
2011.2	6168.5	4469.8	3375.7	4612.8	455.9	917.5	5.2	5.4	140.3	173.8	446.1	426.0
2011.3	6165.8	4467.0	3353.4	4574.6	480.8	958.4	4.9	6.0	162.5	154.9	400.9	391.6
2011.4	6163.1	4465.3	3330.1	4534.6	506.8	1000.1	4.6	3.4	149.3	170.9	296.7	540.3
2012.1	6118.6	4474.0	3337.9	4501.2	543.6	1024.8	3.7	5.1	179.2	182.1	306.5	461.7
2012.2	6117.0	4473.2	3318.1	4468.3	564.9	1058.5	2.8	1.9	109.0	139.6	359.8	348.6
2012.3	6115.2	4471.9	3302.0	4440.5	582.8	1087.7	3.1	2.5	103.4	112.8	376.5	363.9
2012.4	6114.3	4471.2	3285.7	4411.7	600.0	1117.0	1.7	1.6	122.7	132.9	414.0	213.4
2013.1	6077.2	4479.2	3302.2	4406.4	620.6	1114.4	0.9	4.1	137.9	122.6	492.0	470.3
2013.2	6070.8	4473.1	3291.1	4387.8	638.2	1139.1	11.9	12.7	91.0	105.4	410.8	532.6
2013.3	6056.9	4468.7	3287.9	4370.1	655.1	1161.2	23.4	10.4	94.4	90.1	110.4	87.5
2013.4	6046.1	4460.3	3280.8	4349.5	673.1	1190.2	18.2	16.9	100.0	121.4	342.4	116.1

Note: 2010.*. represents the quarter * of the year 2010

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

SUPPLEMENTARY DATA FOR Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

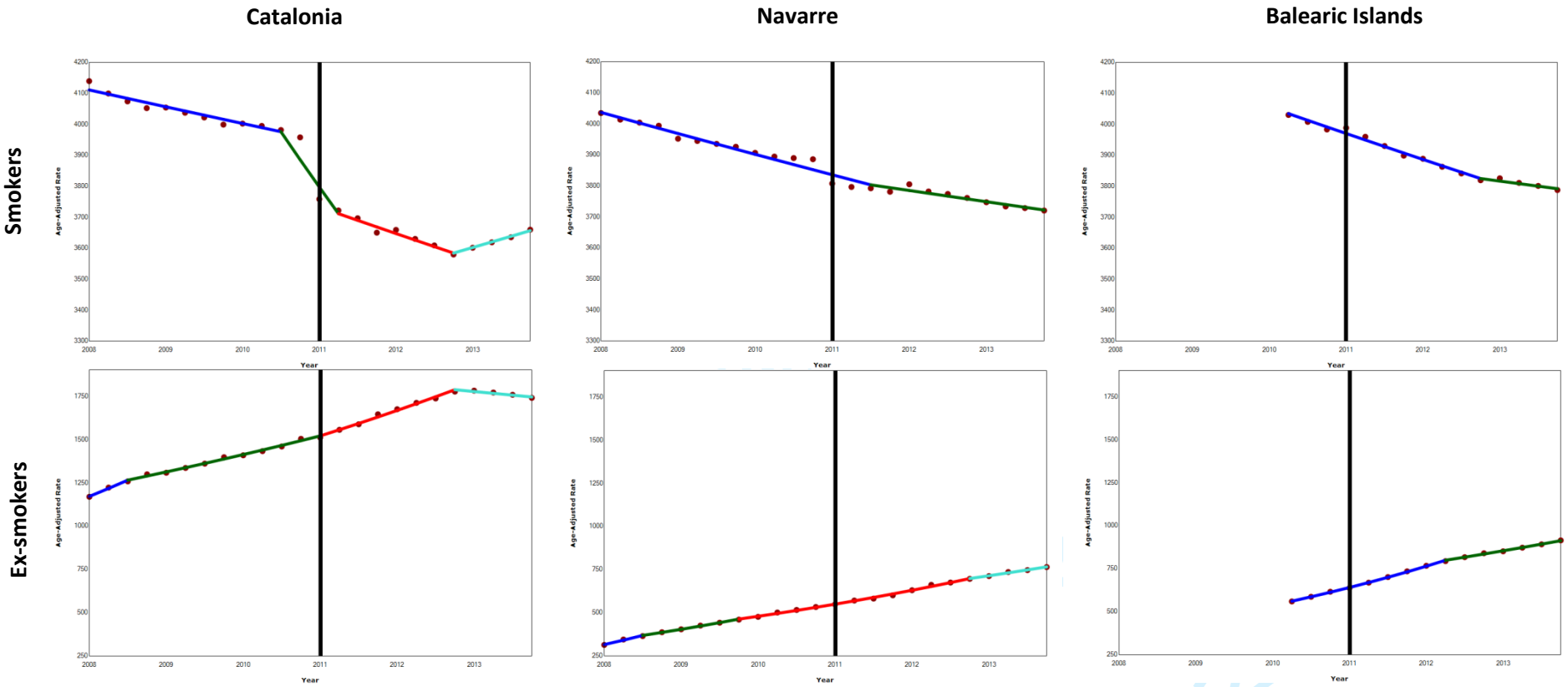

Figure S1: Overall trends of age-standardized prevalence rates of smoking status in Catalonia, Navarre and the Balearic Islands.
Solid lines represent the Joinpoint regression lines (each colour is a different trend); circle red points represent the age-adjusted prevalence rates. Black vertical lines represent the year when the Spanish comprehensive smoke-free law was introduced (2011).

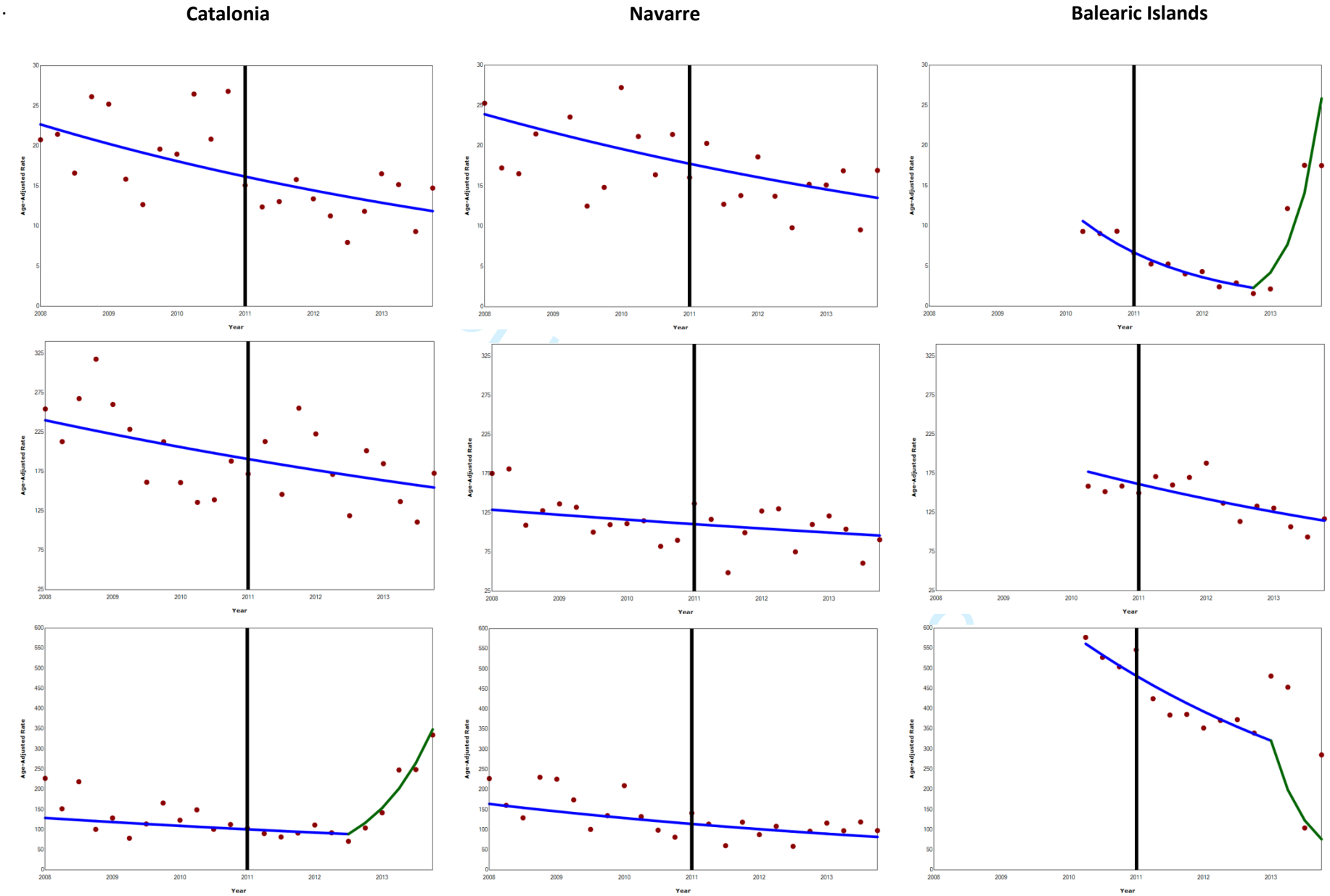

Figure S2: Overall trends of age-standardized incidence rates of new smokers, ex-smokers and ex-smoker relapse in Catalonia, Navarre and the Balearic Islands. Solid lines represent the Joinpoint regression lines (each colour is a different trend); circle red points represent the age-adjusted incidence rates. Black vertical lines represent the year when the Spanish comprehensive smoke-free law was introduced (2011).

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6-7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	6 + Figure 1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7-8
		(*b*) Describe any methods used to examine subgroups and interactions	7-8
		(*c*) Explain how missing data were addressed	6 + 15
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6, 8. Figure 1
		(b) Give reasons for non-participation at each stage	6. Figure 1
		(c) Consider use of a flow diagram	6. Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8. Table 1.
		(b) Indicate number of participants with missing data for each variable of interest	8
Outcome data	15*	Report numbers of outcome events or summary measures	8-12. Tables 2-4
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-12. Tables 2-4
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14-15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	15-16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

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Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

ABSTRACT

Objective: This study aimed to analyse the impact of comprehensive smoke-free legislation on the prevalence and incidence of adult smoking in Primary Health Care patients from three Spanish regions, overall and stratified by sex.

Design: Longitudinal observational study conducted between 2008 and 2013.

Setting: 66 Primary Health Care teams in Catalonia, Navarre and the Balearic Islands (Spain).

Participants: Population over 15 years of age assigned to Primary Health Care teams.

Primary and secondary outcomes measures: Quarterly age-standardized prevalence of non-smoker, smoker and ex-smoker and incidence of new smoker, new ex-smoker and ex-smoker relapse rates were estimated with data retrieved from PHC electronic health records. Joinpoint analysis was used to analyse the trends of age-standardized prevalence and incidence rates**.** Trends were expressed as annual percentage change and average annual percent change.

Results: The overall standardized smoker prevalence rate showed a significant downward trend (higher in men than women) and the overall standardized ex-smoker prevalence rate showed a significant increased trend (higher in women than men) in the three regions. Standardized smoker and ex-smoker prevalence rates were higher for men than women in all regions. With regard to overall trends of incidence rates, new smokers decreased significantly in Catalonia and Navarre and similarly in men and women, new ex-smokers decreased significantly and more in men in Catalonia and the Balearic Islands**,** and ex-smoker relapse increased in Catalonia, particularly in women, and decreased in Navarre.

Conclusions: Trends on smoking behaviour in Primary Health Care patients remain unchanged after the implementation of comprehensive smoke-free legislation. The impact of the comprehensive SFL might have been lessened by the effect of the preceding partial SFL.

Keywords: Electronic health records; Joinpoint analysis; Primary Health Care; Smoke-Free Policy; Smoking.

Strengths and limitations of this study

- To our knowledge, no studies have been published on the impact of the Spanish comprehensive smoke-free legislation in all adult Primary Health Care patients
- Used as a research tool, electronic health records portray real-life conditions and provide comprehensive, long-term health histories from a large population sample
- The results of quarterly data by joinpoint analysis provides more precise information than an analysis before-after the implementation of the Law
- This study only considered age and sex since other variables were not available for the adjusted analysis.
- The study period started later (shorter follow-up) in the Balearic Islands to ensure reliability of data

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INTRODUCTION

Smoking is the leading worldwide cause of preventable death.[1] According to the World Health Organization (WHO), it is estimated that at least 30 million people may die prematurely from tobacco-related diseases.[2] Legislative measures have been adopted to protect people's health in public areas and workplaces. These include increasing the price of cigarettes, banning advertising, sponsorship and smoking in workplaces and public spaces, displaying warnings on tobacco packets and implementing prevention programs.[3]

Some studies show a decrease in smoking prevalence since the introduction of smoke-free legislation (SFL).[4–9] A metanalysis of 26 studies on the effect of the smoke-free workplace in various countries concluded in 2002 that smoke-free workplaces protect not only non-smokers from the dangers of passive smoking, but they also encourage smokers to reduce tobacco consumption. The authors concluded that SFL is associated with a 3% to 4% reduction in tobacco consumption.[10] In contrast, a Cochrane review published in 2016 which included 24 studies on smoking behaviour showed inconsistencies regarding the impact of smoking bans on smoking prevalence and tobacco consumption.[11]

On January 1, 2006, the Spanish government introduced a partial SFL (Law 28/2005),[12] which included regulations on the sale, supply, consumption and advertising of tobacco products. Smoking was banned in all indoor public and private workplaces with the exception of the hospitality sector, where partial restrictions were established depending on the size of the establishment, i.e., in bars or restaurants smaller than 100 m2 the managers could decide whether to allow smoking in the premises (Law 28/2005). The mean concentration of nicotine subsequently decreased by 60% in public administration offices and by 97.4% in private workplaces, but in areas where smoking was permitted, including bars and nightclubs, no changes were found.[13–15] This prompted the enactment of a comprehensive SFL (Law 42/2010),[16] which came into force in January 2011. This comprehensive law expanded smoking restriction to all hospitality venues of any size and, as a result, smoking was forbidden in all enclosed public places, including bars, restaurants and nightclubs, and in some open-air public places such as playgrounds.

Some studies have analysed the impact of these two Spanish laws on smoking prevalence. However, most have been based on health surveys[13,17–20] and surveys of hospitality workers.[21,22] Moreover, some studies evaluate only the partial law,[13,17,18] whereas others analyse the compound impact of both laws.[19,20,23,24] The results of these studies are often conflicting; while some conclude that the partial SFL does not have any effect on the downward trend in the prevalence of smokers,[13,19,23] other studies show a reduction in smoking prevalence[24], an increase of the smoking quit-ratio in the short term[18] and minor increases in the prevalence of active smoking.[20]

Only one study conducted in primary health care (PHC) patients evaluates the impact of the Spanish partial SFL, including smoking prevalence in active smoker workers that attended PHC visits; one month after the implementation of the law, a 9.5% decline of smokers was observed.[25] To our knowledge, no studies have been published on the impact of the Spanish comprehensive SFL in all adult PHC patients. In view of the pivotal role of PHC services in smoking habits, we consider that the information registered in PHC records is a good proxy to generate up-to-date evidence and to evaluate the impact of comprehensive SFL in the general population.

We hypothesized that Law 42/2010 does not only reduce exposure to environmental cigarette smoke and its harmful effects but crucially, it promotes smoking denormalisation in society, thus encouraging smokers to quit or reduce consumption and discouraging non-smokers from initiating this habit. Accordingly, the aim of this study was to examine the impact of the Spanish comprehensive SFL (Law 42/2010) on the prevalence and incidence of adult smoking in PHC patients in three regions (Catalonia, Navarre and Balearic Islands), during the 2008-2013 period, overall and stratified by sex.

METHODS

Design, study participants and information source

Longitudinal observational study of the adult population assigned to 66 Primary Health Care teams (PHCT) in three Spanish regions: Catalonia, Navarre and the Balearic Islands (22 PHCT per region). Inclusion criteria of the PHCT were: 1) computerization of electronic health records (EHR) by January 1, 2005 in Catalonia and Navarre, and 2008 in the Balearic Islands; and 2) agreement to participate in the study by over 80% health-care professionals working in each PHCT. Random cluster sampling was stratified by region, with the PHCT as randomization unit.[26] In each PHCT, General Practitioners (GP) with a patient list between 400 and 3000 were selected. GP with shorter patient lists were accepted if it was their first year in the PHCT.

The study period included from the first quarter of 2008 to the fourth quarter of 2013 in Catalonia and Navarre; and from the second quarter of 2010 to the fourth quarter of 2013 in the Balearic Islands. The study started in 2008 to obtain data from the 2 years prior analysis, a requirement to adequately construct the variable ex-smoker. In the case of the Balearic Islands, the study started later to ensure reliability of data.

Inclusion criteria for patients were: 1) Population allocated to the selected PHCT for the whole 2007-2013 period in Catalonia and Navarre; in the Balearic Islands, patients allocated to the selected PHCT in 2013 and evaluated retrospectively (no historical annual comprehensive register of allocation of patients was available). 2) Age ≥16 and ≤100 years in 2007 in Catalonia and Navarre, and 2010 in the Balearic Islands. 3) In order to have data in the EHR collected during the study period, a minimum of one visit to their PHCT during the 2007-2013 period in Catalonia and Navarre and 2010-2013 in the Balearic Islands; and 4) Information on smoking habit recorded in the EHR for the quarter prior to the onset of the study: last quarter of 2007 in Catalonia and Navarre and first quarter of 2010 in the Balearic Islands, to enable the adequate

construction of the various variables. Since smoking is not an acute condition, this information was considered valid until new information was entered. Thus, closed cohorts (with fixed membership, where nobody is added nor excluded after the study begins) were constituted in the three regions. Figure 1 shows the flowchart of the study.

Data were retrieved from the REGIPREV database,[26] which contains encrypted and anonymized clinical information recorded in the EHR by these 66 PHCT. An algorithm was applied to extract equivalent data from the health records software used in each region: "ECAP" in Catalonia, "Atenea" in Navarre and "e-siap" in the Balearic Islands. Codes of the International Classification of Diseases, 9th revision in the Balearic Islands (ICD-9) and 10th in Catalonia (ICD 10th revision)[27] and the International Classification of Primary Care, Second edition, in Navarre (ICPC-2)[28] were used.

Variables

Information on smoking is registered in the electronic health records using diagnostic codes to classify diseases (codes F17.0 to F17.9 and Z72.0 of the ICD-10, 305.1 of the ICD-9 and P17 of the ICPC-2), and also clinical variables (number of cigarettes per day, history of smoking, history of advice for smoking cessation). This information is stored with the entry date (Supplementary File Table S1). With the information on smoking status and entry date we created the following dependent variables at the end of each quarter of the study period:

- Smoking status (three categories): 1) non-smoker: patient that has never been a tobacco consumer, 2) smoker: tobacco consumer or patient that has quit smoking for less than 12 months; and 3) ex-smoker: patient who used to smoke but has quit smoking for at least 12 continuous months. When the EHR did not contain a new entry related to smoking status (diagnostic codes or clinical variables), we considered that no changes in smoking status had taken place and thus that the last observation was still valid.
- New smoker: patient non-smoker for the 12 months prior to the considered quarter that has started smoking during said quarter.
- New ex-smoker: the patient was a smoker two years before the considered quarter and has continuously abstained from tobacco for at least 12 months.
- Ex-smoker relapse: patient ex-smoker during the 12 months prior to the considered quarter that has started smoking again during said quarter.

For higher accuracy in prevalence and incidence changes, quarterly estimates were calculated.

The following variables of each patient were collected at baseline (2008 in Catalonia and Navarre; 2010 in the Balearic Islands): age, sex (male/female), annual number of health problems and annual number of PHC visits. The number of health problems was used as a morbidity indicator; it was calculated as the sum of the number of different active health problems (chronic and acute, coded by ICPC-2).

Data analyses

Descriptive statistics were used to summarize overall information. Categorical variables were expressed as percentage, and continuous variables as mean (standard deviation) or median (interquartile range [IQR]).

Because the three regions used different EHR systems (different standards and computer programs), have different socioeconomic characteristics, different complementary measures to the SFL and also due to the shorter study period in the Balearic Islands, we performed a stratified analysis per region, overall and by sex. Age-standardized prevalence (non-smokers, smokers and ex-smokers) and incidence (new smokers, new ex-smokers and ex-smoker relapse) rates were calculated for each quarter using the direct method, and based on the European Standard Population (rates per 10,000 inhabitants).

Joinpoint analysis was used to analyse the trends of age-standardized prevalence (smokers and ex-smokers) and incidence rates (new smokers, new ex-smokers and ex-smoker relapse) and to identify the best-fitting points (the 'joinpoints', in calendar quarters) where the rate changes significantly in the linear slope of the temporal trend. Significant changes include changes in direction or in the rate of increase or decrease[29]. Joinpoint analysis estimates the magnitude of the increase or the decrease observed in each specified time interval by estimating the annual percentage change (APC). In addition, temporal trends were expressed as the average annual percent change (AAPC), computed to summarize and compare these trends over the entire time period. Because the outcomes originate from repeated measurements, control for the autocorrelation errors was used. Ninety-five percent confidence intervals (95% CI) of APC and AAPC were calculated. The trend of non-smoker prevalence rates was not calculated because the study consisted of a closed cohort where no new participants are recruited, and thus the prevalence of non-smokers can either remain the same or decrease, but never increase.

Analyses were performed using Stata/SE version 14.2 for Windows (Stata Corp. LP, College Station, Texas, US). The joinpoint regression analysis was carried out using the joinpoint software from the Surveillance Research Program of the US National Cancer Institute [ref. Joinpoint Regression Program, Version 4.6.0. April, 2018; Statistical Research and Applications Branch, National Cancer Institute] (National Cancer Institute. Statistical Research and Applications Branch) [On-line: https://surveillance.cancer.gov/branches/srab/].

Patient and public involvement

Study participants were not involved in the development of the research question or the outcome measures nor the design of the study. The results will be presented to citizens through informative activities and the media.

RESULTS

The study population was 392,966 patients: 141,071 in Catalonia, 73,644 in Navarre and 178,251 in the Balearic Islands (Figure 1). At the onset of the study, the mean age was 50.4 years in Catalonia, 54.0 in Navarre and 47.7 in the Balearic

Islands. In the three cohorts more than half were women (>51 %). Catalonia presented the highest median number of visits (9, IQR: 3 -16) and the Balearic Islands presented the highest number of recorded active health problems per patient (median 10, IQR: 6-16) (Table 1).

Table 1: Characteristics of the cohort study population by region at the onset of the study (2008 in Catalonia and Navarre, 2010 in the Balearic Islands).

	Catalonia N =141,071	**Navarre** N = 73,644	**Balearic Islands** N =178,251
Age (years), SD	50.37 (17.23)	54.04 (18.26)	47.65 (17.56)
Sex (female), number (%)	72340 (51.28)	37898 (51.46)	94164 (52.83)
Number of visits, mean (SD); median (IQR)	11.69 (12.19); 9.00 (3.00-16.00)	8.93 (9.30); 7.00 (3.00-12.00)	11.01 (13.25); 7.00 (3.00-15.00)
Number of health problems, mean (SD); median (IQR)	6.23 (4.58); 5.00 (3.00-8.00)	9.95 (5.39); 9.00 (6.00-13.00)	11.85 (7.74); 10.00 (6.00-16.00)

Abbreviations: SD, standard deviation; IQR, interquartile range. Patients belonged to 22 Primary Health Care Teams in each region.

The **overall standardized smoker prevalence rates** per 10,000 inhabitants were of similar magnitude in the three regions (ranges of 3579.2 - 4138.9 in Catalonia; 3719.8 - 4034.2 in Navarre; and 3787.4 - 4029.7 in the Balearic Islands). The prevalence rate decreased in Navarre during the whole study period, decreased in the Balearic Islands in most quarters, and also in Catalonia except for the last year. These rates were higher for men than for women in all regions (Supplementary File Tables S2-S7). A significant downward **overall trend of smoker prevalence rates** was found in Catalonia (AAPC= -2.18), Navarre (AAPC= -1.44) and the Balearic Islands (AAPC= -1.75); this downward trend was higher for men than for women in the three regions. In Catalonia, the most significant reduction occurred during the period 2010.3-2011.4 (APC= -6.75), similarly to the Balearic Islands (2010.2-2012.4; APC= -2.19), whereas in Navarre it occurred between 2008.1-2013.4 (APC= -1.44) (Tables 2, 3, 4, Supplementary File Figure S1).

For the whole period, the **overall standardized ex-smoker prevalence rates** per 10,000 inhabitants increased in Navarre, in the Balearic Islands and in Catalonia except for the last year. The rates in Catalonia were higher (ranges of: 1168.5 - 1781.2 in Catalonia; 313.3 - 764.1 in Navarre; and 559.3 - 914.1 in the Balearic Islands). The standardized ex-smoker prevalence rates were higher for men than for women in all regions (Supplementary File Tables S2-S7). The **overall trend of ex-smoker prevalence rates** increased significantly in the three regions throughout the study period but was higher in Navarre (Navarre AAPC= 16.67; Catalonia AAPC= 7.19; Balearic Islands AAPC= 14.96). The increase in the prevalence rate of ex-smokers was higher for the 2008.1-2008.2 period in Catalonia, 2008.1-2008.4 in Navarre, and for 2010.2-2012.2 in the Balearic Islands, and higher in women in the three regions (women: Catalonia AAPC= 10.87; Navarre AAPC=17.30 and Balearic Islands AAPC= 19.51) (Tables 2, 3, 4, Supplementary File Figure S1).

The **overall new smoker standardized incidence rates** per 10,000 inhabitants showed low values in the three regions (ranges of 7.9 - 26.8 in Catalonia; 9.5 - 30.9 in Navarre; 1.6 - 17.5 in the Balearic Islands) and higher for men than for women in Catalonia and Navarre (Supplementary File Tables S2-S7). The **overall trend of new smoker incidence rates** decreased significantly in Catalonia (AAPC= -10.39) and Navarre (AAPC= -9.49); additionally, the decline was similar for men and women. In contrast, the overall trend remained stable in the Balearic Islands despite a decrease until 2012.4 (APC= -46.20) and a considerable increase from 2012.4 to 2013.4 (APC= 1054.2) (Tables 2, 3, 4, Supplementary File Figure S2).

The **overall standardized new ex-smoker incidence rates** per 10,000 inhabitants showed higher values in Catalonia (range: 110.7 - 317.6) than in Navarre (range: 48.6 - 181.0) and the Balearic Islands (range: 93.7 - 188.1) (Supplementary File Tables S2-S7). The **overall trend of new ex-smoker incidence rates** showed a significant decrease in Catalonia (AAPC= -7.27) and especially in the Balearic Islands (AAPC= -11.24). This downward trend was higher for men than for women in Catalonia and the Balearic Islands (Tables 2, 3, 4, Supplementary File Figure S2).

The **overall standardized ex-smoker relapse incidence rates** per 10,000 inhabitants presented higher values in the Balearic Islands (range: 103.9 - 576.6) than in Catalonia (range: 70.7 - 334.5) and Navarre (range: 58.6 - 230.3) (Supplementary File Tables S2-S7). The **overall trend of ex-smoker relapse incidence rates** showed significant increases in Catalonia (AAPC= 18.60), particularly in women (AAPC= 14.56), although a decrease from 2008.1 to 2012.3 was observed (APC= -8.40). In contrast, Navarre showed significant decreases (AAPC= -11.42)(Tables 2, 3, 4, Supplementary File Figure S2).

Table 2. Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse for age standardized rates. Jointpoints overall and by sex in CATALONIA. N=141,071 (2008-2013)

	Trend 1		Trend 2		Trend 3		Trend 4		Trend 5		AAPC (95% IC) 2008.1 - 2013.4
	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC(95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	
Smoker prevalence											
F	2008.1 - 2010.3	-0.72[d] (-1.51 ; 0.09)	2010.3 - 2011.2	-9.85[b] (-16.24 ; -2.98)	2011.2 - 2013.4	-0.53[d] (-1.29 ; 0.24)					-1.88[a] (-2.85 ; -0.90)
M	2008.1 - 2010.3	-2.12[a] (-2.52 ; -1.71)	2010.3 - 2011.2	-8.17[a] (-11.24 ; -4.99)	2011.2 - 2012.4	-2.93[a] (-3.88 ; -1.98)	2012.4 - 2013.4	2.81[a] (1.47 ; 4.17)			-2.31[a] (-2.83 ; -1.79)
G	2008.1 - 2010.3	-1.71[b] (-2.88 ; -0.53)	2010.3 - 2011.4	-6.75[b] (-10.46 ; -2.89)	2011.4 - 2013.4	0.19[d] (-1.37 ; 1.78)					-2.18[a] (-3.22 ; -1.13)
Exsmoker prevalence											
F	2008.1 - 2008.4	17.54[a] (12.88 ; 22.40)	2008.4 - 2011.2	11.25[a] (10.17 ; 12.34)	2011.2 - 2012.1	15.73[a] (9.03 ; 22.85)	2012.1 - 2013.1	9.55[a] (5.91 ; 13.31)	2013.1 - 2013.4	0.65[d] (-2.49 ; 3.89)	10.87[a] (9.68; 12.07)
M	2008.1 - 2012.4	6.64[a] (6.01 ; 7.30)	2012.4 - 2013.4	4.45[c] (-8.23 ;-0.51)							4.63[a] (3.79 ; 5.48)
G	2008.1 - 2008.2	16.70[b] (7.23 ; 27.01)	2008.2 - 2011.1	7.63[a] (6.96 ; 8.30)	2011.1 - 2012.4	9.68[a] (8.50 ; 10.86)	2012.4 - 2013.4	-2.34[c] (-4.21 ; -0.42)			7.19[a] (6.31 ; 8.07)
New smokers incidence											
F	2008.1 - 2013.4	-10.82[c] (-19.17 ; -1.59)									-10.82[c] (-19.17 ; -1.59)
M	2008.1 - 2013.4	-10.53[b] (-16.03 ; -4.68)									-10.53[b] (-16.03 ; -4.68)
G	2008.1 - 2013.4	-10.39[b] (-16.06 ; -4.33)									-10.39[b] (-16.06 ;-4.33)
New ex-smokers incidence											
F	2008.1 - 2013.4	-4.55[d] (-11.06 ; 2.45)									-4.55[d] (-11.06 ; 2.45)
M	2008.1 - 2013.4	-7.80[c] (-13.44 ; -1.79)									-7.80[c] (-13.44 ; -1.79)
G	2008.1 - 2013.4	-7.27[c] (-12.89 ; -1.29)									-7.27[c] (-12.89 ; -1.29)
Ex-smokers relapse incidence											
F	2008.1 - 2012.3	-9.20[d] (-18.05 ; 1.03)	2012.3 - 2013.4	162.73[a] (67.31 ; 312.56)							14.56[c] (1.65 ; 29.11)
M	2008.1 - 2009.3	-47.47[d] (-81.34 ; 47.84)	2009.3 - 2013.4	115.64[d] (-100 ; 1930603)	2010.2 - 2012.3	-27.20[d] (-44.70 ; 1.35)	2012.3 - 2013.2	515.1[d] (-80.2 ; 18963.4)	2013.2 - 2013.4	77.79[d] (-72.27 ; 1040)	9.97[d] (-64.32 ;238.91)
G	2008.1 - 2012.3	-8.40[c] (-15.98 ; -0.13)	2012.3 - 2013.4	200.54[a] (120.8 ; 309.0)							18.60[a] (8.50 ;29.64)

Note: 2008.*. represents the trimester * of the year 2008

APC, annual percentage change and AAPC, average annual percent change estimated by joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.
[a] p≤ 0.001; [b] p≤ 0.01; [c] p≤ 0.05; [d] p>0.05

Table 3. Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse for age standardized rates. Jointpoints overall and by sex in NAVARRE. N=73,644 (2008-2013)

	Trend 1		Trend 2		Trend 3		AAPC (95% IC)
	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	2008.1 - 2013.4
Smoker prevalence							
F	2008.1 - 2013.4	-0.93[a] (-1.11 ; -0.75)					-0.93[a] (-1.11 ; -0.75)
M	2008.1 - 2013.4	-1.95[a] (-2.09 ; -1.81)					-1.95[a] (-2.09 ; -1.81)
G	2008.1 - 2013.4	-1.44[a] (-1.59 ; -1.28)					-1.44[a] (-1.59 ; -1.28)
Ex-smoker prevalence							
F	2008.1 -2008.4	35.81[a] (25.56 ; 46.90)	2008.4 - 2012.2	16.50[a] (15.45 ; 17.56)	2012.2 - 2013.4	10.66[a] (8.31 ; 13.06)	17.30[a] (15.88 ; 18.67)
M	2008.1 - 2009.2	25.93[a] (20.68 ; 31.41)	2009.2 - 2012.4	13.90[a] (12.85 ; 14.97)	2012.4 - 2013.4	9.32[a] (5.21 ; 13.59)	15.59[a] (14.24 ; 16.95)
G	2008.1 - 2008.4	34.30[a] (24.61 ; 44.74)	2008.4 - 2012.2	15.80[a] (14.78 ; 16.83)	2012.2 - 2013.4	10.68[a] (8.41 ; 12.99)	16.67[a] (15.35 ; 18.01)
New smokers incidence							
F	2008.1 - 2013.4	-9.43[c] (-15.95 ; -2.75)					-9.43[c] (-15.95 ; -2.75)
M	2008.1 - 2013.4	-9.40[b] (-14.96 ; -3.48)					-9.40[b] (-14.96 ; -3.48)
G	2008.1 - 2013.4	-9.49[a] (-14.31 ; -4.40)					-9.49[a] (-14.31 ; -4.40)
New ex-smokers incidence							
F	2008.1 - 2013.4	-9.67[b] (-15.05 ; -3.96)					-9.67[b] (-15.05 ; -3.96)
M	2008.1 - 2013.4	-2.83[d] (-8.94 ; 3.70)					-2.83[d] (-8.94 ; 3.70)
G	2008.1 - 2013.4	-5.01[d] (-10.74 ; 1.09)					-5.01[d] (-10.74 ; 1.09)
Ex-smoker relapse incidence							
F	2008.1 - 2013.4	-13.85[b] (-20.68 ; -6.42)					-13.85[b] (-20.68 ; -6.42)
M	2008.1 - 2013.4	-11.77[c] (-18.33 ; -4.69)					-11.77[c] (-18.33 ; -4.69)
G	2008.1 - 2013.4	-11.42[a] (-16.95 ; -5.51)					-11.42[a] (-16.95 ; -5.51)

Note: 2008.*. represents the trimester * of the year 2008

APC, annual percentage change and AAPC, average annual percent change estimated by joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.

[a] p≤ 0.001; [b] p≤ 0.01; [c] p≤ 0.05; [d] p>0.05

Table 4. Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse for age standardized rates. Jointpoints overall and by sex in THE BALEARIC ISLANDS. N=178,251 (2010-2013)

	Trend 1		Trend 2		Trend 3		AAPC (95% IC)
	Time	APC (95% IC)	Time	APC (95% IC)	Time	APC (95% IC)	2008.1 - 2013.4
Smoker prevalence							
F	2010.2 - 2013.4	-1.20[a] (-1.40 ; -1.01)					-1.20[a] (-1.40 ; -1.01)
M	2010.2 - 2012.4	-2.73[a] (-2.93 ; -2.54)	2012.4 - 2013.4	-1.39[b] (-2.16 ; -0.65)			-2.35[a] (-2.58 ; -2.12)
G	2010.2 - 2012.4	-2.19[a] (-2.33 ; -1.89)	2012.4 - 2013.4	-0.86[d] (-1.90 ; 0.18)			-1.75[a] (-2.05 ; -1.46)
Ex-smoker prevalence							
F	2010.2 - 2012.1	26.19[a] (25.24 ; 27.15)	2012.1 - 2013.4	13.18[a] (12.46 ; 13.91)			19.51[a] (18.99 ; 20.03)
M	2010.2 - 2012.1	15.82[a] (14.04 ; 17.62)	2012.1 - 2013.4	7.44[a] (5.37 ; 9.56)			12.15[a] (10.96 ; 13.36)
G	2010.2 - 2012.2	19.29[a] (18.34 ; 20.24)	2012.2 - 2013.4	9.43[a] (8.37 ; 10.50)			14.96[a] (14.34 ; 15.59)
New smokers incidence							
F	2010.2 - 2012.4	-46.09[b] (-60.51 ; -26.40)	2012.4 - 2013.4	1370.6[b] (169.9 ; 7913.0)			38.65[d] (-13.24 ; 121.58)
M	2010.2 - 2012.4	-44.29[c] (-64.78 ; -11.87)	2012.4 - 2013.4	610.8[b] (98.1 ; 2530.4)			15.32[d] (-25.52 ; 78.56)
G	2010.2 - 2012.4	-46.20[b] (-60.28 ; -27.12)	2012.4 - 2013.4	1054.2[b] (222.2 ; 4034.8)			29.19[d] (-11.04 ; 87.61)
New ex-smokers incidence							
F	2010.2 - 2013.4	-11.68[c] (-19.32 ; -3.31)					-11.68[c] (-19.32 ; -3.31)
M	2010.2 - 2013.4	-10.94[c] (-20.39 ; -0.38)					-10.94[c] (-20.39 ; -0.38)
G	2010.2 - 2013.4	-11.24[b] (-18.61 ; -3.21)					-11.24[b] (-18.61 ; -3.21)
Ex-smokers relapse incidence							
F	2010.2 – 2012.1	-33.75[b] (-47.83 ; -15.88)	2012.1 - 2013.1	47.37[d] (-75.08 ; 771.40)	2013.1 - 2013.4	-89.71[d] (-99.7 ; 313)	-44.15[d] (-74.54 ;22.53)
M	2010.2 - 2013.4	-36.30[a] (-44.63 ; -26.72)					-36.30[a] (-44.63 ; -26.72)
G	2010.2 - 2013.2	-18.19[a] (-23.60 ; -12.40)	2013.2 - 2013.4	-95.73[d] (-99.99 ; 1380.5)			-46.35[d] (-74.32 ; 12.09)

Note: 2010.*. represents the quarter * of the year 2010

APC, annual percentage change and AAPC, average annual percent change estimated by joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.
[a] p≤ 0.001; [b] p≤ 0.01; [c] p≤ 0.05; [d] p>0.05

DISCUSSION

The previous implementation of the partial Spanish SFL could account for the low effectiveness of the comprehensive SFL observed in this study. A significant downward trend of smoker prevalence rates, higher in men than in women, was found in the three regions throughout the study period. Correspondingly, the trend of ex-smoker prevalence rates increased in the three regions, particularly in Navarre and during the period 2008.1-2008.2 in Catalonia, 2008.1-2008.4 in Navarre, and the period 2010.2-2012.2 in the Balearic Islands. Even though the standardized ex-smoker prevalence rate was higher for men, the increase in the trend of ex-smoker prevalence rate was higher in women in the three regions. The overall trends of new smoker incidence rates decreased significantly in Catalonia and Navarre and were similar for men and women. Also, the overall trends of new ex-smokers decreased significantly in Catalonia and the Balearic Islands, particularly for men. In addition, the overall trends of ex-smoker relapse increased in Catalonia and decreased in Navarre, more for women than for men in both cases.

The trends of smoker prevalence declined throughout the study and no changes were observed after the implementation of the comprehensive SFL. Indeed, the most significant decrease begins in 2010 in Catalonia (3rd quarter) and the Balearic Islands and in 2008 in Navarre, prior to the implementation of the comprehensive SFL (January 1, 2011). However, the trend in Catalonia shows a drop in the prevalence rate of smokers around the time of the implementation of the Law. In contrast, trends in Navarre and the Balearic Islands show a more progressive decline. Comparisons are difficult due to the lack of studies on smoking prevalence and incidence from a PHC perspective and because some studies evaluate the impact of SFL on smoking prevalence with surveys that use different methodologies. Two studies that analysed data from surveys to the general population[19,20] did not find a significant decrease in the prevalence of smokers after the Spanish comprehensive law. In contrast, Lidón *et al.*[24] showed that after the implementation of both Spanish SFL, a significant decrease was observed in the smoking prevalence (from 34.5% to 26.1%, Prevalence Ratio = 0.76, $p < 0.001$) of people 16 years of age and older living in Barcelona surveyed in 2004–2005 and followed-up in 2013–2014. In addition, National Health Survey data from the 1987-2005 period revealed an annual average absolute decline of 1.0% in the prevalence of male smokers, whereas women showed an annual average absolute increase in prevalence of 0.2%. Between 2006 and 2014, the prevalence of smokers declined annually by 0.7% in men and 0.5% in women.[23] Although the values of the current study are higher, the steeper decline in the prevalence of smokers in men agree with these data.[23] Also, one study that estimated the effect of the Spanish SFL for the 2012-2025 period predicted a decrease in smoking prevalence in all age groups and for both sexes, except for women aged 40–64.[30]

Concomitantly with the decline in the prevalence trends in smokers, a constant increase of prevalence trends in ex-smokers was observed in the three regions. Other studies failed to note a significant change in the prevalence of ex-smokers after the comprehensive SFL: a difference of only 0.3 % between 2007 and 2011[20] and a non-significant increase of 3.3% between 2006 and 2011.[19] In agreement with a recent evidence review,[23] we observed a higher increase in the trend of ex-smokers prevalence in women. This review showed that the rate of smoking cessation in men increased 0.9% annually during the

1987-2014 period, and 1.5% in women after the Partial SFL came into force. The later incorporation of women to smoking might explain these gender differences. We should underscore that other studies that use health surveys as information source have a higher prevalence of ex-smokers than the prevalence we obtained in this study, especially for Navarre and the Balearic Islands.[31] This discrepancy could be explained by the misclassification of long-term ex-smokers as non-smokers during the process of computerization of medical records in the cases where the smoking habit was not sufficiently investigated.[32]

We observed a gradual decline in the new smoker incidence trends in Catalonia and Navarre throughout the study period, whereas incidence trends remained stable in the Balearic Islands (possibly due to the shorter study period or lower rates). A review by Wilson *et al.*[33] of two studies that evaluated smoking initiation reported mixed results, while Guerrero *et al*.[34] concluded that the Spanish partial SFL had no effect on new smokers in 2009. In contrast, Pinilla and Abásolo[35] observed a 6% decrease in the rate of smoking initiation among young people after the implementation of the same law, with a more positive impact in higher socioeconomic strata. We have not found studies that evaluate the impact of the comprehensive SFL on the incidence of new smokers. However, our data show a continuation in the trend observed in Pinilla's study[35] on the impact of the partial law.

The incidence trend in new ex-smokers declined gradually throughout the study period in Catalonia and the Balearic Islands. While the literature to date lacks data on the effect of the SFL on the incidence of new ex-smokers, it provides some information on prevalence. In this respect, one study on the Spanish partial SFL observed an increase of 8% between 2006 and 2011 in the rate of cessation among adult smokers (age 21 years and older) according to data from the National Health Survey.[35] In Luxembourg, smoking cessation attributed to the SFL was higher among daily smokers with a higher socioeconomic status.[8] In our cohort, we observed apparent random increases and declines in the adjusted rates in the three regions throughout the study.

The incidence trend in ex-smoker relapses increased in Catalonia and declined in Navarre constantly throughout the whole period, particularly for women, but the overall trend remained stable in the Balearic islands (most likely because of the shorter study period). However, the literature presents conflicting results regarding smoking relapse. One study on the partial Spanish SFL observed that most people who had succeeded in giving up smoking in 2006 had not relapsed by 2009.[34] On the other hand, a quasi-experimental study conducted in the United States observed that relapse was similar between employees in workplaces with SFL and employees where smoking was permitted.[36] In contrast, Shang found that a comprehensive SFL in bars significantly deters smoking relapse among people ages 21 and older.[37] According to Buczkowski *et al.*,[38] the main reasons for relapse are stress, missing the pleasure obtained from smoking and the smoking environment. Other factors not analysed in our study that might influence relapse rates could explain the variations between regions, for instance living with other smokers, being enrolled in work or clinics cessation programmes[39] or the region-specific complementary measures to the SFL (for instance, Foral Law 6/2003,[40] February 14, of smoking prevention, protection from

secondhand tobacco smoke and promotion of health with regard to smoking in Navarre). In addition, we should consider the impact of the financial crisis during the study period and the subsequent increase of anxiety and depression in the population.[41] In this respect, Navarre was the region with the lowest unemployment rate in Spain according to the 2010 Economically Active Population Survey (unemployment of 11.6% in Navarre, versus 18.0% in Catalonia and 22.2% in the Balearic Islands). According to the 2009 European Health Survey in Spain, these unemployment figures correlate with the prevalence of chronic depression, which was of 3.4% in Navarre versus 5.4% in Catalonia and 7.0% in the Balearic Islands.

The SFL is a keystone of the WHO Framework Convention on Tobacco Control (FCTC) and the MPOWER policy package (M=Monitor; P=Protect; O=Offer; W=Warm; E=Enforce; R= Raise).[42] The enforcement of Laws 28/2005 and 42/2010 have significantly advanced smoking control in Spain, in particular the "Protect people from tobacco" strategy. However, the remaining MPOWER strategies have been patchily implemented and require further development.[23] On balance, a combination of specific, feasible, pragmatic, sufficiently funded policies and interventions aimed at populations and individuals is essential to achieve progress regarding smoking behaviour.

Limitations and strengths of the study

It is important to take into account that other than the Law, the pattern of tobacco consumption is influenced by factors such as health interventions, level of education, age, civil status, having children and being unemployed.[43] However, this study only considered age, sex, number of health problems and number of PHC visits since other variables were not available. In addition, many patients were excluded from the study because of lack of baseline data on smoking (missing data is a common problem in studies based on EHR). In order to prevent bias caused by improved smoking records, we excluded the cases with no information at the beginning of the study. The selection criteria and the longitudinal design aimed to maximize the internal validity of the study. Moreover, young people might be underrepresented due to their lower use of PHC services. On the other hand, 70% of the population attends PHC services at least once a year and smokers attend more frequently than no smokers.[44] In view of the limited length of the study period, particularly in the Balearic Islands, we consider these results a first approximation to be succeeded by follow-up research. We should underscore that rather than just comparing two different periods, joinpoint analysis evaluates longitudinal trends, thus producing a more accurate assessment. The following characteristics of the study were taken into consideration: scarcity of data prior to the implementation of the SFL; delayed changes in smoking status; possibility of detecting more than one change in smoking trends; and influence of unanticipated factors. While other statistical models could have been used, we believe that joinpoint is a suitable method to achieve the study objectives, as shown in previous studies.[45-47]

This study provides useful data on the impact of the Spanish comprehensive SFL on adult smoking behaviour in PHC patients. It is crucial to analyse the consequences of a public health law on PHC users. Primary health care has a pivotal role in smoking cessation because it is the gatekeeper of the health services, it is accessible and provides continuity of care to smokers.[48] We should also highlight that this study includes the evaluation of novel variables such as incidence of new

smokers, new ex-smokers and ex-smoker relapse, which we consider of great relevance in relation to PHC interventions for smoking cessation. Used as a research tool, EHR portray real-life conditions and provide comprehensive, long-term health histories from a large population sample, ensure high representativeness and external validity and minimize potential recall bias. The results are only generalizable to PHC users. To our knowledge, this study is amongst the first to show quarterly data from EHR.

CONCLUSIONS

The introduction of the Spanish comprehensive SFL (Law 42/2010) does not significantly modify incidence and prevalence trends of smoking behaviour in PHC adult patients in Catalonia, Navarre and the Balearic Islands. The impact of the comprehensive SFL might have been lessened by the effect of the previous implementation of the partial SFL (Law 28/2005). The current article provides baseline data for future research into the effectiveness of this Law. In addition to specific factors associated with smoking behaviour (such as the price of a pack of cigarettes or funding of smoking cessation services), future studies should consider socio-economic status and age groups.

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Contributors: BB, TRB, MPV, JBM, and CVF designed the study and wrote the protocol. YRM, MPV and JBM conducted literature searches and provided summaries of previous research studies. BB, JLL, JM, JR and MPV obtained the data. TRB and TLJ conducted the statistical analysis. All authors contributed to the interpretation of the results. YRM and MPV wrote the first draft of the manuscript. All authors read, contributed and approved the final version of the manuscript.

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Competing interest: The authors declare no conflict of interest.

Ethical aspects: This study follows the tenets of the Helsinki Declaration and of Good Clinical Research Practice and has been approved by the Ethical and Clinical Research Committee of the IDIAP Jordi Gol. Confidentiality was guaranteed through data encryption and anonymization in agreement with the data confidentiality Law 15/1999.

Data sharing statement: No additional data are available.

Figure 1: Flow-chart of patients included in the study, by region.

REFERENCES

1. Jha P. Avoidable global cancer deaths and total deaths from smoking. *Nat Rev Cancer* 2009;9:655–64.
2. Murray CJL, Lopez AD. Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. *Lancet* 2017;349:1498–504.
3. World Health Organization, and Tobacco Free Initiative. Building blocks to tobacco control: a hand-book. (Tools for advancing tobacco control in the 21st century). Geneva*: WHO;* 2004.
4. Federico B, Mackenbach JP, Eikemo TA, *et al*. Impact of the 2005 smoke-free policy in Italy on prevalence, cessation and intensity of smoking in the overall population and by educational group. *Addiction* 2012;107:1677–86.
5. Hahn EJ, Rayens MK, Butler KM, *et al*. Smoke-free laws and adult smoking prevalence. *Prev Med* 2008;47:206–9.
6. Nagelhout GE, Willemsen MC, de Vries H. The population impact of smoke-free workplace and hospitality industry legislation on smoking behaviour. Findings from a national population survey. *Addiction* 2011;106:816–23.
7. Hublet A, Schmid H, Clays E, *et al*. Association between tobacco control policies and smoking behaviour among adolescents in 29 European countries. *Addiction* 2009;104:1918–26.
8. Tchicaya A, Lorentz N, Demarest S. Socioeconomic inequalities in smoking and smoking cessation due to a smoking ban: General population-based cross-sectional study in Luxembourg. *PLoS One* 2016;11:1–15.
9. Ye X, Chen S, Yao Z, *et al*. Smoking behaviors before and after implementation of a smoke-free legislation in Guangzhou, China. *BMC Public Health* 2015;15:982.
10. Fichtenberg CM, Glantz SA. Effect of smoke-free workplace on smoking behaviour: systematic review. BMJ 2002;325:188.
11. Frazer K, Callinan JE, McHugh J, *et al.* Legislative smoking bans for reducing harms from secondhand smoke exposure, smoking prevalence and tobacco consumption. *Cochrane database Syst Rev* 2016;2:CD005992.
12. Ley de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro y la publicidad de los productos del tabaco. L. N. 28/2005 (27 diciembre 2005). Available at: https://www.boe.es/buscar/doc.php?id=BOE-A-2005-21261 . Accessed 6-3-2017.
13. Nebot M, Fernández E, (Coords) Evaluación del impacto de la ley de medidas sanitarias frente al tabaquismo. Grupo de Trabajo en Tabaquismo de la Sociedad Española de Epidemiología. Barcelona: Sociedad Española de Epidemiología y Ministerio de Sanidad y Política Social, 9-43. 2009. Available in: URL: http://www.seepidemiologia.es/documents/dummy/Monografia-Grupo%20Trabajo%20sobre%20tabaquismo.pdf)
14. Cordoba R, Villalbi JR, Salvador-Llivina T, *et al*. El proceso en España de la adopción de una legislación eficaz para la prevención del tabaquismo [Spain's process of passing effective smoking prevention legislation]. *Rev Esp Salud Publica* 2006;80:631–45.
15. Nebot M, López MJ, Ariza C, Pérez-Ríos M, *et al*. Impact of the Spanish smoking law on exposure to secondhand smoke in offices and hospitality venues: Before-and-after study. *Environ Health Perspect* 2009;117:344–7.
16. Ley de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro y la publicidad de los productos del tabaco (30 December 2010), por la que se modifica la Ley 28/2005, de 26 de diciembre, de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro, el consumo y la publicidad de los productos del tabaco. Boletín Oficial del Estado (Spanish Official State Bulletin). L. N. 42/2010.No. 318. Available at: https://www.boe.es/buscar/act.php?id=BOE-A-2010-20138 . Accessed 6-3-2017.
17. Regidor E, de Mateo S, Ronda E, *et al.* Heterogeneous trend in smoking prevalence by sex and age group following the implementation of a national smoke-free law. *J Epidemiol Community Health* 2011;65:702–8.
18. Regidor E, Pascual C, Giráldez-García C, *et al.* Impact of tobacco prices and smoke-free policy on smoking cessation, by gender and educational group: Spain, 1993-2012. *Int J Drug Policy* 2015;26:1215–21.
19. Perez-Rios M, Fernandez E, Schiaffino A, *et al*. Changes in the prevalence of tobacco consumption and the profile of Spanish smokers after a comprehensive smoke-free policy. *PLoS One* 2015;10:1–9.
20. Jiménez Ruiz CA, Riesco Miranda JA, Altet Gómez N, *et al*. Impact of legislation on passive smoking in Spain. *Respiration* 2014;87:190–5.
21. Catalina Romero C, Gelpi Médez JA, Cortés Arcas MV, *et al.* Evolución en España del consumo de tabaco en población trabajadora desde la entrada en vigor de la Ley 28/2005 de medidas sanitarias frente al tabaquismo [Prevalence of Tobacco Consumption Among Working Population after the Law 42/2010, Spain]. *Rev Esp salud pública* 2010;84:223–7.
22. Catalina Romero C, Sainz Gutiérrez JC, Quevedo Aguado L*, et al.* Prevalencia de consumo de tabaco en población trabajadora tras la entrada en vigor de la Ley 42/2010 [Prevalence of tobacco consumption among working

population after the law 42/2010, Spain]. *Rev Esp Salud Publica* 2012;86:177–88.
23. Pérez-Ríos M, Galán I(editors) Evaluación de las políticas de control del tabaquismo en España (Leyes 28/2005 y 42/2010) Revisión de la evidencia. Grupo de Trabajo en Tabaquismo de la Sociedad Española de Epidemiología. Barcelona: Sociedad Española de Epidemiología y Ministerio de Sanidad y Política Social, 2017;11-74. Available in: URL: http://www.seepidemiologia.es/documents/dummy/V9.0%2520-%2520Libro%2520Tabaquismo%25202017%2520-%2520Abierto%2520Final.pdf
24. Lidón-moyano C, Fu M, Ballbè M, *et al*. Addictive Behaviors Impact of the Spanish smoking laws on tobacco consumption and secondhand smoke exposure : A longitudinal population study. *Addict Behav* 2017;75:30–5.
25. Bauzà-Amengual M, Blasco-González M, Sánchez-Vazquez E, *et al.* Impacto de la Ley del tabaco en el lugar de trabajo: estudio de seguimiento de una cohorte de trabajadores en España 2005--07 [Impact of the Tobacco Law on the workplace: a follow up study of a cohort of workers in Spain 2005–2007]. *Atención primaria* 2010;42:309–13.
26. Bolíbar B, Pareja C, Astier-Peña MP, *et al*. Variability in the performance of preventive services and in the degree of control of identified health problems: a primary care study protocol. *BMC Public Health* 2008;8:281.
27. The International Statistical Classification of Diseases and Related Health Problems (ICD-10th revision) classification of mental and behavioural disorders: clinical descriptions and diagnostic guidelines. Geneva: World Health Organization, 1992. Available at: http://www.who.int/classifications/icd/en/bluebook.pdf . Accessed 6-3-2017..
28. Okkes IM, Becker HW, Bernstein RM, *et al*.The March 2002 update of the electronic version of ICPC-2. A step forward to the use of ICD-10 as a nomenclature and a terminology for ICPC-2. *Fam Pract* 2002;19:543–6.
29. Kim H-J, Fay MP, Feuer EJ, *et al*. Permutation tests for joinpoint regression with applications to cancer rates. *Stat Med* 2000;19:335–51. Available at: http://onlinelibrary.wiley.com/doi/10.1002/(SICI)1097-0258(20000215)19:3%253C335::AID-SIM336%253E3.0.CO;2-Z/abstract. Accessed 8-3-2017.
30. Martín-Sánchez JC, Martinez-Sanchez JM, Bilal U, *et al*. Sex and Age Specific Projections of Smoking Prevalence in Spain: A Bayesian Approach. *Nicotine Tob Res* 2017; ntx120, https://doi.org/10.1093/ntr/ntx120.
31. Ministerio de Sanidad Servicios Sociales e Igualdad. Encuesta Europea de Salud en España: Determinantes de salud [Internet]. 2014. Available from: http://www.msssi.gob.es/estadEstudios/estadisticas/EncuestaEuropea/pdf/MODULO3RELATIVOweb.pdf
32. Ramos R, Balló E, Marrugat J, *et al.* Validity for Use in Research on Vascular Diseases of the SIDIAP (Information System for the Development of Research in Primary Care): the EMMA Study. *Rev Española Cardiol* (English Ed [Internet]. 2012;65:29–37. Available from: http://www.revespcardiol.org/en/validity-for-use-in-research/articulo/90072112/ Accessed 25-5-2018.
33. Wilson LM, Avila Tang E, Chander G, *et al.* Impact of tobacco control interventions on smoking initiation, cessation, and prevalence: A systematic review. *J Environ Public Health* 2012; doi:10.1155/2012/961724
34. Guerrero F, Santonja F-J, Villanueva R-J. Analysing the Spanish smoke-free legislation of 2006: a new method to quantify its impact using a dynamic model. *Int J Drug Policy* 2011 Jul;22:247–51.
35. Pinilla J, Abásolo I. The effect of policies regulating tobacco consumption on smoking initiation and cessation in Spain: is it equal across socioeconomic groups? *Tob Induc Dis* 2017;15:8.
36. Longo DR, Johnson JC, Kruse RL, *et al.* A prospective investigation of the impact of smoking bans on tobacco cessation and relapse. *Tob Control* 2001;10:267–72.
37. Shang C. The effect of smoke-free air law in bars on smoking initiation and relapse among teenagers and young adults. *Int J Environ Res Public Health* 2015;12:504–20.
38. Buczkowski K, Marcinowicz L, Czachowski S, *et al.* Motivations toward smoking cessation, reasons for relapse, and modes of quitting: results from a qualitative study among former and current smokers. *Patient Prefer Adherence* 2014;8:1353–63.
39. Schillo BA, Keller PA, Betzner AE, *et al*. Minnesota's smokefree policies: Impact on cessation program participants. *Am J Prev Med* 2012;43:S171–8.
40. Ley foral 6/2003, de 14 de febrero, de prevención del consumo de tabaco, de protección del aire respirable y de la promoción de la salud en relación al tabaco (Navarra). Available at: http://www.lexnavarra.navarra.es/detalle.asp?r=3323. Accessed 31-7-2017
41. Gili M, Garcia Campayo J, Roca M. Crisis económica y salud mental. Informe SESPAS 2014 [Economic crisis and mental health. SESPAS report 2014]. *Gac Sanit* 2014;28 Suppl 1:104–8.
42 World Health Organization. WHO report on the global tobacco epidemic, 2009: implementing smoke-free environments. Geneva: World Health Organization; 2009.
43. Buonanno P, Ranzani M. Thank you for not smoking: Evidence from the Italian smoking ban. *Health Policy*

2013;109:192–9.
44. Camarelles Guillem F, Dalmau González-Gallarza R, Clemente Jiménez L, *et al*. Documento de consenso para la atención clínica al tabaquismo en España [Consensus report for the clinical care of smoking cessation in Spain]. *Med Clin* 2013;140:272.e1-272.e12.
45. Lopez-Campos JL, Ruiz-Ramos M, Fernandez E, *et al.* Recent lung cancer mortality trends in Europe: effect of national smoke-free legislation strengthening. *Eur J Cancer Prev*. 2017 Apr 4. doi: 10.1097/CEJ.0000000000000354.
46. Jan C, Lee M, Roa R, *et al*. The association of tobacco control policies and the risk of acute myocardial infarction using hospital admissions data. *PLoS One*. 2014;9(2). doi: 10.1371/journal.pone.0088784
47. Rando-Matos Y, Pons-Vigués M, Rodriguez-Blanco T, *et al*. Effect of comprehensive smoke-free legislation on asthma and coronary disease trends in Spanish primary care patients. *Eur J Public Health* [Internet]. 2018;cky010. doi: 10.1093/eurpub/cky010.
48. Córdoba R, Cabezas C, Camarelles F, *et al.* Recomendaciones sobre el estilo de vida. *Atención primaria* 2012;44:16–22.

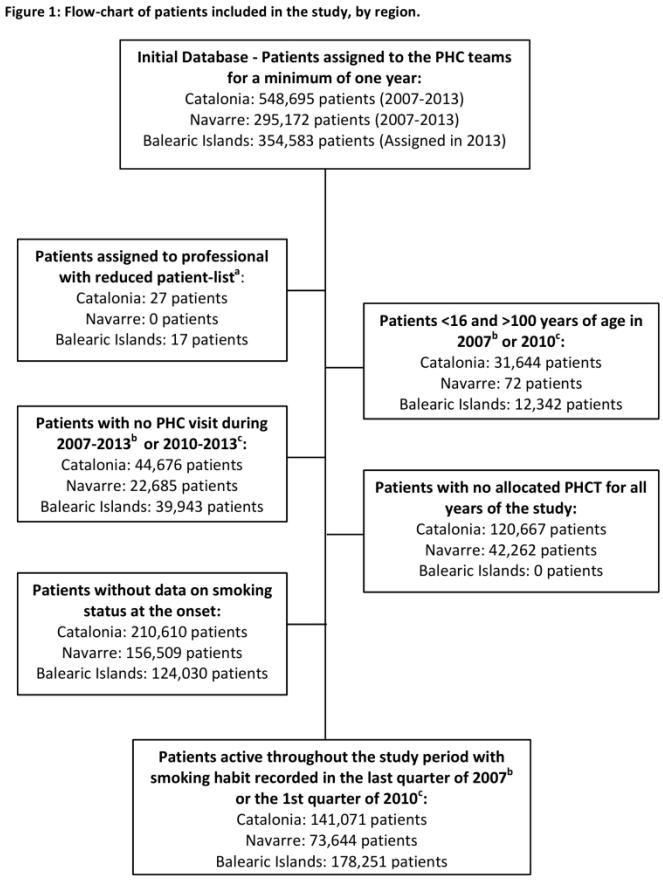

Figure 1: Flow-chart of patients included in the study, by region.

209x297mm (300 x 300 DPI)

SUPPLEMENTARY DATA FOR Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

Table S1: Information concerning smoking status in the electronic health records by region

<table>
<tr><th>Information from electronic health records</th><th>Catalonia</th><th>Navarre</th><th>Balearic Islands</th></tr>
<tr><td rowspan="2">Diagnostic codes related to smoking
(with entry date)</td><td>Smoker: F17, F17.0, F17.1 F17.2, F17.5, F17.6, F17.7, F17.8, F17.9 in ICD-10</td><td rowspan="2">Smoker: code P17 in ICPC-2</td><td rowspan="2">Smoker: 305.1 in ICD-9</td></tr>
<tr><td>Ex-smoker: Z72.0</td></tr>
<tr><td rowspan="3">Clinical variables related to smoking in the medical history
(with entry date)</td><td colspan="3">Smoking habit:
0: non-smoker.
1: smoker.
2: ex-smoker</td></tr>
<tr><td colspan="3">Number of cigarettes per day:
0 to 300</td></tr>
<tr><td colspan="3">Smoking cessation advice:
1: yes
0: no</td></tr>
</table>

Abbreviations: ICPC-2, International Classification of Primary Care, second edition; ICD-9 and 10, International Classification of Diseases, 9th and 10th revision.

Table S2: Age-adjusted rates by direct method per 10,000 inhabitants based on the European Standard Population. CATALONIA N=141,071 (2008-2013).

Quarter	Smoking status prevalence			New smokers incidence	New ex-smokers incidence	Ex-smoker relapses incidence
	Non smokers	Smokers	Ex-smokers			
2008.1	4692.6	4138.9	1168.5	20.8	254.3	226.9
2008.2	4679.3	4099.0	1221.7	21.4	212.9	151.4
2008.3	4668.8	4073.6	1257.6	16.6	267.5	218.5
2008.4	4650.2	4051.7	1298.1	26.1	317.6	100.4
2009.1	4638.8	4053.6	1307.6	25.2	260.1	128.6
2009.2	4628.1	4036.8	1335.1	15.8	228.5	78.3
2009.3	4618.4	4021.6	1360.0	12.7	161.3	113.7
2009.4	4604.4	3998.5	1397.2	19.6	212.7	165.6
2010.1	4590.0	4001.8	1408.2	19.0	160.9	123.1
2010.2	4573.5	3994.3	1432.2	26.4	135.8	148.8
2010.3	4560.0	3981.0	1459.0	20.8	139.0	100.5
2010.4	4539.7	3957.4	1503.0	26.8	188.1	112.5
2011.1	4077.0	3758.0	1510.3	15.1	171.9	103.2
2011.2	4068.6	3721.4	1555.3	12.4	213.0	90.0
2011.3	4061.6	3696.3	1587.3	13.0	145.9	81.4
2011.4	4050.8	3649.8	1644.7	15.8	255.4	91.3
2012.1	4012.6	3658.7	1673.9	13.4	222.7	111.1
2012.2	4004.9	3629.6	1710.7	11.3	171.3	91.9
2012.3	4000.4	3608.5	1736.3	7.9	118.8	70.7
2012.4	3990.2	3579.2	1775.8	11.8	201.3	103.9
2013.1	3963.0	3601.1	1781.2	16.5	184.9	141.7
2013.2	3956.3	3618.6	1770.3	15.2	136.7	247.6
2013.3	3952.8	3635.1	1757.3	9.3	110.7	248.6
2013.4	3946.5	3659.3	1739.5	14.7	172.8	334.5

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S3: Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population. NAVARRE N=73,644 (2008-2013).

Quarter	Smoking status prevalence			New smokers incidence	New ex-smokers incidence	Ex-smoker relapses incidence
	Non smokers	Smokers	Ex-smokers			
2008.1	5652.5	4034.2	313.3	25.3	175.3	227.0
2008.2	5642.5	4013.0	344.5	17.2	181.0	160.4
2008.3	5632.4	4003.3	364.3	16.5	109.1	129.4
2008.4	5620.0	3993.3	386.7	21.4	127.7	230.3
2009.1	5645.0	3951.4	403.7	30.9	136.4	225.4
2009.2	5630.8	3944.1	425.1	23.5	132.1	174.0
2009.3	5623.5	3934.7	441.8	12.5	100.3	100.7
2009.4	5614.7	3925.5	459.8	14.8	109.9	134.7
2010.1	5618.3	3905.9	475.8	27.2	111.2	209.4
2010.2	5605.5	3893.8	500.7	21.1	114.9	132.5
2010.3	5595.1	3889.1	515.8	16.4	82.2	98.7
2010.4	5581.9	3885.3	532.8	21.4	89.9	81.2
2011.1	4990.3	3806.9	548.1	16.0	136.8	141.3
2011.2	4979.2	3795.8	570.2	20.3	116.7	113.8
2011.3	4972.0	3791.6	581.6	12.7	48.6	60.2
2011.4	4964.3	3780.5	600.4	13.8	99.6	118.6
2012.1	4910.7	3804.6	630.0	18.6	127.3	87.6
2012.2	4902.9	3781.3	661.1	13.7	130.1	108.4
2012.3	4897.7	3773.3	674.3	9.8	75.2	58.6
2012.4	4888.9	3760.5	695.8	15.2	110.2	96.0
2013.1	4886.8	3746.7	711.8	15.1	121.0	116.4
2013.2	4876.8	3733.2	735.2	16.9	104.2	97.4
2013.3	4870.8	3727.9	746.6	9.5	60.7	119.1
2013.4	4861.3	3719.8	764.1	16.9	90.7	97.8

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S4: Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population. THE BALEARIC ISLANDS N=178,251 (2010-2013).

Quarter	Smoking status prevalence			New smokers incidence	New ex-smokers incidence	Ex-smoker relapses incidence
	Non smokers	Smokers	Ex-smokers			
2010.2	5411.0	4029.7	559.3	9.3	158.5	576.6
2010.3	5406.4	4007.3	586.2	9.0	151.6	527.0
2010.4	5401.6	3982.7	615.7	9.3	158.7	503.7
2011.1	5374.9	3987.9	637.1	6.6	149.9	545.7
2011.2	5372.4	3959.3	668.3	5.2	170.9	424.4
2011.3	5369.7	3929.5	700.8	5.2	160.1	383.9
2011.4	5367.4	3898.4	734.2	4.0	169.8	385.6
2012.1	5345.3	3888.3	766.4	4.3	188.1	351.8
2012.2	5344.0	3862.4	793.6	2.4	137.0	370.6
2012.3	5342.5	3841.0	816.6	2.9	113.5	372.6
2012.4	5341.7	3818.9	839.4	1.6	133.0	339.2
2013.1	5324.1	3825.3	850.7	2.1	130.5	480.5
2013.2	5317.8	3810.5	871.7	12.1	106.7	453.0
2013.3	5308.3	3800.6	891.1	17.5	93.7	103.9
2013.4	5298.6	3787.4	914.1	17.5	116.8	285.1

Note: 2010.*. represents the quarter * of the year 2010

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S5. Age-adjusted rates by the direct method for 10,000 inhabitants based on the European Standard Population in CATALONIA. N=72,340 (2008-2013).

Quarter	Smoking Status prevalence						New smokers incidence		New ex-smokers incidence		Ex-smoker relapse incidence	
	Non smokers		Smokers		Ex-smokers							
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
2008.1	5909.5	3349.2	3411.5	4910.7	679.0	1740.1	16.6	27.8	246.7	260.5	315.2	158.2
2008.2	5900.4	3331.6	3385.4	4856.2	714.2	1812.2	14.3	34.4	266.5	202.9	101.2	195.0
2008.3	5891.9	3318.8	3368.4	4822.1	739.7	1859.1	14.0	21.8	275.0	265.9	289.0	166.5
2008.4	5876.9	3296.1	3356.2	4789.4	766.9	1914.5	24.0	31.9	254.1	329.2	112.0	99.6
2009.1	5832.7	3323.5	3379.8	4769.9	787.5	1906.6	27.8	26.3	289.2	234.0	148.8	105.2
2009.2	5823.1	3311.7	3366.5	4749.0	810.4	1939.3	13.7	19.7	182.0	237.8	89.5	79.2
2009.3	5814.6	3300.6	3356.2	4728.4	829.2	1971.1	11.9	15.3	154.4	165.7	181.4	65.8
2009.4	5804.4	3282.4	3335.4	4702.6	860.2	2015.0	14.3	28.0	243.3	203.9	188.5	152.0
2010.1	5757.2	3312.5	3359.5	4679.7	883.3	2007.8	14.0	26.7	201.5	144.1	133.5	109.4
2010.2	5744.1	3292.3	3355.5	4668.2	900.4	2039.6	24.1	30.4	146.6	131.6	164.1	152.0
2010.3	5730.0	3279.4	3345.8	4650.5	924.2	2070.2	20.7	22.7	156.1	134.4	106.6	98.0
2010.4	5710.9	3256.8	3332.3	4616.4	956.8	2126.8	30.9	24.3	205.4	177.3	132.2	114.9
2011.1	5231.2	2821.0	3138.8	4408.8	975.2	2115.4	15.0	16.8	181.1	166.1	62.6	146.7
2011.2	5223.4	2811.7	3115.8	4356.5	1006.0	2177.1	12.2	14.3	231.6	203.8	118.9	65.4
2011.3	5216.7	2804.3	3095.4	4326.8	1033.2	2214.1	12.4	15.2	166.4	136.0	93.0	68.5
2011.4	5209.6	2789.1	3057.6	4270.9	1078.0	2285.2	12.1	21.2	308.9	241.6	111.0	78.8
2012.1	5142.2	2792.0	3082.8	4259.8	1120.2	2293.5	9.3	19.1	251.1	216.5	140.4	83.6
2012.2	5136.1	2782.4	3059.1	4225.1	1150.0	2337.7	10.4	12.4	215.6	162.3	107.4	75.8
2012.3	5132.0	2777.7	3041.8	4200.0	1171.4	2367.6	8.7	7.3	135.6	113.1	61.0	80.2
2012.4	5123.4	2765.4	3020.5	4161.9	1201.3	2417.9	10.2	16.2	192.8	203.5	128.5	89.1
2013.1	5063.9	2781.5	3055.9	4167.2	1225.4	2396.5	15.4	19.9	213.2	180.4	167.8	123.5
2013.2	5058.8	2773.4	3057.2	4202.9	1229.3	2368.9	10.2	21.9	146.9	131.3	216.4	251.9
2013.3	5055.0	2770.2	3060.2	4234.1	1230.0	2340.9	9.0	10.7	127.0	106.7	217.7	263.3
2013.4	5049.2	2763.3	3063.6	4281.9	1232.5	2300.1	11.8	21.1	202.8	159.2	325.6	315.6

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S6. Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population in NAVARRE. N=37,898 (2008-2013).

Quarter	Smoking Status prevalence						New smokers incidence		New ex-smokers incidence		Ex-smoker relapse incidence	
	Non smokers		Smokers		Ex-smokers							
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
2008.1	6224.8	5021.1	3542.5	4569.6	232.7	409.3	22.3	31.0	152.7	172.3	164.4	295.8
2008.2	6215.3	5010.6	3527.8	4539.7	256.9	449.7	15.2	20.3	168.7	187.7	136.9	173.7
2008.3	6207.4	4998.8	3518.5	4528.6	274.2	472.6	11.5	22.1	147.1	97.1	147.9	123.7
2008.4	6198.6	4982.4	3510.9	4515.4	290.4	502.2	14.8	30.0	157.9	125.6	296.5	98.8
2009.1	6209.7	5028.3	3485.7	4451.5	304.6	520.2	24.9	39.7	184.8	111.3	254.0	197.0
2009.2	6197.8	5011.6	3480.3	4441.1	321.9	547.3	17.4	32.6	177.2	127.7	152.7	171.7
2009.3	6191.6	5003.2	3475.5	4426.3	332.9	570.4	10.7	15.2	108.4	98.3	73.4	111.5
2009.4	6186.2	4990.0	3470.2	4413.1	343.6	596.9	8.4	24.0	97.2	115.8	126.6	134.7
2010.1	6175.4	5014.1	3464.6	4375.5	360.0	610.4	22.6	33.5	115.7	112.9	224.3	208.6
2010.2	6164.6	4999.4	3455.7	4359.8	379.7	640.8	16.4	27.9	119.1	114.5	106.4	129.5
2010.3	6154.5	4988.6	3456.0	4350.4	389.5	661.0	16.2	17.0	111.3	75.9	88.3	94.5
2010.4	6142.1	4974.6	3455.4	4343.4	402.5	682.1	17.8	26.3	126.9	80.9	71.3	85.7
2011.1	5541.4	4399.8	3388.4	4248.3	415.4	697.1	12.2	21.0	146.2	135.4	91.3	183.2
2011.2	5532.4	4386.6	3381.0	4233.7	431.9	724.9	15.5	26.8	151.1	110.6	117.2	103.9
2011.3	5524.7	4379.8	3377.8	4228.5	442.7	737.0	12.6	13.7	55.8	44.9	61.6	54.1
2011.4	5518.9	4370.0	3369.7	4213.6	456.6	761.7	9.6	19.5	118.2	95.4	70.0	160.8
2012.1	5452.1	4335.6	3408.9	4217.7	484.2	792.0	15.9	22.5	129.3	126.5	106.9	65.3
2012.2	5445.6	4326.1	3389.4	4190.1	510.2	829.0	11.7	17.2	125.1	131.6	95.3	114.5
2012.3	5442.6	4318.6	3385.2	4178.7	517.4	847.9	6.2	14.2	67.6	78.0	68.6	41.2
2012.4	5434.5	4308.9	3379.5	4159.1	531.2	877.2	12.5	19.6	130.7	110.0	66.7	126.7
2013.1	5420.0	4323.0	3380.9	4128.0	544.3	894.1	14.1	16.4	133.8	124.7	68.6	157.5
2013.2	5413.7	4309.1	3367.7	4114.5	563.9	921.6	10.1	25.2	103.2	104.7	87.0	98.4
2013.3	5408.6	4302.1	3363.6	4108.1	573.1	935.1	7.2	12.7	72.3	57.3	152.7	85.9
2013.4	5399.9	4291.6	3360.4	4094.8	584.9	958.8	13.9	21.7	65.6	102.8	72.2	116.0

Note: 2008.*. represents the quarter * of the year 2008

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

Table S7. Age-adjusted rates by the direct method per 10,000 inhabitants based on the European Standard Population in THE BALEARIC ISLANDS. N= 94,164 (2010-2013).

Quarter	Smoking Status prevalence						New smokers incidence		New ex-smokers incidence		Ex-smoker relapse incidence	
	Non smokers		Smokers		Ex-smokers							
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
2010.2	6224.8	4484.3	3412.3	4723.7	362.9	792.0	8.9	9.9	106.8	169.6	631.1	560.7
2010.3	6220.5	4479.3	3395.5	4695.0	384.0	825.7	8.2	10.4	149.6	147.6	576.9	435.9
2010.4	6215.8	4474.3	3376.3	4664.4	408.0	861.2	8.8	10.1	179.2	150.7	484.7	571.5
2011.1	6171.2	4472.1	3395.3	4651.7	433.5	876.2	6.7	6.6	141.1	146.7	562.7	508.9
2011.2	6168.5	4469.8	3375.7	4612.8	455.9	917.5	5.2	5.4	140.3	173.8	446.1	426.0
2011.3	6165.8	4467.0	3353.4	4574.6	480.8	958.4	4.9	6.0	162.5	154.9	400.9	391.6
2011.4	6163.1	4465.3	3330.1	4534.6	506.8	1000.1	4.6	3.4	149.3	170.9	296.7	540.3
2012.1	6118.6	4474.0	3337.9	4501.2	543.6	1024.8	3.7	5.1	179.2	182.1	306.5	461.7
2012.2	6117.0	4473.2	3318.1	4468.3	564.9	1058.5	2.8	1.9	109.0	139.6	359.8	348.6
2012.3	6115.2	4471.9	3302.0	4440.5	582.8	1087.7	3.1	2.5	103.4	112.8	376.5	363.9
2012.4	6114.3	4471.2	3285.7	4411.7	600.0	1117.0	1.7	1.6	122.7	132.9	414.0	213.4
2013.1	6077.2	4479.2	3302.2	4406.4	620.6	1114.4	0.9	4.1	137.9	122.6	492.0	470.3
2013.2	6070.8	4473.1	3291.1	4387.8	638.2	1139.1	11.9	12.7	91.0	105.4	410.8	532.6
2013.3	6056.9	4468.7	3287.9	4370.1	655.1	1161.2	23.4	10.4	94.4	90.1	110.4	87.5
2013.4	6046.1	4460.3	3280.8	4349.5	673.1	1190.2	18.2	16.9	100.0	121.4	342.4	116.1

Note: 2010.*. represents the quarter * of the year 2010

Rates are per 10,000 inhabitants and age-standardized on the European Standard Population (direct method)

SUPPLEMENTARY DATA FOR Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

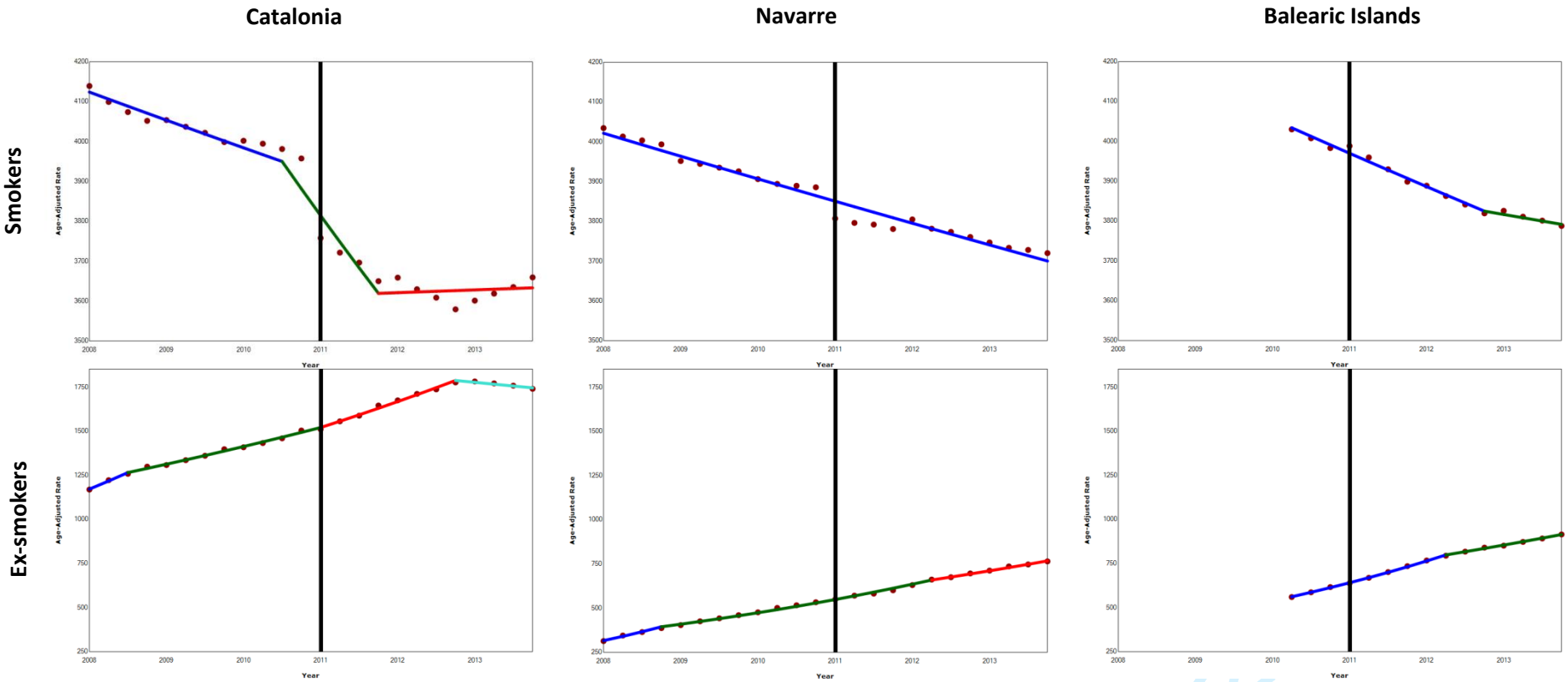

Figure S1: Overall trends of age-standardized prevalence rates of smoking status in Catalonia, Navarre and the Balearic Islands.
Solid lines represent the Joinpoint regression lines (each colour is a different trend); circle red points represent the age-adjusted prevalence rates. Black vertical lines represent the year when the Spanish comprehensive smoke-free law was introduced (2011).

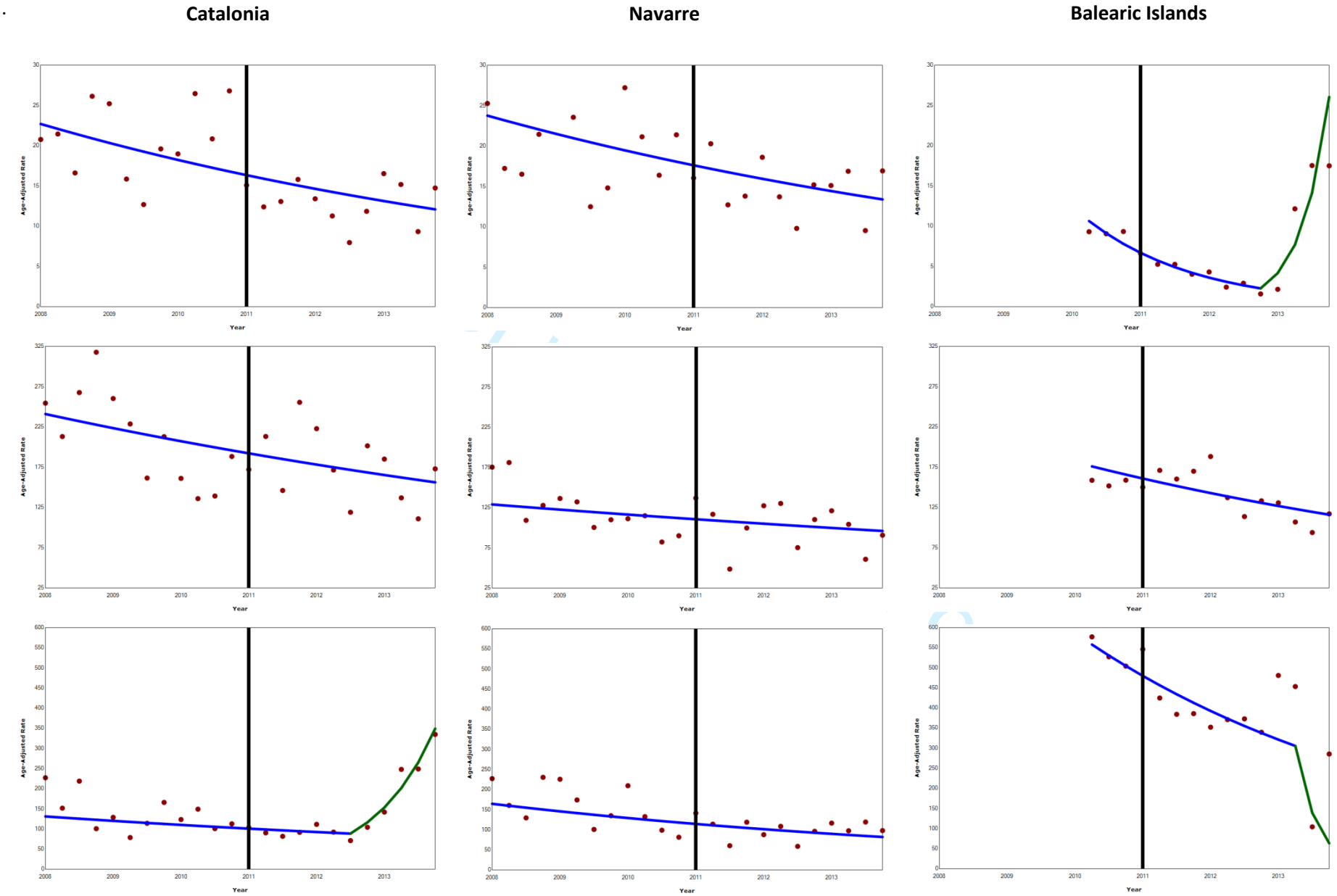

Figure S2: Overall trends of age-standardized incidence rates of new smokers, ex-smokers and ex-smoker relapse in Catalonia, Navarre and the Balearic Islands. Solid lines represent the Joinpoint regression lines (each colour is a different trend); circle red points represent the age-adjusted incidence rates. Black vertical lines represent the year when the Spanish comprehensive smoke-free law was introduced (2011).

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6-7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	6 + Figure 1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7-8
		(*b*) Describe any methods used to examine subgroups and interactions	7-8
		(*c*) Explain how missing data were addressed	6 + 15
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6, 8. Figure 1
		(b) Give reasons for non-participation at each stage	6. Figure 1
		(c) Consider use of a flow diagram	6. Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8. Table 1.
		(b) Indicate number of participants with missing data for each variable of interest	8
Outcome data	15*	Report numbers of outcome events or summary measures	8-12. Tables 2-4
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-12. Tables 2-4
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14-15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	15-16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.