Universitat Autònoma de Barcelona

# EVALUACIÓN DE LA LEY LIBRE DE HUMO ESPAÑOLA 42/2010 SOBRE TABAQUISMO, ASMA, Y ENFERMEDAD CORONARIA EN ATENCIÓN PRIMARIA DE SALUD

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# Abreviaturas

ABS: Área básica de salud

aIRR: Razón de incidencia ajustada

APS: Atención Primaria de Salud

CAP: Centro de Atención Primaria

CPA: Cambio porcentual anual

CPAP: Cambio porcentual anual promedio

CO: Monóxido de carbono

CMCT: Convenio Marco para el Control del Tabaco

CNPT: Comité Nacional para la Prevención del Tabaquismo

DMAE: Degeneración macular asociada a la edad

ECV: Enfermedades cerebrovasculares

EPOC: Enfermedad pulmonar obstructiva crónica

HCE: Historia clínica electrónica

IAM: Infarto agudo de miocardio

IARC: *International Agency for Research on Cancer*

IC 95%: Intervalo de Confianza del 95%

ICS: Institut Català de la Salut

Mg: Miligramos

Ng: Nanogramos

OMS: Organización Mundial de la Salud

RR: Riesgo relativo

PACAP: Programa de actividades comunitarias en Atención Primaria

PAPPS: Programa de actividades para la promoción de la salud

SEE: Sociedad Española de Epidemiología

SEMFYC: Sociedad Española de Medicina de Familia y Comunitaria

SNS: Sistema Nacional de Salud

TCS: *Tobacco Control Scale*

TIC: Tecnologías de la información y la comunicación

ZBS: Zona básica de salud

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# Resumen


**Antecedentes y objetivos**

Desde principios del siglo XXI se ha legislado la prohibición de fumar en espacios públicos cerrados a fin de proteger la salud de las personas trabajadoras y de las personas no fumadoras. En España en 2006, se aplicó una Ley libre de humo parcial (Ley 28/2005), que prohibía fumar en los centros de trabajo cerrados públicos y privados pero se permitía fumar en algunos establecimientos de la hostelería en función del área del local. Esta ley se reforzó más tarde con la Ley integral 42/2010 que prohibía completamente fumar en espacios cerrados. Algunos estudios han analizado el impacto de estas dos leyes españolas sobre la prevalencia del tabaquismo, con resultados contradictorios. Además, no existen datos sobre el impacto de la Ley 42/2010 en el contexto de Atención Primaria de Salud (APS) que juega un papel prínceps en la prevención y tratamiento del tabaquismo. Por ello, el primer objetivo de la tesis ha sido analizar el impacto de la Ley integral en la prevalencia e incidencia del tabaquismo en personas adultas atendidas en APS.

Las leyes libres de humo deberían ocasionar una disminución de la exposición del humo de segunda mano y del tabaquismo activo con lo que mejorarían los trastornos respiratorios y sensoriales en la población. Sin embargo, los efectos no son concluyentes en este aspecto según la bibliografía previa. Por este motivo, el segundo objetivo fue sintetizar la evidencia disponible en los artículos científicos de los efectos de la legislación libre de humo sobre trastornos respiratorios y sensoriales en toda la población.

En España, la implantación de la Ley parcial 28/2005 conllevó una disminución en la incidencia de ingresos hospitalarios de enfermedad coronaria y resultados no concluyentes para los ingresos por asma. Según el conocimiento actual, no se han publicado estudios sobre el impacto de la Ley 42/2010 sobre el asma y la enfermedad cardíaca en el contexto de la APS, puerta de entrada al sistema sanitario. Así, el tercer objetivo ha sido evaluar la tendencia en la incidencia y prevalencia de asma y enfermedad coronaria aguda en APS en el contexto de la Ley integral.

**Métodos**

Se han realizado tres estudios. Para evaluar el impacto de la Ley integral española en hábito tabáquico, asma y enfermedad coronaria en APS (objetivos 1 y 3) se diseñaron dos estudios observacionales longitudinales en Cataluña, Navarra e Islas Baleares. La fuente de información en estos dos estudios fue la historia clínica informatizada de APS. Se escogieron 22 zonas básicas de salud de cada región. Se calcularon las prevalencias de personas fumadoras y ex fumadoras; incidencias de nuevas personas fumadoras, nuevas ex fumadoras y recaída de ex fumadoras del 2008 al 2013 (en Baleares, del 2010 al 2013); además de las prevalencias e

incidencias de asma y de enfermedad coronaria del 2007 al 2013 (en Baleares, del 2010 al 2013). Se calcularon las tasas de incidencia y prevalencia estandarizadas por edad globales y por sexos, por región. Se evaluó la evolución temporal en la incidencia y prevalencia (expresados como cambio porcentual anual [CPA] y cambio porcentual anual promedio [CPAP]).

Para revisar el impacto de las leyes libres de humo en la literatura (objetivo 2) se realizó una revisión sistemática desde 1995 hasta 2015 y meta-análisis. Se buscó en diferentes bases de datos y se escogieron estudios originales que tuvieran datos antes y después de ley libre de humo e impacto en trastornos respiratorios o sensoriales. Las variables dependientes fueron sintomatología sensorial o respiratoria, patología respiratoria y mortalidad respiratoria. Se realizó un meta-análisis de efectos aleatorios con análisis de subgrupos, de sensibilidad y evaluación del sesgo de publicación.

**Resultados**

Se halló una disminución significativa en la tendencia de las tasas de prevalencia de personas fumadoras (CPAP Cataluña -2,18%; Navarra -1,44%; Islas Baleares -1,75%), mayor en hombres que en mujeres, y un aumento significativo en la tendencia de la prevalencia de personas ex fumadoras en las tres regiones estudiadas (CPAP Cataluña 7,19%; Navarra 16,67%; Islas Baleares 14,96%), mayormente en las mujeres. Respecto a la incidencia, la tendencia de las tasas de nuevas personas fumadoras disminuyó significativamente en Cataluña (CPAP -10,39%) y Navarra (CPAP -9,49%, similar en hombres y mujeres), pero también disminuyó la tendencia de los nuevas personas ex fumadoras en Cataluña (CPAP -7,27%) y las Islas Baleares (CPAP -11,24%), especialmente entre los hombres. Las tendencias de las tasas de incidencia de recaída de personas exfumadoras mostraron datos contradictorios entre regiones.

En el ámbito de la APS y en las tres regiones estudiadas, la tendencia de prevalencia de asma aumentó significativamente del 2007 al 2013, en menor medida durante el período 2009-13 en Cataluña (CPA 4,22% vs CPA 7,13% en el periodo 2007-2009) y Navarra (CPA 6,07% vs CPA 9,09% en el periodo 2007-2009), y mayormente en los hombres en todas las regiones. En cambio, las tendencias de las tasas de incidencia de asma no obtuvieron resultados significativos. Las tasas de incidencia de la enfermedad coronaria mostraron una tendencia descendente significativa a lo largo del período estudiado en Cataluña (CPAP -8,00%) y Navarra (CPAP -3,66%). Por el contrario, la tendencia de las tasas de prevalencia aumentó significativamente en Cataluña de 2007 a 2010 en global (CPA 1,52%) y en los hombres (CPA 1,90%) y también en las Islas Baleares durante todo el período de estudio (CPAP global 10,01%).

En la revisión sistemática y meta-análisis realizados se ha observado efectos beneficiosos de las leyes libres de humo en los trabajadores tanto con leyes integrales como parciales con respecto a la sintomatología respiratoria (disminución significativa de cualquier síntoma respiratorio después de la ley del 19% y 20% en el meta-análisis, respectivamente) como en la sintomatología sensorial (disminución de cualquier síntoma sensorial del 34% y del 30%, respectivamente). También se halló una disminución significativa de los ingresos hospitalarios por asma en población adulta e infantil del 15% tras la legislación en ambos casos. Los rangos de disminución de asma tras las legislaciones integrales según la revisión narrativa era de entre el 9,0% y el 18,2% para la población infantil y de entre el 4,9 al 36,0% para la población adulta. Hubo una mayoría de estudios que reportaron disminuciones en los ingresos por enfermedad pulmonar obstructiva crónica (EPOC) en la revisión narrativa (rango de disminución del 1% al 36%) pero sin significación en el meta-análisis. Respecto a otras enfermedades pulmonares, mortalidad respiratoria y parámetros espirométricos, los resultados fueron heterogéneos y discrepantes.

**Conclusiones**

La introducción de la Ley 42/2010 no modificó significativamente las tendencias de incidencia y prevalencia del hábito tabáquico, de asma y de enfermedad coronaria de personas adultas atendidas en APS en Cataluña, Navarra y las Islas Baleares tras tres años de su implantación, ni en global ni estratificado por sexos. La aplicación de las legislaciones libres de humo disminuye la sintomatología sensorial (sobretodo en ámbitos con leyes integrales), la sintomatología respiratoria en los trabajadores y en población infantil y los ingresos por asma en todas las poblaciones. Sin embargo, los resultados sobre función pulmonar, EPOC, infección respiratoria y mortalidad respiratoria no son concluyentes.

**Palabras clave**

Análisis Joinpoint; Asma; Atención Primaria de Salud; Enfermedades respiratorias; Evaluación de política pública; Hábito de fumar; Meta-análisis; Población adulta; Política libre de humo; Registros electrónicos de salud; Revisión sistemática; Síndrome coronario agudo; Tabaco; Tendencias; Todas las poblaciones.

# Resum

**Antecedents i objectius**

Des de principis del segle XXI s'ha legislat la prohibició de fumar en espais públics tancats per tal de protegir la salut de les persones treballadores i de les persones no fumadores. A Espanya el 2006, es va aplicar una llei lliure de fum parcial (Llei 28/2005), que prohibia fumar als centres de treball tancats públics i privats però es permetia fumar en alguns establiments de l'hostaleria en funció de l'àrea del local. Aquesta llei es va reforçar més tard amb la Llei integral 42/2010 que prohibia completament fumar en espais tancats. Alguns estudis han analitzat l'impacte d'aquestes dues lleis espanyoles sobre la prevalença del tabaquisme, amb resultats contradictoris. A més, no hi ha dades sobre l'impacte de la Llei 42/2010 en el context d'Atenció Primària de Salut (APS) que juga un paper prínceps a la prevenció i tractament del tabaquisme. Per això, el primer objectiu de la tesi ha estat analitzar l'impacte de la Llei integral en la prevalença i incidència del tabaquisme en persones adultes ateses en APS.

Les lleis lliures de fum haurien ocasionar una disminució de l'exposició del fum de segona mà i del tabaquisme actiu amb el que millorarien els trastorns respiratoris i sensorials en la població. No obstant això, els efectes són no concloents en aquest aspecte segons la bibliografia prèvia. Per aquest motiu, el segon objectiu va ser sintetitzar l'evidència disponible en els articles científics dels efectes de la legislació lliure de fum sobre trastorns respiratoris i sensorials en tota la població.

A Espanya, la implantació de la Llei parcial 28/2005 va comportar una disminució en la incidència d'ingressos hospitalaris de malaltia coronària i resultats no concloents per als ingressos per asma. Segons el coneixement actual, no s'han publicat estudis sobre l'impacte de la Llei 42/2010 sobre l'asma i la malaltia cardíaca en el context de l'APS, porta d'entrada al sistema sanitari. Així, el tercer objectiu ha estat avaluar la tendència en la incidència i prevalença d'asma i malaltia coronària aguda en APS en el context de la Llei integral.

**Mètodes**

S'han realitzat tres estudis. Per avaluar l'impacte de la Llei integral espanyola en hàbit tabàquic, asma i malaltia coronària en APS (objectius 1 i 3) es van dissenyar dos estudis observacionals longitudinals a Catalunya, Navarra i Illes Balears. La font d'informació en aquests dos estudis va ser la història clínica informatitzada d'APS. Es van escollir 22 zones bàsiques de salut de cada regió. Es van calcular les prevalences de persones fumadores i exfumadores; incidències de noves persones fumadores, noves exfumadores i recaiguda d'ex fumadores del 2008 al 2013

(a Balears, del 2010 al 2013); a més de les prevalences i incidències d'asma i de malaltia coronària del 2007 al 2013 (a Balears, del 2010 al 2013). Es van calcular les taxes d'incidència i prevalença estandarditzades per edat globals i per sexes, per regió. Es va avaluar l'evolució temporal en la incidència i prevalença (expressats com a canvi percentual anual [CPA] i canvi percentual anual mitjana [CPAP]).

Per revisar l'impacte de les lleis lliures de fum a la literatura (objectiu 2) es va realitzar una revisió sistemàtica des de 1995 fins a 2015 i meta-anàlisi. Es va buscar en diferents bases de dades i es van escollir estudis originals que tinguessin dades abans i després de llei lliure de fum i impacte en trastorns respiratoris o sensorials. Les variables dependents van ser simptomatologia sensorial o respiratòria, patologia respiratòria i mortalitat respiratòria. Es va realitzar una metaanàlisi d'efectes aleatoris amb anàlisi de subgrups, de sensibilitat i avaluació del biaix de publicació.

**Resultats**

Es va trobar una disminució significativa en la tendència de les taxes de prevalença de persones fumadores (CPAP Catalunya -2,18%; Navarra -1,44%; Illes Balears -1,75%), major en homes que en dones, i un augment significatiu en la tendència de la prevalença de persones exfumadores en les tres regions estudiades (CPAP Catalunya 7,19%; Navarra 16,67%; Illes Balears 14,96%), majorment en les dones. Pel que fa a la incidència, la tendència de les taxes de noves persones fumadores va disminuir significativament a Catalunya (CPAP -10,39%) i Navarra (CPAP -9,49%, similar en homes i dones), però també va disminuir la tendència dels noves persones exfumadores a Catalunya (CPAP -7,27%) i les Illes Balears (CPAP -11,24%), especialment entre els homes. Les tendències de les taxes d'incidència de recaiguda de persones exfumadores van mostrar dades contradictòries entre regions.

En l'àmbit de l'APS i en les tres regions estudiades, la tendència de prevalença d'asma va augmentar significativament del 2007 al 2013, en menor mesura durant el període 2009-13 a Catalunya (CPA 4,22% vs CPA 7,13% en el període 2007-2009) i Navarra (CPA 6,07% vs CPA 9,09% en el període 2007-2009), i majorment en els homes en totes les regions. En canvi, les tendències de les taxes d'incidència d'asma no van obtenir resultats significatius. Les taxes d'incidència de la malaltia coronària van mostrar una tendència descendent significativa al llarg del període estudiat a Catalunya (CPAP -8,00%) i Navarra (CPAP -3,66%). Per contra, la tendència de les taxes de prevalença va augmentar significativament a Catalunya de 2007 a 2010 en global (CPA 1,52%) i en els homes (CPA 1,90%) i també a les Illes Balears durant tot el període de estudi (CPAP global 10,01%).

En la revisió sistemàtica i meta-anàlisis realitzades s'ha observat efectes beneficiosos de les lleis lliures de fum als treballadors tant amb lleis integrals com parcials pel que fa a la simptomatologia respiratòria (disminució significativa de qualsevol símptoma respiratori després de la llei del 19% i 20% en el meta-anàlisi, respectivament) com en la simptomatologia sensorial (disminució de qualsevol símptoma sensorial del 34% i del 30%, respectivament). També es va trobar una disminució significativa dels ingressos hospitalaris per asma en població adulta i infantil del 15% després de la legislació en els dos casos. Els rangs de disminució d'asma després de les legislacions integrals segons la revisió narrativa era d'entre el 9,0% i el 18,2% per a la població infantil i d'entre el 4,9 al 36,0% per a la població adulta. Va haver-hi una majoria d'estudis que van reportar disminucions en els ingressos per malaltia pulmonar obstructiva crònica (MPOC) en la revisió narrativa (rang de disminució de l'1% al 36%) però sense significació en el meta-anàlisi. Respecte a altres malalties pulmonars, mortalitat respiratòria i paràmetres espiromètrics, els resultats van ser heterogenis i discrepants.

**Conclusions**

La introducció de la Llei 42/2010 no va modificar significativament les tendències d'incidència i prevalença de l'hàbit tabàquic, d'asma i de malaltia coronària de persones adultes ateses en APS a Catalunya, Navarra i les Illes Balears després de tres anys de la seva implantació, ni en global ni estratificat per sexes. L'aplicació de les legislacions lliures de fum disminueix la simptomatologia sensorial (sobretot en àmbits amb lleis integrals), la simptomatologia respiratòria en els treballadors i en població infantil i els ingressos per asma en totes les poblacions. No obstant això, els resultats sobre funció pulmonar, MPOC, infecció respiratòria i mortalitat respiratòria no són concloents.

**Paraules clau**

Anàlisi Joinpoint; Asma; Atenció Primària de Salut; Avaluació de política pública; Hàbit de fumar; Malalties respiratòries; Meta-anàlisi; Població adulta; Política lliure de fum; Registres electrònics de salut; Revisió sistemàtica; Síndrome coronària aguda; Tabac; Tendències; Totes les poblacions.

# Summary

**Background and objectives**

Since the beginning of the 21st century, the prohibition of smoking in closed public spaces has been legislated in order to protect the health of working people and non-smokers. In Spain in 2006, a Partial Smoke-Free Law was applied (Law 28/2005), which banned smoking in closed public and private work centers but allowed smoking in some catering establishments depending on the area of the premises. This law was reinforced later with the comprehensive Law 42/2010 that completely prohibited smoking in enclosed spaces. Some studies have analyzed the impact of these two Spanish laws on the prevalence of smoking, with contradictory results. In addition, there are no data on the impact of Law 42/2010 in the context of Primary Health Care (PHC) that plays a leading role in the prevention and treatment of smoking. Therefore, the first objective of the thesis has been to analyze the impact of comprehensive law on the prevalence and incidence of smoking in adults served in PHC.

Smoke-free laws should lead to a decrease in the exposure of secondhand smoke and active smoking, which would improve respiratory and sensory disturbances in the population. However, the effects are inconsistent in this aspect according to the previous bibliography. For this reason, the second objective was to synthesize the evidence available in the scientific articles on the effects of smoke-free legislation on respiratory and sensory disorders in all populations.

In Spain, the implementation of Partial Law 28/2005 entailed a decrease in the incidence of hospital admissions for coronary heart disease and inconclusive results for asthma admissions. According to current knowledge, no studies have been published on the impact of Law 42/2010 on asthma and heart disease in the context of PHC, the gateway to the health system. Thus, the third objective has been to evaluate the trend in the incidence and prevalence of asthma and acute coronary disease in PHC in the context of the Comprehensive Law.

**Methods**

There have been three studies. To evaluate the impact of the Spanish Comprehensive Law on smoking, asthma and coronary disease in PHC (objectives 1 and 3), two longitudinal observational studies were designed in Catalonia, Navarra and the Balearic Islands. The source of information in these three studies was the computerized clinical history of PHC. Twenty two basic health zones of each region were chosen. The prevalences of smokers and ex-smokers were calculated; incidents of new smokers, new ex-smokers and relapse of ex-smokers from

2008 to 2013 (in the Balearic Islands, from 2010 to 2013); in addition to the prevalences and incidences of asthma and coronary heart disease from 2007 to 2013 (in the Balearic Islands, from 2010 to 2013). The incidence and prevalence rates standardized by age, global and by sex, were calculated by region. The temporal evolution in incidence and prevalence was evaluated (expressed as annual percentage change [APC] and average annual percent change [AAPC]).

To review the impact of smoke-free laws in the literature (objective 2), a systematic review was carried out from 1995 to 2015 and meta-analysis. We searched different databases and chose original studies that had data before and after smoke-free law and impact on respiratory or sensory disorders. The dependent variables were sensory or respiratory symptoms, respiratory pathology and respiratory mortality. A meta-analysis of random effects was performed with subgroup analysis, sensitivity and evaluation of publication bias.

**Results**

There was a significant decrease in the trend of the prevalence rates of smokers (AAPC Catalonia -2.18%, Navarra -1.44%, Balearic Islands -1.75%), higher in men than in women, and a significant increase in the prevalence trend of ex-smokers in the three regions studied (AAPC Catalonia 7.19%, Navarra 16.67%, Balearic Islands 14.96%), mainly in women. Regarding the incidence, the trend of the rates of new smokers decreased significantly in Catalonia (AAPC -10.39%) and Navarra (AAPC -9.49%, similar in men and women), but the tendency of the new ex-smokers in Catalonia (AAPC -7.27%) and the Balearic Islands (AAPC-11.24%), especially among men. The trends of incidence rates of ex-smokers relapse showed contradictory data between regions.

In the area of PHC and in the three regions studied, the prevalence of asthma increased significantly from 2007 to 2013, to a lesser extent during the 2009-13 period in Catalonia (APC 4.22% vs. APC 7.13% in the 2007-2009 period) and Navarra (APC 6.07% vs. APC 9.09% in the 2007-2009 period), and mostly in men in all regions. In contrast, trends in asthma incidence rates did not yield significant results. Coronary disease incidence rates showed a significant downward trend over the period studied in Catalonia (AAPC -8.00%) and Navarra (AAPC -3.66%). On the contrary, the trend of prevalence rates increased significantly in Catalonia from 2007 to 2010 overall (APC 1.52%) and in men (APC 1.90%) and also in the Balearic Islands during the entire period of study (overall AAPC 10.01%).

In the systematic review and meta-analysis carried out, beneficial effects of smoke-free laws have been observed in workers with both comprehensive and partial laws regarding respiratory symptomatology (significant reduction of any respiratory symptoms after the 19% law and 20%

in the meta-analysis, respectively) as in the sensory symptomatology (decrease of any sensory symptom of 34% and 30%, respectively). We also found a significant decrease in hospital admissions for asthma in the adult and children population of 15% after the legislation in both cases. The ranges of asthma reduction after comprehensive legislation according to the narrative review was between 9.0% and 18.2% for the children population and between 4.9 to 36.0% for the adult population. There were a majority of studies that reported decreases in the income from chronic obstructive pulmonary disease (COPD) in the narrative review (range of decrease from 1% to 36%) but without significance in the meta-analysis. Regarding other pulmonary diseases, respiratory mortality and spirometric parameters, the results were heterogeneous and discrepant.

**Conclusions**

The introduction of Law 42/2010 did not significantly modify the trends of incidence and prevalence of smoking, asthma and coronary heart disease in adults attended in PHC in Catalonia, Navarra and the Balearic Islands after three years of implementation, nor in global nor stratified by sexes. The application of smoke-free legislation decreases sensory symptoms (especially in areas with comprehensive laws), respiratory symptoms in workers and children and asthma income in all populations. However, the results on lung function, COPD, respiratory infection and respiratory mortality are inconsistent.

**Keywords**

Acute coronary syndrome; Adult population; All populations; Asthma; Electronic health records; Joinpoint analysis; Meta-analysis; Primary Health Care; Public policy evaluation; Respiratory Tract Diseases; Smoke-Free Policy; Smoking; Systematic review; Tobacco; Trends.

# 1. INTRODUCCIÓN

## 1.1. Los efectos del tabaquismo sobre la salud

El tabaco es la única droga legal que provoca la muerte de gran parte de sus consumidores (personas fumadoras activas o que fuman de forma habitual y tienen adicción), causando una de cada 10 muertes en todo el mundo (1). No sólo es causa de muerte y de enfermedades en las personas fumadoras activas sino también en las expuestas al humo proveniente de la combustión del tabaco (humo de segunda mano), es decir, personas fumadoras pasivas. Según el informe del *Surgeon General* del 2006 (figura operativa en servicios de salud pública del gobierno federal de Estados Unidos) sobre las consecuencias en la salud de la exposición involuntaria al humo de tabaco, más de 126 millones de personas no fumadoras seguían expuestas involuntariamente a éste (2). La Organización Mundial de la Salud (OMS) estimaba en 2015 que el consumo de tabaco (activo y pasivo) era responsable de la muerte de alrededor de seis millones de personas anualmente en todo el mundo, y que muchas de estas muertes ocurrían prematuramente. Alrededor de 600,000 personas fallecerían por los efectos del humo de segunda mano (3).

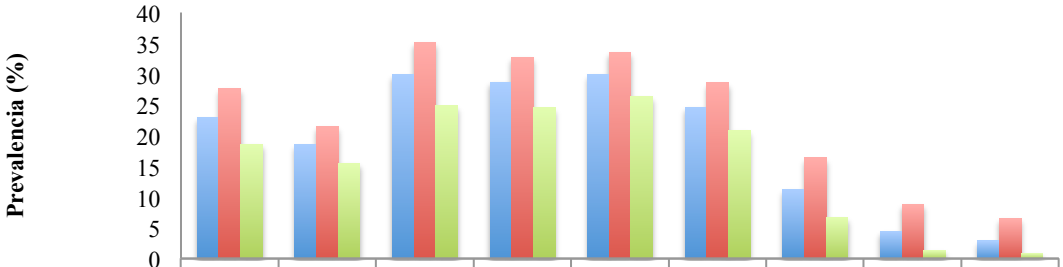
### 1.1.1. Efectos del tabaquismo activo

En 1950 Richard Doll y Austin Bradford Hill hallaron que el tabaco era perjudicial para la salud, al demostrar que fumar cigarrillos causaba cáncer de pulmón y años más tarde observaron la relación con el cáncer de vejiga y de otros tipos de cáncer, así como enfermedades cardiovasculares (4). Como se ha mencionado anteriormente, el consumo de tabaco continuaba siendo la causa prevenible más importante de muerte prematura y enfermedad del mundo en 2011 (5). Entre estas enfermedades destacan el citado cáncer de pulmón, las enfermedades respiratorias obstructivas, la cardiopatía isquémica y las enfermedades cerebrovasculares (ECV). Además de ocasionar múltiples enfermedades, se continúan identificando otras enfermedades causadas por el tabaco como la diabetes mellitus y la artritis reumatoide, y efectos adversos sobre la salud como el deterioro del sistema inmunológico. Se ha postulado que fumar causa exacerbación de asma y posiblemente asma de nueva aparición en población adolescente. Asimismo, causa todos los fenotipos de enfermedad pulmonar obstructiva crónica (EPOC), incluido el enfisema y el daño a las vías respiratorias del pulmón. La mortalidad por EPOC ha aumentado dramáticamente en hombres y mujeres desde el informe del *Surgeon General* de 1964, siendo en 2014 mayor en mujeres que en hombres en Estados Unidos (6). A nivel mundial, según un informe de la OMS del 2012, el 42% de las muertes por EPOC y el 71% de todas las muertes por cáncer de pulmón eran atribuibles al consumo de tabaco. En relación a las

enfermedades cardiovasculares, casi el 10% estaba causado por el tabaco. Los adultos más jóvenes eran los más perjudicados por las muertes de causa cardiovascular relacionadas con el tabaco. El 38% de las muertes de adultos de 30 a 44 años que fallecieron por cardiopatía isquémica se debieron al tabaco (50% en hombres y 8% en mujeres) (7). En la Tabla 1.1 se resumen los diferentes efectos del tabaquismo activo sobre la salud (6).

En España, hay un 28% de personas fumadoras en la población mayor de 14 años según el Eurobarómetro europeo de 2017 (8). En 2015, el 38,5% de la población entre 15 y 64 años admitía haber fumado en el último mes y se estimó que 244.000 personas iniciaron su consumo de tabaco en los últimos 12 meses (incidencia de tabaquismo) siendo igual en hombres y mujeres (122.000) (9). En la figura 1.1 se describe la distribución por edades y sexo del consumo diario de tabaco en la población española en 2014 según la Encuesta Europea de Salud.

**Figura 1.1. Prevalencia de personas fumadoras diarias según sexo y edad en la población española a partir de 15 años en 2014.**




| | Total | 15- 24 años | 25 -34 años | 35 -44 años | 45 - 54 años | 55 - 64 años | 65 - 74 años | 75 - 84 años | ≥ 85 años |
|---|---|---|---|---|---|---|---|---|---|
| Ambos sexos | 22,98 | 18,51 | 29,96 | 28,7 | 30 | 24,61 | 11,25 | 4,48 | 2,86 |
| Hombres | 27,57 | 21,43 | 35,09 | 32,74 | 33,57 | 28,56 | 16,38 | 8,81 | 6,48 |
| Mujeres | 18,6 | 15,46 | 24,84 | 24,52 | 26,42 | 20,82 | 6,74 | 1,38 | 0,9 |

Fuente: Elaboración propia a partir de la Encuesta Europea de Salud 2014.

El consumo de tabaco se ha descrito como la primera causa de enfermedad, invalidez y muerte evitable en España. Concretamente, el 13% de las muertes ocurridas en España en el periodo 2010-2014 fueron atribuibles al consumo de tabaco (23% en hombres y 3% en mujeres). Del conjunto de muertes atribuibles al tabaco, 33,1%, fueron debidas a muertes por cáncer de pulmón, 20,3% a muertes por EPOC y 12,5% a muertes por cardiopatía isquémica (10). En España, los costes sanitarios directos producidos por las cinco enfermedades más importantes relacionadas con el tabaquismo supusieron 7.695,29 millones de euros anuales en 2009. Además el coste económico indirecto del tabaquismo a nivel laboral ascendió a 8.780 millones de euros, que incluye el absentismo laboral debido a enfermedades relacionadas con el tabaco, la pérdida de productividad, y el mantenimiento y limpieza de las instalaciones (11). Según un

estudio que comprobaba si existían diferencias en el uso de recursos sanitarios, en el gasto sanitario y en el número de bajas laborales entre personas fumadoras y no fumadoras atendidas en una zona de salud urbana española, el coste sanitario anual fue de 848,64 euros en las personas fumadoras y de 474,71 euros en no fumadoras, lo que suponía un sobrecoste del 44%(12).

**Tabla 1.1. Efectos del tabaquismo activo sobre la salud**

| Efecto | Consecuencias |
|---|---|
| Adicción | Capacidad de causar dependencia 80% (heroína, 35%) |
| Cáncer | Pulmón, laringe, faringe, cavidad oral, estómago, hígado, colon y recto, esófago, páncreas, riñón, vejiga, cuello uterino, leucemia mieloide aguda |
| Enfermedad cardiovascular | Enfermedad coronaria<br>Accidente cerebrovascular<br>Enfermedad vascular periférica<br>Aneurisma de aorta abdominal |
| Enfermedad pulmonar | Sobreinfección por virus y bacterias<br>Menor rendimiento deportivo<br>Enfermedad pulmonar obstructiva crónica<br>Exacerbación de asma en adultos<br>Síntomas respiratorios (tos, flema) |
| Piel | Cáncer de piel<br>Arrugas prematuras<br>Sequedad de cabello<br>Manchas amarillentas en dedos<br>Olor corporal a tabaco<br>Dificultad en cicatrización<br>Envejecimiento prematuro de la piel sobretodo en mujeres<br>Carcinoma de células escamosas y melanomas con peor pronóstico. |
| Complicaciones odontológicas | Manchas en los dientes<br>Halitosis<br>Enfermedad periodontal<br>Palanitis nicotínica<br>Leucoplasias |
| Enfermedad digestiva | Úlcera péptica (sobretodo gástrica) |
| Enfermedad ocular | Cataratas<br>Degeneración macular asociada a la edad<br>Enfermedades vasculares oculares<br>Enfermedad ocular tiroidea<br>Sequedad ocular |
| Diabetes | Intolerancia a la glucosa<br>Diabetes mellitus tipo 2 |
| Sistema osteoarticular | Fractura de cadera<br>Osteoporosis en mujeres<br>Artritis reumatoide |
| Tuberculosis | Mayor riesgo de mortalidad<br>Mayor riesgo de recurrencia |
| Sistema reproductivo del hombre | Disfunción eréctil<br>Reducción volumen de la eyaculación<br>Disminución de la fertilidad |
| Sistema reproductivo de la mujer | Alteraciones del ciclo menstrual<br>Infertilidad primaria y secundaria<br>Menopausia 2-3 años antes |
| Embarazo y salud perinatal | Embarazo ectópico<br>Ruptura prematura de membranas |

| | |
|---|---|
| | Desprendimiento placentario<br>Parto prematuro<br>Bajo peso al nacer del bebé<br>Malformaciones oro-faciales congénitas del bebé |

Fuente: Elaboración propia a partir de The Health Consequences of Smoking- 50 years. A Report of the Surgeon General, 2014, Association between passive and active smoking and incident type 2 diabetes in women. Diabetes Care 34:892–897, 2011 e Investigación Nacional Domiciliaria sobre uso de drogas en Estados Unidos. National Health Institute, 2001.

### 1.1.2. Efectos del tabaquismo pasivo

Hasta 1972 no se había hablado de los efectos sobre la salud del tabaquismo pasivo. Este se refiere a la inhalación involuntaria de humo de tabaco (del cigarrillo, cigarro, pipa y otros) consumido por una persona no fumadora. La evidencia señala que no hay un nivel de exposición libre de riesgo y que sistemas de ventilación o limpieza del aire de los espacios cerrados no sirven para proteger a las personas no fumadoras de los efectos del tabaco (13).

El humo de tabaco respirado por personas no fumadoras (o humo de segunda mano) es una mezcla de componentes: el humo de la combustión del cigarrillo, el humo emitido por el fumador, los contaminantes del cigarrillo en el momento de fumar y los contaminantes que se difunden por el papel entre caladas. Se denomina corriente principal al humo inhalado por el fumador y corriente secundaria a la formada por el humo que emite el otro extremo del cigarrillo, con más monóxido de carbono (CO), acroleína, cadmio, amoniaco y nitrosaminas que hacen que tenga que considerarse más nociva (Tabla 1.2) (14).

**Tabla 1.2. Composición y características de la corriente principal y secundaria del humo del tabaco**

| Componente | Corriente principal | Corriente secundaria |
|---|---|---|
| Tamaño partículas | 0,1-1,0 µg | 0,01-1,0 µg |
| pH | 6,0-6,7 | 6,7-7,5 |
| Temperatura | 800-900ºC | 600ºC |
| Oxígeno | 16% | 2% |
| Monóxido de Carbono | 10-23 mg | 25-100 mg |
| Cianhídrico | 400-500 µg | 40-125 µg |
| Amoniaco | 50-130 µg | 200-520 µg |
| Nitrosaminas | 10-40 ng | 200-4.000 ng |
| Acroleína | 60-100 µg | 480-1.500 µg |
| Óxidos de Nitrógeno | 100-600 µg | 400-6.000 µg |

Fuente: E.P.A. 600/6-90/006F, 1992 (15)
Abreviaturas: mg miligramos; µg microgramos; ng nanogramos

Según el informe del 2010 de la *Royal College of Physici*ans de Londres, la exposición pasiva al humo de tabaco en población infantil, tanto antes como después del nacimiento, tiene un impacto sobre el peso al nacer y posiblemente sobre la mortalidad fetal y perinatal, riesgo de

anomalías congénitas, riesgo de muerte súbita del lactante, infección respiratoria baja, enfermedad del oído medio, sibilancias, asma y meningitis (16). En Estados Unidos se calculó que entre el 20,2% y el 29,3% de las muertes súbitas del lactante se debieron al tabaquismo prenatal en 2009 (17), y en España entre el 18 y el 23% en 2005 se ocasionaron por la exposición al tabaquismo pasivo (18). Las infecciones del tracto respiratorio inferior en la población infantil eran un 82% más frecuentes cuando ambos padres eran fumadores y un 62% cuando el tabaquismo era únicamente materno según un meta-análisis del 2016 (19). Los síntomas respiratorios como tos, flema, sibilancias y disnea en población en edad escolar tenían evidencia suficiente para inferir su relación causal con el tabaquismo de los padres, según el informe del *Surgeon General* del 2006. Sin embargo, algunos estudios de este informe sugerían que el inicio del asma en la infancia estaba relacionada con el tabaquismo pasivo pero eran necesarios más estudios para confirmarlo (2).

En población adulta, la inhalación involuntaria de humo de tabaco asociada a vivir con una persona fumadora provocaba un aumento del 20 al 30% en el riesgo de cáncer de pulmón en 2006 (2), 300% en el caso de tumor de células pequeñas (20). Por otra parte, el tabaquismo pasivo se ha asociado con un aumento en el riesgo relativo (RR) de enfermedad coronaria que estaría entre el 25 al 30% (2). En el año 2004, se estimó que esta exposición causó 379 000 muertes por cardiopatía isquémica, 165 000 de infecciones respiratorias bajas, 36 900 de asma y 21 400 de cáncer de pulmón en todo el mundo (13) (Tabla 1.3). Así mismo, el tabaquismo pasivo produce consecuencias difíciles de estimar en términos económicos, pero según un informe publicado en 2006, los costes del tabaquismo podían incrementar un 15% en función de las medidas reguladoras establecidas en cada país (2).

**Tabla 1.3. Efectos del tabaquismo pasivo sobre la salud**

| **Efectos** | **Población infantil** | **Población adulta** |
|---|---|---|
| Mortalidad | Muerte súbita del lactante | Mortalidad coronaria |
| Cáncer | | Pulmón (incremento de riesgo 20 -30%) |
| Enfermedad cardiovascular | | Enfermedad coronaria (incremento de riesgo 25 -30%)<br>Enfermedad cerebrovascular (incremento de riesgo 20-30%) |
| Enfermedad pulmonar | Infección de vías respiratorias bajas<br>Asma infantil<br>Reducción de función pulmonar<br>Síntomas respiratorios | Riesgo de Tuberculosis |
| Enfermedades otorrinolaringológicas | Otitis media aguda y crónica | Síntomas sensoriales (irritación nasal) |
| Salud perinatal | Bajo peso al nacer del bebé | |

Fuente: Elaboración propia a partir de The Health Consequences of Smoking- 50 years. A Report of the Surgeon General, 2014 y de Systematic Reviews and Meta-analyses of the Effects of Smoking on Respiratory Health. Chest. 150:164–79. 2016

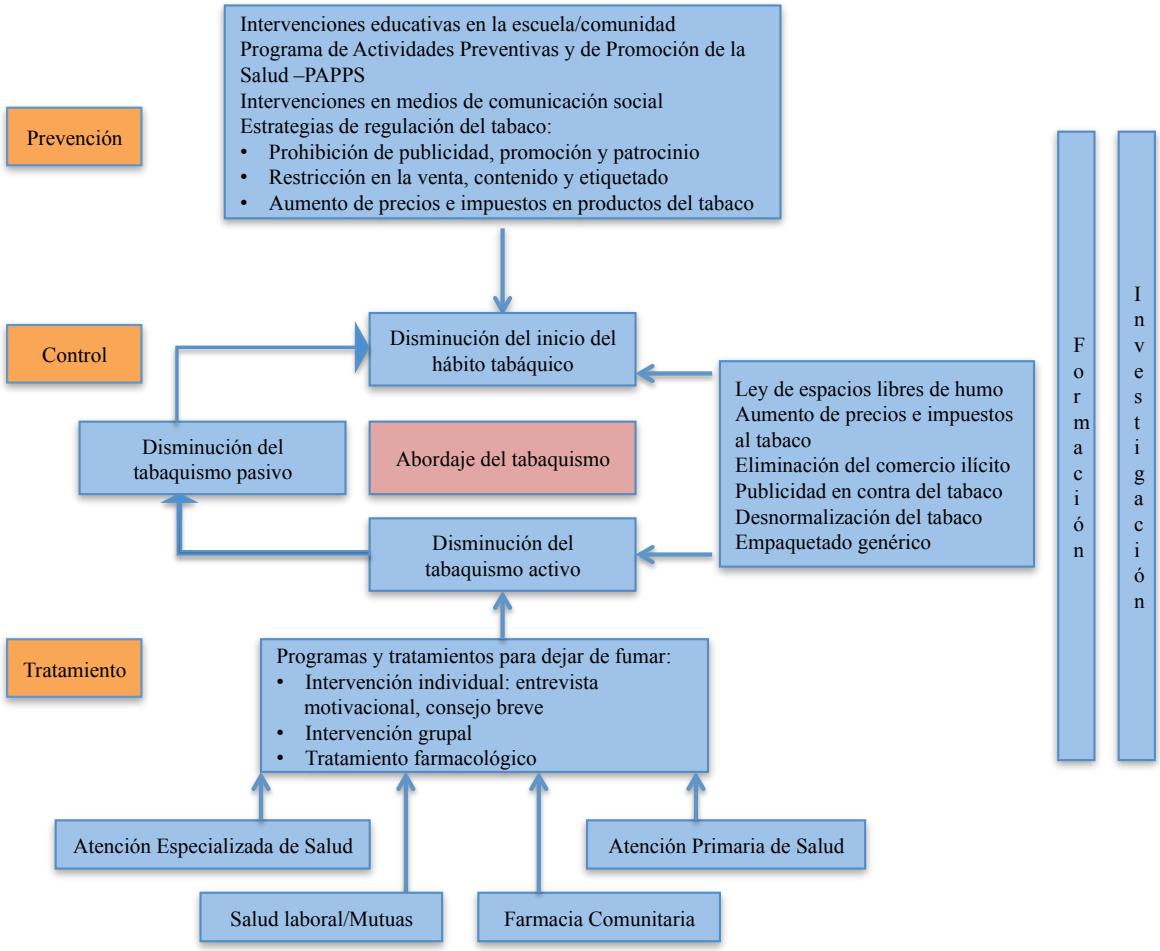
En España, un total de 586 muertes en hombres y 442 muertes en mujeres podrían atribuirse a la exposición pasiva al tabaco en el hogar y en el trabajo en 2011. Dentro de estas muertes, el número total por cáncer de pulmón sería de 124 (12,1%), mientras que por cardiopatía isquémica supondrían 904 (87,9%). La inclusión de personas ex fumadoras (aquellas que habiendo sido fumadoras se han mantenido en abstinencia al menos un año) o de personas con exposición pasiva al tabaco en el tiempo libre aumentaría considerablemente el número total de muertes atribuibles (en un 20% y 130%, respectivamente)(21).

### 1.2. Estrategias claves para controlar el tabaquismo

El tabaco es un problema de salud pública que ha de ser abordado de forma multidimensional. Este abordaje se puede realizar desde la prevención del consumo tabáquico o desde el control una vez establecido el hábito o desde el tratamiento para conseguir dejar de fumar. Según Simon Chapman, académico y activista australiano del control del tabaquismo, existen múltiples determinantes a nivel micro-sociológico que intervienen en la decisión de dejar de fumar: la publicidad, una ley que prohíba fumar en espacios cerrados, el impacto en la salud de la familia, el trabajo, noticias en los medios de comunicación, etc. (22). Análogamente a la visión micro-sociológica mencionada por Simon Chapman, ante un problema de salud como es el tabaquismo es importante reflexionar sobre cómo abordarlo desde diferentes puntos de vista macro-contextualmente: publicitario, legislativo, político, sanitario, laboral, social, educacional o informativo, por poner algunos ejemplos.

No hay una sola medida eficaz sino que lo mejor es la combinación de varias de ellas (23). Algunas de estas medidas inciden sobre la persona fumadora activa, como por ejemplo los tratamientos farmacológicos para dejar de fumar (subvencionados por el sistema sanitario o no) o las ayudas específicas en unidades especializadas en tabaquismo, en Atención Primaria de Salud (APS), en la farmacia comunitaria, etc. Otras incidirían en la protección al fumador pasivo, como por ejemplo las legislaciones libres de humo en espacios cerrados a través de la disminución del tabaquismo activo. Las medidas coste-efectivas prioritarias en programas integrales de control de tabaquismo son los impuestos sobre el tabaco, las leyes libres de humo, la información pública, las prohibiciones en la publicidad, las advertencias sanitarias directas y el acceso al tratamiento para dejar de fumar (24). La medida más efectiva es el incremento de impuestos sobre los productos del tabaco (25). Desde el punto de vista de la prevención, las intervenciones educativas y las estrategias reguladoras como el aumento de precio del tabaco juegan un papel importante. La formación y la investigación formarían parte tanto de la prevención como del control y del tratamiento del tabaquismo. En la figura 1.2 se detallan algunas de estas medidas de nuestro contexto (España).

**Figura 1.2. Estrategias de abordaje de tabaquismo: prevención, control y tratamiento.**




Fuente: elaboración propia a partir de Estrategias de Intervención del Plan Regional de Prevención y Control del tabaquismo en la Comunidad de Madrid. Consejería de Sanidad y Consumo, 2007 y Smoking- Capítulo 4 de Key topics in Public Health, L Ewles, 2005, p 59-76.

## 1.3. Concepto de ley de control del tabaquismo. Convenio Marco de Control del Tabaco y MPOWER

Como se ha detallado en las posibles medidas para el control del tabaquismo, la implementación de una ley sería una de ellas. Relacionado con este punto, en 2003 se creó el Convenio Marco para el Control del Tabaco (CMCT) de la OMS, con entrada en vigor en 2005, que es un tratado multilateral que promueve una respuesta política internacional coordinada contra la epidemia global del consumo de tabaco y ofrece medidas o políticas de control de tabaquismo para la reducción de la demanda y la oferta de tabaco. Este primer tratado exigía que los países adoptaran políticas de aire limpio, así como iniciativas tales como aumentos de precios e impuestos, prohibiciones de publicidad y etiquetas de advertencia para los paquetes de tabaco (26). También proponía medidas dirigidas a reducir la oferta de tabaco para eliminar todas las formas de comercio ilícito de productos y la venta a menores. Dentro de este tratado, el artículo

8 del CMCT hacía referencia específicamente a la protección eficaz de las personas a la exposición al humo de segunda mano. Las políticas de espacios sin humo se centraron inicialmente en proporcionar protección universal contra el humo del tabaco en los lugares públicos cerrados, en el interior de los lugares de trabajo y en el transporte público (27). En la tabla 1.4 se resumen algunos artículos claves del CMCT que ayudan a controlar el tabaquismo activo y pasivo (28).

**Tabla 1.4. Políticas clave del Convenio Marco de la Organización Mundial de la Salud para el control del tabaco**

| Artículo | Tabaquismo pasivo | Artículo | Tabaquismo activo |
|---|---|---|---|
| **8** | Proteger a los ciudadanos de la exposición al tabaco en lugares de trabajo, transporte público y lugares públicos cerrados | **6** | Incrementar los impuestos del tabaco |
| **9** | Regular las directrices para probar y medir los contenidos y las emisiones de productos de tabaco, y para la regulación de estos contenidos y emisiones | | |
| | | **11** | Regular el empaquetado y etiquetado de los productos del tabaco para evitar el uso de términos confusos como "ligeros" y "suaves" para asegurar que se comunican advertencias adecuadas sobre el producto a los consumidores y puedan incluir fotos o pictogramas |
| **12** | Promover la conciencia general de aspectos relacionados con el tabaco para asegurar un amplio acceso a programas educativos eficaces e integrales y despertar el interés público en los programas relacionados con el riesgo para la salud que representan el tabaco y la exposición al humo. | | |
| **13** | Decretar prohibiciones integrales en la publicidad, promoción y patrocinio relacionados con el tabaco. | | |
| | | **14** | Promover e instituir programas eficaces que tengan como propósito cesar el consumo del tabaco |
| | | **16** | Aplicar legislaciones y programas para prohibir la venta de productos del tabaco a menores de edad |

Fuente: Elaboración propia adaptada a partir de Evaluación de las políticas contra el tabaquismo en países latinoamericanos en la era del Convenio Marco para el Control del Tabaco. Trasher JF *et al*. Salud Publica Mex, 2006 (29)

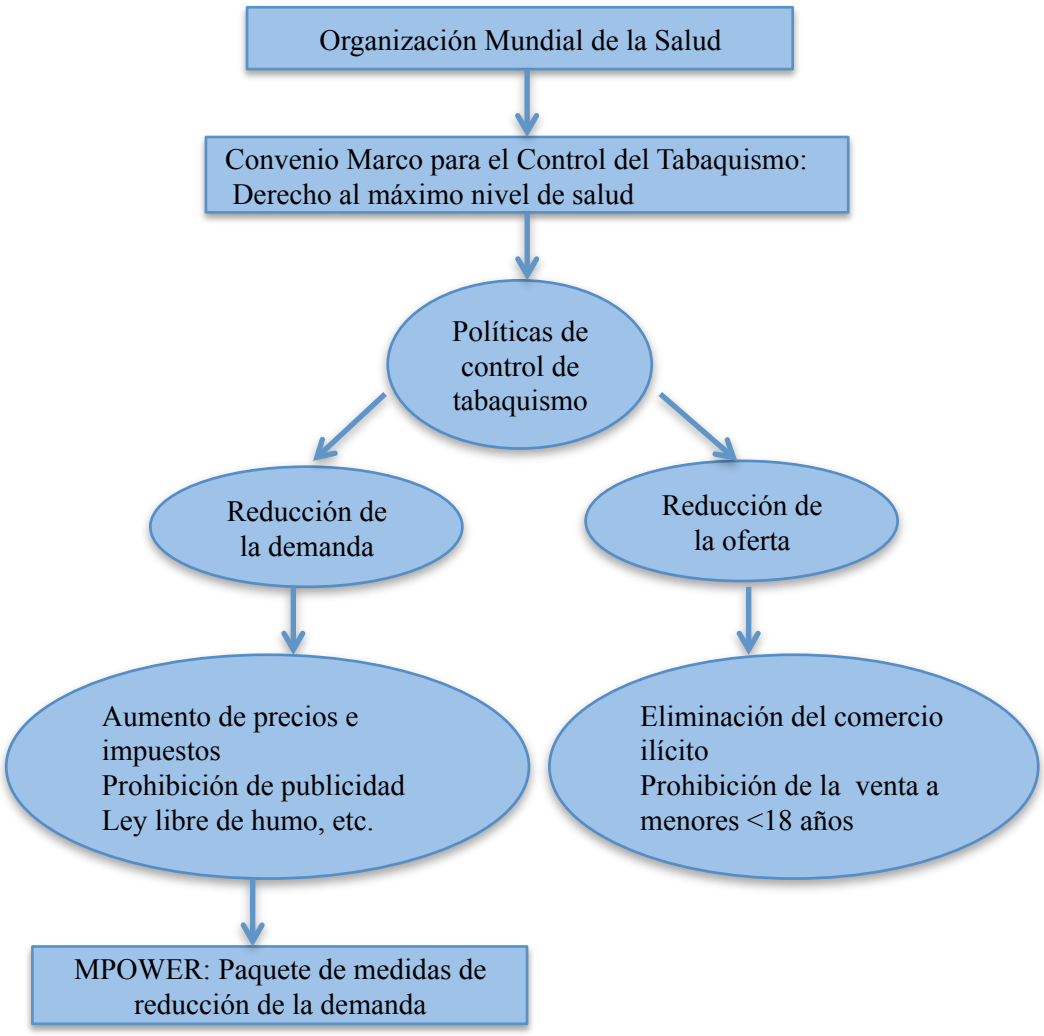
En 2008, la OMS introdujo el paquete MPOWER de las seis medidas más costo-efectivas de control del tabaquismo que habían demostrado reducir el consumo de tabaco y salvar vidas, y ayudar así a los países a cumplir sus obligaciones del CMCT de la OMS (5) (Figura 1.3). Las medidas MPOWER ofrecen una asistencia práctica para reducir la demanda de tabaco mediante la implementación de políticas efectivas a nivel nacional. Estas medidas se correspondían a una o más de las medidas de reducción de la demanda contenidas en el CMCT de la OMS, a saber:

- M: *Monitor,* vigilar atentamente la epidemia y las medidas de prevención,
- P: *Protect,* proteger a la población del humo de segunda mano,
- O: *Offer,* ofrecer ayuda a quienes quieran abandonar el tabaco,

- W: W*arn,* advertir acerca de los peligros del tabaco,
- E: *Enforce,* prohibir la publicidad, la promoción y el patrocinio y
- R: *Raise,* aumentar los impuestos y precios del tabaco.

En la tabla 1.5 se especifican las medidas MPOWER con ejemplos de ellas. El número de implementaciones de alto nivel (es decir, con puntuación MPOWER elevada) de medidas clave de reducción de la demanda del CMCT de la OMS (artículos 6, 8, 11, 13 y 14) se ha asociado fuertemente a reducciones en la prevalencia del tabaquismo en estudios realizados en Europa o a nivel mundial (30,31).

**Figura 1.3. Convenio Marco de Control de Tabaco y MPOWER**




Fuente: Elaboración propia.

**Tabla 1.5. Medidas MPOWER**

| | Significado | Ejemplos |
|---|---|---|
| **M** | Monitorizar el consumo de tabaco y las políticas de prevención | Encuestas recientes, representativas y periódicas para adultos y jóvenes |
| **P** | Proteger a la población del humo ambiental del tabaco | Leyes o políticas de espacios libres de humo |
| **O** | Ofrecer ayuda para dejar de fumar | Programas de cese y deshabituación tabáquica |
| **W** | Advertir de los peligros del tabaco | Advertencias en los paquetes de tabaco. Campañas en los medios de comunicación |
| **E** | Hacer cumplir las prohibiciones sobre publicidad, promoción y patrocinio del tabaco | Prohibición total de toda publicidad, promoción y patrocinio del tabaco, incluso en el punto de venta (Senegal). |
| **R** | Aumentar los impuestos al tabaco | Recaudación de impuesto sobre el tabaco que represente al menos el 75% del precio de venta (Argentina) |

Fuente: Elaboración propia a partir del WHO report on the global tobacco epidemic, 2017: monitoring tobacco use and prevention policies (1)

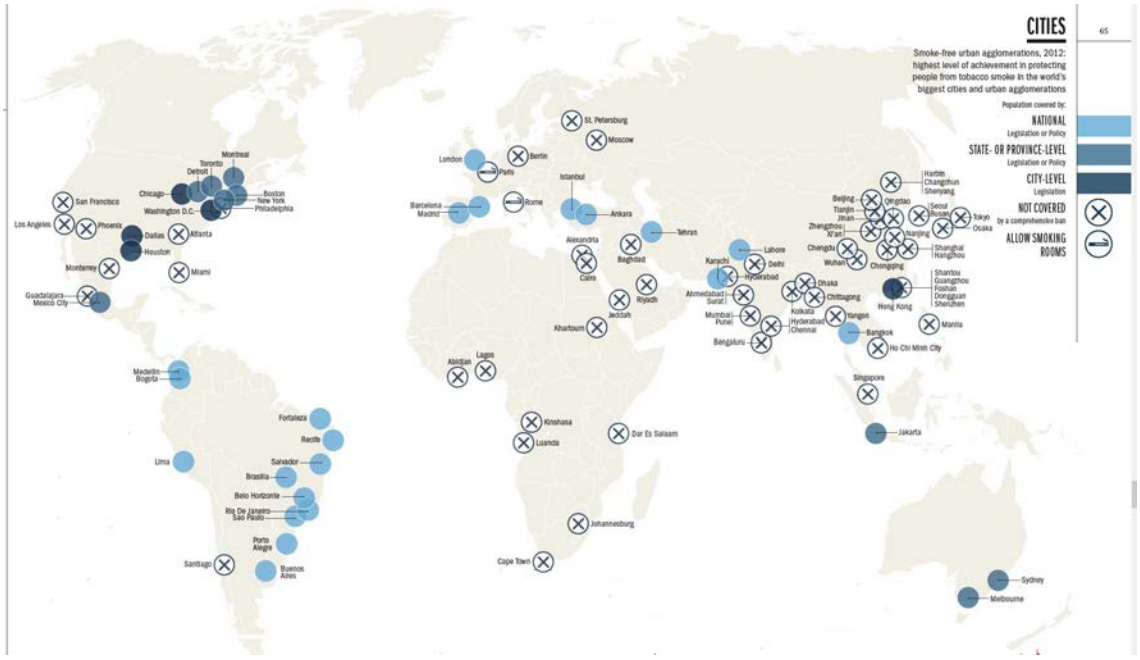
### 1.3.1. Conceptos de leyes libres de humo parciales e integrales

El artículo 8 del CMCT y la correspondiente P de "Protect" de las medidas MPOWER exigen la adopción de medidas efectivas para proteger a las personas de la exposición al humo de tabaco en lugares cerrados de trabajo, lugares interiores públicos, transporte público y en "otros lugares públicos" si "es apropiado" (32). Según la restricción aplicada, las leyes se clasifican en parciales o integrales.

En esta tesis se ha definido como ley libre de humo integral (en inglés "comprehensive") aquella ley que cubre el 100% de todos lugares públicos y lugares de trabajo cerrados (no se permiten salas designadas de personas fumadoras), incluidos bares, restaurantes y transporte público mediante la prohibición de fumar (33). La ley libre de humo parcial sería la que incumpliera alguno de estos supuestos. En la mayoría de casos, suele ser que se permite fumar en determinadas áreas de establecimientos de la hostelería.

Las leyes libres de humo, tanto las parciales como las integrales, pueden englobar diferentes territorios para lograr la mayor cobertura de protección de la población. Así, se pueden implementar a nivel nacional (como es el caso de España), provincial o estatal (como es el caso de algunos estados de los Estados Unidos) y a nivel de ciudad (como por ejemplo, Chicago). En la Figura 1.4 se muestra un mapa mundial con diferentes niveles de aplicación de las leyes en el año 2012 (34).

**Figura 1.4. Mapa de coberturas geográficas de leyes libres de humo a nivel mundial en al año 2012.**




Fuente: The Tobacco Atlas. Fifth edition. Eriksen M *et al.* American Cancer Society, 2015

### 1.3.4. Historia de la creación de leyes libres de humo y situación actual a nivel mundial

Desde 1964 existen diferentes informes del *Surgeon General* de los Estados Unidos que reportan los efectos adversos del tabaquismo activo y pasivo (35). A principios de la década de 1970, el médico, funcionario en salud pública y undécimo Cirujano General de los Estados Unidos, Jesse L. Steinfeld, declaró que las personas no fumadoras tenían derecho a respirar aire interior limpio (33), libre de humo de tabaco, proponiendo prohibir fumar en todos los lugares públicos cerrados, como restaurantes, teatros, aviones, trenes y autobuses. En la década de 1970, en Estados Unidos se empezó a restringir fumar en lugares públicos, edificios gubernamentales y aviones. La mayoría de estas restricciones limitaban pero no prohibían fumar. California fue el primer estado en exigir que todos los lugares de trabajo, bares y restaurantes estuvieran libres de humo en 1998. Anteriormente a esa fecha existían pocas leyes estrictas libres de humo en el mundo, algunas se limitaban a normas voluntarias en el lugar de trabajo para exigir espacios sin humo (33). En la Tabla 1.6. se resumen algunos de los acontecimientos importantes en la historia de las leyes libres de humo.

**Tabla 1.6. Resumen de acontecimientos para disminuir el humo de tabaco**

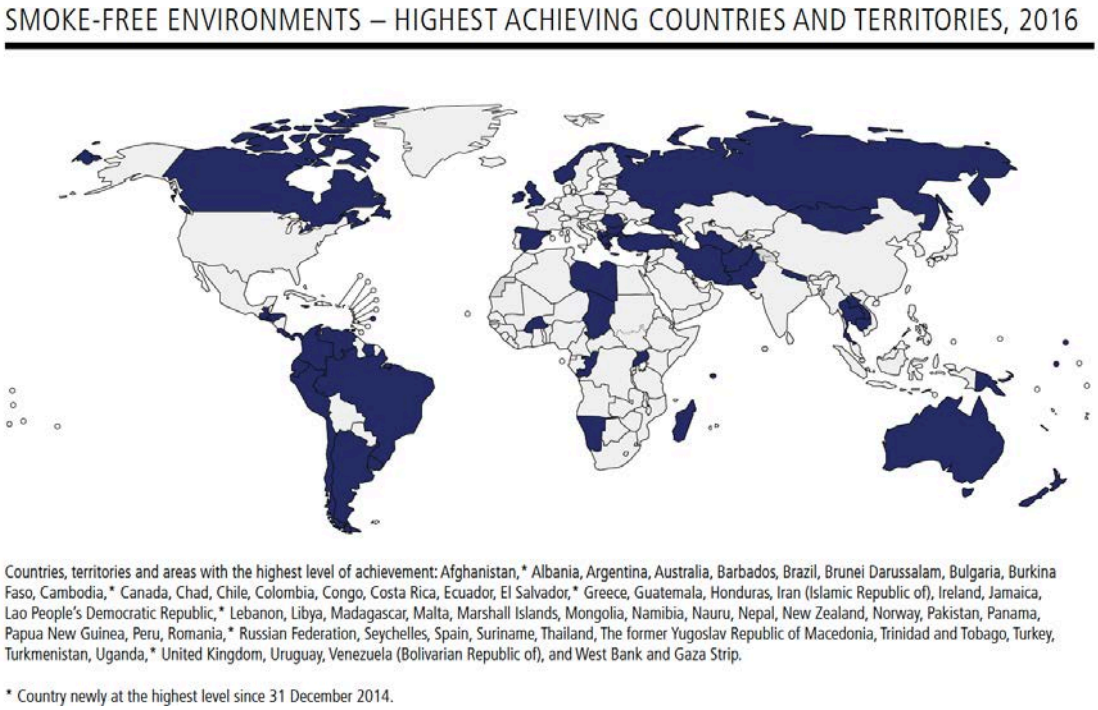
| Año | Acontecimiento |
|---|---|
| 1971 | El *Surgeon General* de Estados Unidos propone una prohibición federal de fumar en lugares públicos en Estados Unidos (EEUU). |
| 1972 | Primer informe del *Surgeon General* se identifica el humo de segunda mano como riesgo para la salud. |
| 1973 | Arizona: primer estado de EEUU en restringir el fumar en varios lugares públicos. La Junta de Aeronáutica Civil exige espacios sin humo en todos los vuelos de aerolíneas comerciales. |
| 1986 | El informe del *Surgeon General* se centra por completo en las consecuencias para la salud del tabaquismo pasivo, proclamando que el humo de segunda mano es una causa de cáncer de pulmón en personas sanas que no fuman. |
| 1988 | Prohibición de fumar en todos los vuelos domésticos de 2 horas o menos en EEUU. Nueva York prohíbe o limita severamente el fumar en varios lugares públicos afectando a 7 millones de personas. California implementa una prohibición estatal de fumar a bordo de todos los aviones comerciales intraestatales, trenes y autobuses. |
| 1990 | Prohibición de fumar en todos los vuelos domésticos de 6 horas o menos en EEUU. La Agencia de Protección Ambiental de Estados Unidos emite un borrador de evaluación de riesgos del humo de segunda mano. |
| 1992 | Los hospitales de EEUU deben desarrollar una política que prohíba fumar a pacientes, visitantes, empleados, voluntarios y personal sanitario. |
| 1995 | La ciudad de Nueva York aprueba una ordenanza exhaustiva que prohíbe fumar en la mayoría de los lugares de trabajo. California aprueba una legislación integral que prohíbe fumar en la mayoría de los lugares de trabajo cerrados. |
| 1996 | Aproximadamente el 80% de los vuelos aéreos directos entre EEUU y destinos fuera de este país son libres de humo. |
| 1999 | Se propone por primera vez el Convenio Marco para el Control del Tabaquismo (CMCT) de la Organización Mundial de la Salud (OMS). |
| 2000 | Sudáfrica aprueba 2 leyes para hacer que los lugares públicos sean libres de humo (se permitieron exenciones para bares y restaurantes) y para regular componentes del tabaco. |
| 2003 | La Asamblea Mundial de la Salud adopta el CMCT de la OMS. |
| 2004 | Irlanda es el 1er país en prohibir fumar en todos los lugares de trabajo cerrados, incluidos restaurantes y bares. Noruega 2º país y Nueva Zelanda en el 3er en regular espacios sin humo. |
| 2005 | Entra en vigor el artículo 8 del CMCT de la OMS, que compromete a las partes "a proteger a todas las personas de la exposición al humo del tabaco", ratificado por 40 países en 2005.<br>Italia cuarto país que tiene una prohibición de fumar en espacios públicos cerrados. |
| 2006 | Uruguay es el primer país de Latinoamérica en instaurar una política nacional libre de humo. España implanta la primera ley libre de humo (Ley 28/2005), que permite fumar en determinados establecimientos de la hostelería (ley parcial). |
| 2007 | Gales, Inglaterra e Irlanda del Norte introducen la legislación libre de humo. 145 países han ratificado el tratado CMCT, pero EEUU no está entre ellos. |
| 2008 | Informe MPOWER de la OMS: "solo el 5% de la población mundial está cubierto por leyes integrales libres de humo", y se estima que en 2030 más de 8 millones de personas al año morirán por el consumo de tabaco. Francia prohíbe fumar en lugares públicos. Once de los 16 estados alemanes prohiben de fumar en el lugar de trabajo. India prohibe de fumar en el lugar de trabajo, el país más grande del mundo que lo hace hasta la fecha. |
| 2009 | 168 de los 192 estados miembros de la OMS son signatarios del artículo 8 del CMCT, cubriendo al 86.24% de la población mundial. |
| 2010 | Prohibición de fumar en el trabajo en Grecia, país con mayor número de fumadores de Europa. |
| 2011 | Nueva ley libre de humo en España que prohíbe fumar en lugares públicos y en parques infantiles, puntos de acceso a escuelas y hospitales (ley integral). Brasil implementa la prohibición de fumar en el lugar de trabajo. |
| 2014 | Rusia implementa una prohibición nacional de fumar en el lugar de trabajo. |
| 2017 | China prohíbe fumar en lugares públicos cerrados, lugares de trabajo, transporte público y en muchos lugares públicos al aire libre en Shanghái. En Shenzen todos los lugares públicos cerrados, los lugares de trabajo y el transporte público se vuelven 100% libres de humo. |

CMCT, Convenio Marco para el Control del Tabaquismo; OMS, Organización Mundial de la Salud .
Fuente: Elaboración propia a partir de Secondhand smoke exposure and cardiovascular effects: making sense of the evidence. 5, The Background of Smoking Bans, 2010 (35), de Making Smoking History Worldwide. NEJM, 358:1496-8, 2007 (26) y WHO report on the global tobacco epidemic, 2017: monitoring tobacco use and prevention policies (1)

En 2003 se creó el Convenio Marco para el Control del Tabaco (CMCT) de la OMS con entrada en vigor en 2005 (26) , como se ha explicado anteriormente en el apartado 1.3. En 2004, la República de Irlanda fue el primer país que ratificó este tratado de forma estricta. Tras Irlanda, otros países tomaron medidas más o menos restrictivas de prevención y control del tabaquismo. Las medidas más restrictivas se implementaron en Reino Unido, Grecia, Hungría, Bulgaria, Malta, Turquía y España. Uruguay se convirtió en el primer país latinoamericano en aprobar una política nacional libre de humo en 2006. Los activistas locales y organizaciones como la Organización Panamericana de la Salud y la Fundación Interamericana del Corazón en los países de América Latina aumentaron sus esfuerzos posteriormente en otros países (33).

Según el informe de la OMS del 2017, 121 países han puesto en marcha al menos una las seis medidas MPOWER implementadas al más alto nivel (es decir, al nivel que ha demostrado lograr el mayor impacto) para proteger a las personas de los efectos del tabaco, y ocho tienen cuatro o más de las medidas implementadas. El seguimiento sistemático de las medidas MPOWER revela que el número de personas protegidas por al menos una medida es de 4.700 millones, casi dos tercios de la población mundial. El 20% de la población mundial (55 países) tiene una legislación integral libre de humo, cubriendo a casi 1.500 millones de personas (Figura 1.5) (1)

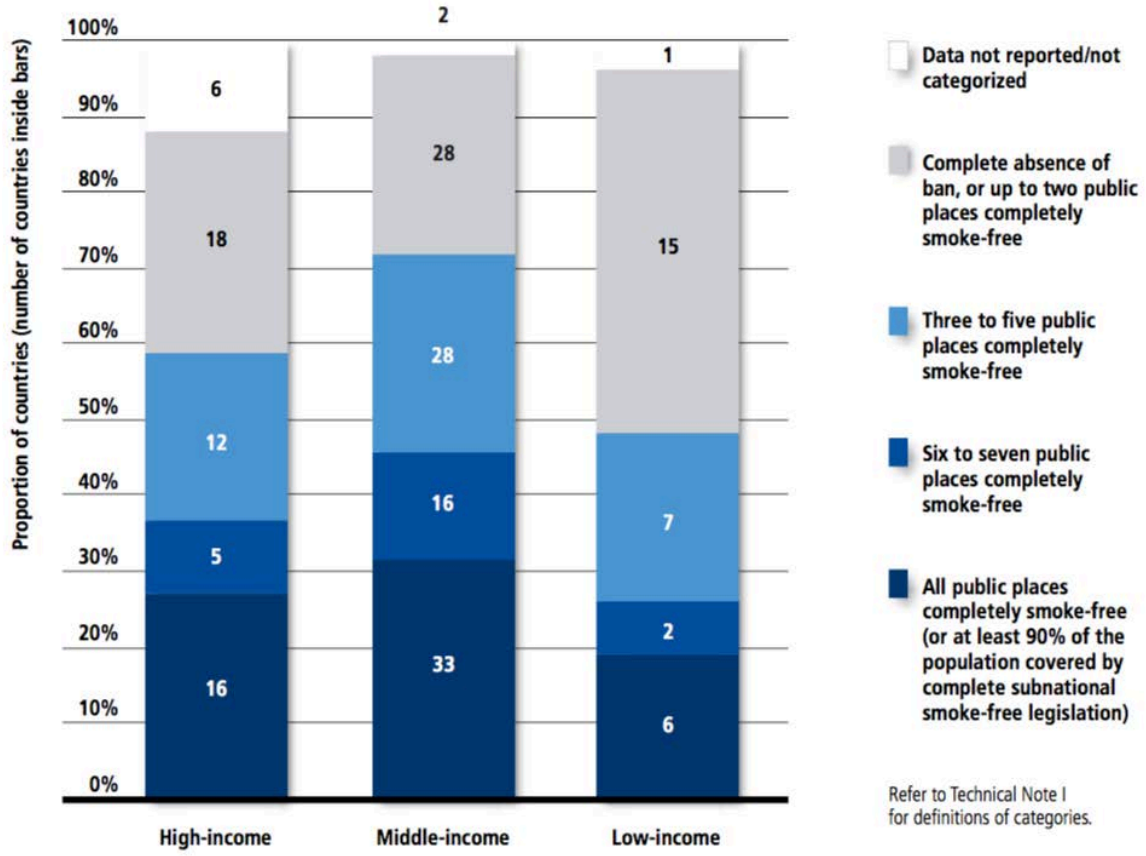
**Figura 1.5. Mapa de los países con leyes 100% libres de humo en el año 2016**




Fuente: WHO report on the global tobacco epidemic, 2017. Monitoring tobacco use and prevention policies.

El progreso en la adopción de leyes libres de humo ha sido particularmente extraordinario en los países de bajos y medios ingresos: desde 2007, 35 países de bajos y medianos ingresos han introducido una legislación integral libre de humo que abarca todas las categorías de lugares públicos, mientras que solo 10 países de altos ingresos lo han hecho. En 2016, alrededor del 72% de todos los países (y el 81% de los países de bajos ingresos) tenían leyes sin humo débiles o inexistentes dejando a sus poblaciones vulnerables a los peligros del humo de segunda mano. Y había 41 países de altos ingresos cuya población permaneció débil o completamente desprotegida en 2016. En la Figura 1.6, extraída del último informe de la OMS del 2017, se especifica el porcentaje de países con leyes integrales o parciales según su nivel de ingresos (1).

**Figura 1.6. Proporción de países con diferentes niveles de cobertura de espacios sin humo según niveles de ingresos económicos.**




Fuente: WHO report on the global tobacco epidemic, 2017: monitoring tobacco use and prevention policies. Las categorías de lugares públicos a las cuales se hace referencia son (5): Centros médicos; Instalaciones educativas distintas de las universidades; Universidades; Instalaciones gubernamentales; Oficinas interiores y lugares de trabajo no considerados en cualquier otra categoría; Restaurantes o instalaciones que sirven principalmente comida; Pubs y bares o instalaciones que sirven principalmente bebidas (no aplicable cuando el alcohol que se sirve es ilegal); Transporte público. En los países en donde los bares y pubs son ilegales, solo se requieren siete lugares libres de humo para calificar este grupo.

Una nueva escala, la *Tobacco Control Scale* (TCS), puntúa medidas como el precio de los cigarrillos, el gasto en campañas de información pública, las prohibiciones integrales de

publicidad y promoción, el etiquetaje de advertencia de salud, el tratamiento para dejar de fumar y la implementación de prohibiciones de fumar en lugares de trabajo y otros espacios públicos. Según un informe del 2016 que describía los resultados de una encuesta de control de tabaquismo en 35 países europeos usando la TCS con todas estas medidas en conjunto, España estaría en octavo lugar del ranking europeo. En cambio, estaría entre los tres primeros países en puntuación de la implementación de prohibiciones en lugares de trabajo y otros espacios públicos. Esta categoría estaba subclasificada como 1) lugares de trabajo excluyendo cafés y restaurantes (2-10 puntos), 2) cafés y restaurantes (2-8 puntos), y 3) transporte público y otros lugares públicos y automóviles privados (1-4 puntos) (Tabla 1.7) (23).

**Tabla 1.7. Ranking de implementación de leyes libres de humo de dieciocho países europeos clasificados por puntuación total de Tobacco Control Scale en 2016**
* Puntuación sobre la prohibición de fumar en espacios públicos. Rango de puntuación posible: 5-22 puntos.

| Ranking 2016 | País | Puntuación * |
|---|---|---|
| 1 | Reino Unido | 22 |
| 2 | Irlanda | 22 |
| 3 | España | 21 |
| 4 | Rumanía | 19 |
| 5 | Turquía | 19 |
| 6 | Ucrania | 19 |
| 7 | Federación Rusa | 19 |
| 8 | Francia | 18 |
| 9 | Finlandia | 18 |
| 10 | Islandia | 17 |
| 11 | Noruega | 17 |
| 12 | Hungría | 17 |
| 13 | Países Bajos | 15 |
| 14 | Suecia | 15 |
| 15 | Bélgica | 15 |
| 16 | Eslovenia | 15 |
| 17 | Luxemburgo | 15 |
| 18 | Italia | 14 |

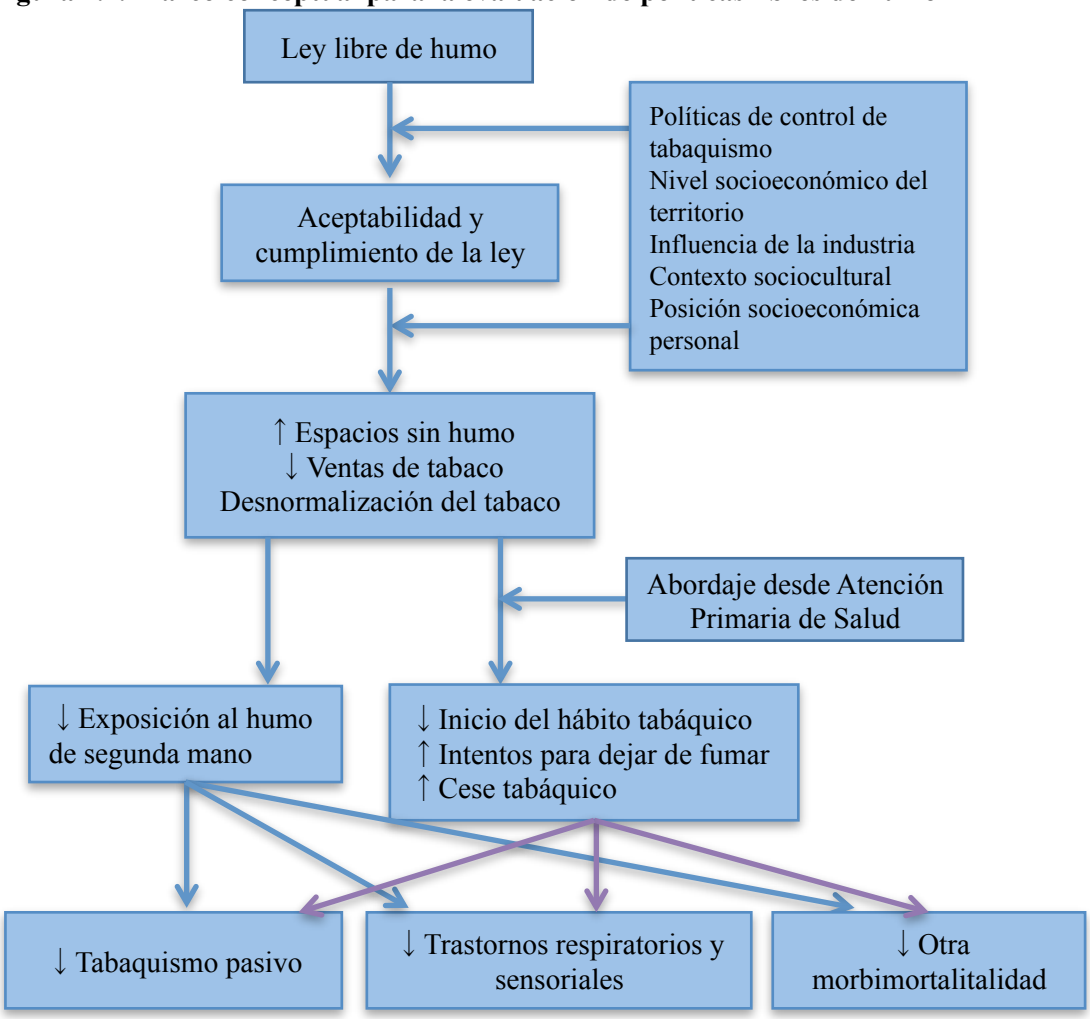
Fuente: Elaboración propia a partir de The tobacco control scale 2016 in Europe. Joossens L, Raw M.

## 1.4. Marco conceptual de impacto de políticas libres de humo

El principal objetivo de las políticas libres de humo es eliminar la exposición al humo de segunda mano y así mejorar la salud de las personas no fumadoras. Hay medidas o factores que alteran el efecto de una ley libre de humo como la participación de la industria del tabaco, la ocupación o nivel socioeconómico individual, otras políticas de control de tabaquismo (como el aumento de la fiscalidad), el contexto sociocultural personal (la percepción de riesgo personal o a terceros, conocimientos, actitudes o creencias). Las leyes libres de humo también ayudan a la desnormalización del tabaco, al disminuir su presencia en la vida pública. La aceptabilidad y el

cumplimiento de la ley provocan un aumento de los espacios sin humo. Así mismo, las leyes junto con el abordaje desde un nivel asistencial de salud como la APS podrían conseguir un menor consumo de cigarrillos (disminución de las ventas), un mayor número de intentos para dejar de fumar y un menor inicio en el hábito tabáquico. De esta manera, no sólo disminuiría el tabaquismo pasivo sino también el activo, con la consecuente disminución de los problemas relacionados con el tabaco (33) (Figura 1.7).

**Figura 1.7. Marco conceptual para la evaluación de políticas libres de humo**




Fuente: Elaboración propia a partir de Smoke-free air policies: past, present and future. Hyland A, Barnoya J, Corral JE. Tob Control, 2012 (33) y de Evaluación de las políticas contra el tabaquismo en países latinoamericanos en la era del Convenio Marco para el Control del Tabaco. Trasher JF et al. Salud Publica Mex, 2006 (29).

### 1.5. Aceptabilidad de las leyes libres de humo

Sin apoyo o la aceptación a las leyes libres de humo por parte de la población no hay cumplimiento. Según el informe del 2009 de la *International Agency for Research on Can*cer (IARC) (36), había un apoyo público a la restricción de fumar en lugares de trabajo, restaurantes

y bares/pubs y otros entornos (escuelas, instalaciones de atención sanitaria, estadios/eventos deportivos cubiertos y centros comerciales) en los países desarrollados, respaldado tanto por personas no fumadoras como por la mayoría de fumadoras. Este apoyo se mantenía a lo largo del tiempo y después de que se establecieran leyes libres de humo de tabaco. Además, en países desarrollados se adoptaban medidas para mantener los automóviles libres de humo voluntariamente y existía mayor disposición a que se legislara sobre este aspecto en presencia de niños en el automóvil. También había evidencia de apoyo mayoritario a las leyes libres de humo en parques, instalaciones deportivas, áreas de transición como entradas y playas (pocos estudios). Sin embargo, cuando las leyes se promulgaban antes de la promoción del apoyo popular, podía ocurrir un cumplimiento deficiente (por ejemplo, algunas leyes en la década de 1990). La experiencia internacional sugería que el cumplimiento era más alto en los países que llevaban a cabo campañas de sensibilización de promoción de la ley.

En España, la regulación del consumo de tabaco en el interior de los centros de trabajo y en los espacios públicos estaba ampliamente aceptada, tanto antes como después de la entrada en vigor de la ley integral del 2010, según un informe de la Sociedad Española de Epidemiología (SEE) del 2017. La población española puntuó con un 7,6 (sobre 10) la adecuación de la Ley 42/2010 un año después de su entrada en vigor siendo estas puntuaciones similares 3 años después en 2014 (datos del Barómetro Sanitario). La aceptabilidad era menor entre las personas fumadoras, aunque los resultados mostraban que el apoyo ha aumentado en toda la población, incluyendo las personas fumadoras (37).

### 1.6. Cumplimiento de las leyes libres de humo

El informe de la OMS del 2017 expone que la vigilancia del cumplimiento de las leyes y regulaciones de control del tabaco de un país se puede realizar a través de inspecciones de lugares designados como libres de humo (incluidos los lugares de trabajo y lugares públicos interiores); inspecciones de locales minoristas para verificar el cumplimiento de las restricciones sobre exhibiciones de productos, publicidad en puntos de venta y ventas a personas menores de edad; y el seguimiento de los medios impresos y de radiodifusión para verificar que se sigan las prohibiciones de publicidad, promoción y marketing (mercadotecnia) (1). Este informe reporta que solo 22 (40%) de los 55 países con una legislación integral libre de humo tenían altas tasas de cumplimiento. Los datos también mostraban que la aplicación de estas leyes era particularmente difícil en cafés, pubs y bares, donde solo el 25% de los países tenían un alto cumplimiento. Las prohibiciones de fumar en las universidades eran igualmente un reto, con solo el 27% de las prohibiciones nacionales con un alto cumplimiento.

La *Smoke Free Partnership*, que es una asociación entre *Cancer Research UK, European Heart Network, Action on Smoking and Health* (Reino Unido) y *Dutch Cancer Society* para promover la promoción del control del tabaco y la investigación de políticas a nivel nacional y de la UE, sitúa a España entre los países que mejor siguen las directrices del Artículo 8 del CMCT de la OMS. En la Tabla 1.8 y en la Figura 1.8 se describen los diferentes niveles de implementación y cumplimiento de este artículo de cada país de la Unión Europea.

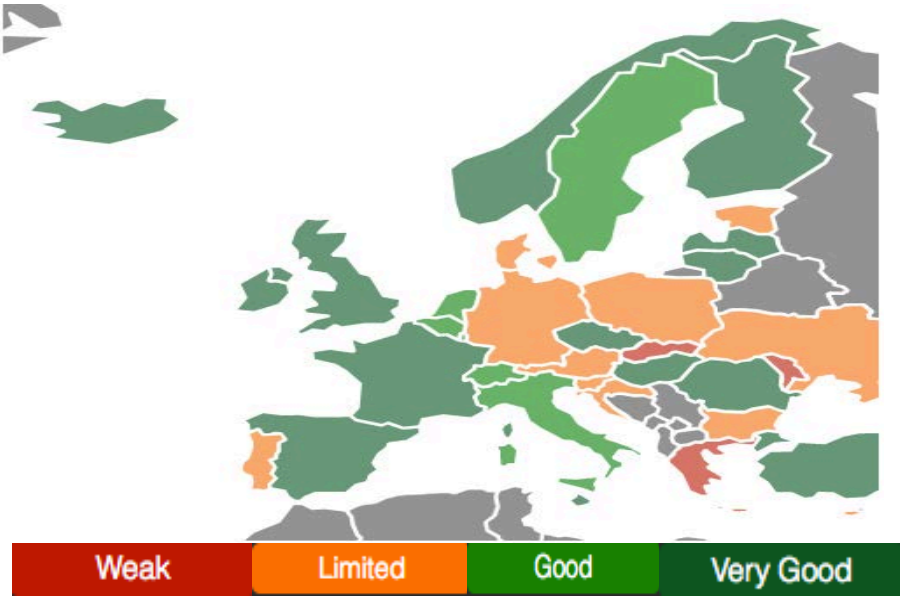
**Tabla 1.8. Implementación y cumplimiento del Artículo 8 del Convenio Marco para el Control del Tabaco en los países de Europa en 2016** (38)

| País | Tipo de implantación de la ley según espacios: | | | | Cumplimiento de la ley | Protección |
|---|---|---|---|---|---|---|
| | Bar | Restaurante | Trabajo | Transporte | | |
| Alemania | Parcial | Parcial | Parcial | Integral | Limitado | Limitada |
| Austria | Parcial | Parcial | Parcial | Integral | Débil | Limitada |
| Bélgica | Parcial | Parcial | Parcial | Integral | Bueno | Buena |
| Bulgaria | Integral | Integral | Integral | Integral | Débil | Débil |
| Chipre | Integral | Integral | Parcial | Integral | Débil | Limitada |
| Croacia | Parcial | Integral | Integral | Integral | Limitado | Limitada |
| Dinamarca | Parcial | Parcial | Parcial | Parcial | Limitado | Limitada |
| Eslovaquia | No ley | Parcial | Integral | Integral | Bueno | Débil |
| Eslovenia | Parcial | Parcial | Parcial | Integral | Débil | Limitada |
| España | Integral | Integral | Integral | Integral | Muy bueno | Muy buena |
| Estonia | Parcial | Parcial | Parcial | Parcial | Limitado | Limitada |
| Finlandia | Parcial | Parcial | Parcial | Parcial | Muy bueno | Muy buena |
| Francia | Parcial | Parcial | Parcial | Integral | Bueno | Muy buena |
| Grecia | Parcial | Integral | Integral | Integral | Débil | Débil |
| Hungría | Integral | Integral | Integral | Integral | Bueno | Muy buena |
| Irlanda | Integral | Integral | Integral | Integral | Bueno | Muy buena |
| Islandia | Integral | Integral | Parcial | Parcial | Bueno | Muy buena |
| Italia | Parcial | Parcial | Parcial | Integral | Muy bueno | Muy buena |
| Letonia | Integral | Integral | Parcial | Parcial | Bueno | Muy buena |
| Lituania | Integral | Integral | Parcial | Parcial | Bueno | Muy buena |
| Luxemburgo | Parcial | Parcial | Parcial | Parcial | Bueno | Buena |
| Malta | Integral | Integral | Integral | Integral | Limitado | Muy buena |
| Moldavia | Parcial | Parcial | Parcial | Integral | Parcial | Débil |
| Noruega | Integral | Integral | Parcial | Integral | Bueno | Muy buena |
| Países Bajos | Integral | Integral | Parcial | Integral | Bueno | B Buena |
| Polonia | Parcial | Parcial | Parcial | Parcial | Limitado | Limitada |
| Portugal | Parcial | Parcial | Parcial | Integral | Limitado | Limitada |
| Reino Unido | Integral | Integral | Integral | Integral | Bueno | Muy buena |
| Rep Checa | Integral | Integral | Integral | Integral | Muy bueno | Muy buena |
| Rumanía | Integral | Integral | Integral | Integral | Bueno | Buena |
| Suecia | Parcial | Parcial | Parcial | Parcial | Bueno | Buena |
| Suiza | Parcial | Parcial | Parcial | Integral | Bueno | Buena |
| Turquía | Integral | Integral | Integral | Integral | Limitado | Muy buena |
| Ucrania | Integral | Integral | Parcial | Integral | Limitado | Limitada |

Fuente: Smoke Free Partnership, a world without tobacco, 2016. https://smokefreepartnership.eu/our-policy-work/smokefree-map.

En las columnas Bar, Restaurante, Trabajo y Transporte se especifica si la ley implementada es parcial o integral. La columna Protección es la conclusión derivada de la implementación en los diferentes lugares y el cumplimiento de la ley libre de humo.

**Figura 1.8. Mapa de Europa con los diferentes niveles de implementación y cumplimiento de leyes sin humo**




Fuente: Smoke Free Partnership, a world without tobacco. https://smokefreepartnership.eu/our-policy-work/smokefree-map.

La conclusión global para cada Estado miembro se ha basado en las implementaciones y el cumplimiento de la ley libre de humo. Los países de color verde oscuro siguen las directrices del Artículo 8 del CMCT de la OMS; la ley libre de humo es muy fuerte y se cumple con fuerza. Como resultado, fumar en lugares de trabajo, lugares de hospitalidad como bares y restaurantes y otros lugares públicos es insignificante. Los países de color verde siguen las directrices del Artículo 8 del CMCT de la OMS; la ley libre de humo es fuerte y está bien aplicada. Los países de color naranja ofrecen protección limitada; muchas áreas públicas pueden estar libres de humo, pero el 100% de protección es inalcanzable debido a exenciones o al cumplimiento deficiente de la ley. Los países de color rojo ofrecen poca o ninguna protección a los ciudadanos; la ley libre de humo es débil y no se cumple. En consecuencia, la exposición al humo de segunda mano es alta.

El informe de la SEE del 2017 resumía que el cumplimiento de la ley libre de humo integral del 2010 española era bueno en los lugares cerrados de trabajo y otros espacios públicos, la mayoría ya incluidos en la legislación parcial previa del 2005. El cumplimiento de la ley también era satisfactorio en los espacios cerrados a los que se amplió la prohibición del consumo de tabaco, como bares y cafeterías, así como en el interior de los vehículos comerciales. Por otra parte, el cumplimiento de la ley en los recintos de los hospitales, terrazas de bares y cafeterías debía mejorar (37). En un reciente estudio del 2018 se ha observado que el incumplimiento de fumar en las terrazas en la ciudad de Madrid en otoño alcanzaba el 77,8% (39).

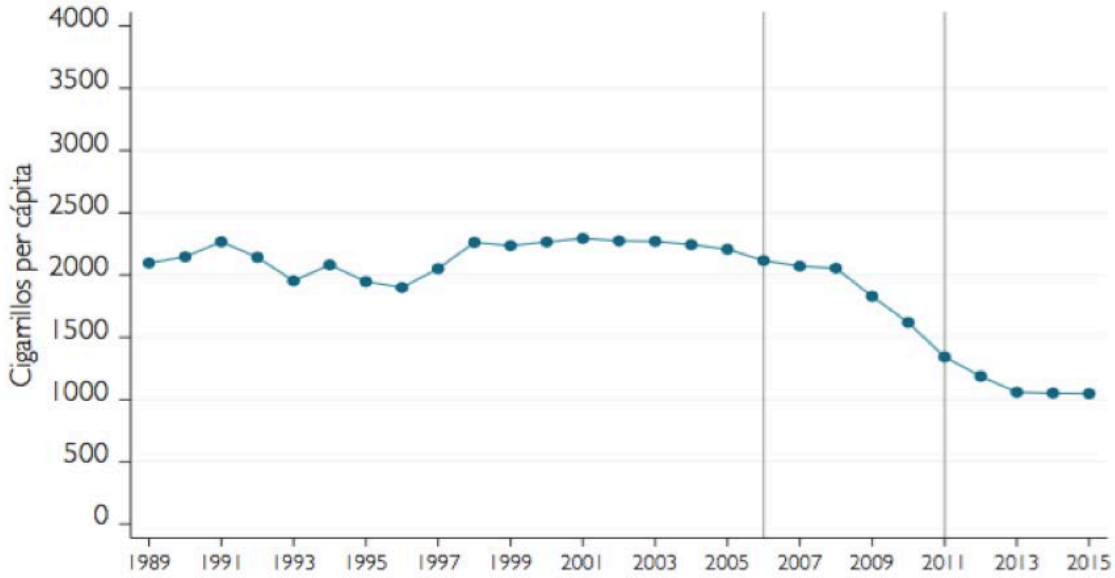
## 1. 7. Repercusión de las leyes libres de humo

A continuación se detallarán la repercusión de las leyes libres de humo en diferentes aspectos como ventas de tabaco, exposición al humo de segunda mano, hábito tabáquico y patología relacionada con el tabaquismo.

### 1.7.1. Ventas de tabaco

En España, se observan tres periodos definidos con dos cambios de tendencia en las ventas de cigarrillos (Figura 1.9): desde 1989 hasta 2005, con un aumento de 12 cigarrillos per cápita anual; desde 2006 hasta 2010, con un descenso de 124 cigarrillos per cápita anual; y desde 2011 hasta 2015, con un descenso de 73 cigarrillos per cápita anual. El descenso más importante de cigarrillos se inició en 2009, debido a la influencia de la crisis económica en la venta de productos de tabaco. El consumo de cigarrillos ha disminuido un 50%, pero se ha compensado parcialmente por el incremento de la picadura para liar (de un 1,3% en 2003 a un 8,8% en 2014) y de cigarros (puros) (el doble en los últimos 10 años). Así, los cigarrillos han pasado de tener un peso del 95% sobre el total de los productos de tabaco a un 86% en 2017. Las leyes libres de humo españolas del 2006 y 2011 no parecen haber impactado a corto o medio plazo en las ventas de tabaco (37).

**Figura 1.9. Evolución de la venta de cigarrillos per cápita en la Península y Baleares** (37)




Fuente: Informe de la Sociedad Española de Epidemiología. Evaluación de las políticas de control del tabaquismo en España (2017), elaborado a partir de datos del Comisionado para el mercado de Tabacos, Ministerio de Hacienda y Función Pública.

### 1.7.2. Exposición al humo de segunda mano

Numerosos estudios han hallado que la exposición al humo de segunda mano (tanto auto-informada como validada con test bioquímico) entre adultos no fumadores disminuye significativamente después de implementar leyes libres de humo (40). La *Community*

*Preventive Services Task Force*, panel independiente de expertos en salud pública y prevención, halló una reducción del 88% en la contaminación del aire interior y una reducción del 50% de los biomarcadores del humo de segunda mano en 2014 (41). Una revisión sistemática de revisiones sistemáticas (Hoffman & Tan, 2015) (42) reportó reducciones en la exposición al humo de segunda mano después de la implementación de políticas libres de humo, tanto en población adulta como infantil, y en varios entornos, incluidos lugares de trabajo, espacios públicos y establecimientos de la hostelería, que además conducen a una disminución de la prevalencia del tabaquismo y el consumo de cigarrillos.

En España, Lidón-Moyano *et al.* (2017) (43) estudiaron el impacto de las dos leyes sin humo en conjunto sobre la exposición al humo de segunda mano en el hogar en una cohorte de población adulta no fumadora en Barcelona (encuestados en 2004-2005 y seguidos en 2013-2014). El porcentaje de participantes con muestras de saliva con concentraciones mensurables de cotinina cayó del 92.4% al 64.2%. Los mismos autores también observaron una disminución significativa en la exposición auto informada del humo de segunda mano en el hogar, trabajo, transporte y tiempo libre en otro estudio (44). Estas conclusiones coinciden con las de Fernández *et al.* (2017) (45) que también hallaron que la prevalencia de la exposición al humo de segunda mano entre las personas no fumadoras disminuyó durante el tiempo de ocio, hogares, paradas de autobús al aire libre y estaciones de tren después de la Ley integral.

### 1.7.3 Hábito tabáquico

Las leyes libres de humo tienen como objetivo proteger la salud de las personas no fumadoras o expuestas al humo de segunda mano. Sin embargo, se ha observado que influyen en que las personas fumadoras dejen de fumar al prohibírselo en lugares de trabajo y de ocio. Así, se ha evaluado cómo repercute la implantación de estas leyes en el hábito tabáquico a nivel de consumo de tabaco, prevalencia o incidencia de tabaquismo (o personas fumadoras), tasas de cese o personas ex fumadoras, recaídas de personas ex fumadoras, etc.

**Consumo de tabaco**

Caroline M. Fichtenberg y Stanton A. Glantz, en su meta-análisis publicado en 2002, concluyeron que las políticas libres de humo estaban relacionadas con una disminución del 3% al 4% en el consumo de tabaco (46). Sin embargo, una revisión Cochrane realizada en 2016 mostró un impacto no concluyente de la prohibición legislativa de fumar en el consumo de tabaco (40).

**Prevalencia de tabaquismo (o personas fumadoras)**

En un estudio italiano del 2013, se estimó que la prohibición de fumar en lugares privados abiertos al público reduce la prevalencia de tabaquismo en un 1,3%, encontrando efectos heterogéneos por género, estado civil y región de residencia (47). Y en otro estudio realizado en 27 países europeos en 2017, se observó que el nivel de legislación libre de humo (medido con la TCS) se correlaciona con una disminución en la prevalencia de fumar cigarrillos convencionales (48).

**Nuevas personas fumadoras o iniciación del hábito tabáquico**

El estudio de Farrelly *et al.* (2014) valoró el inicio del tabaquismo durante el año anterior en adultos jóvenes de Estados Unidos. Una mayor cobertura de las leyes libres de humo se asoció con un menor inicio con una significación marginal (p 0,058) (49). Shang *et al*. (2015) hallaron que las leyes sin humo en bares con exenciones (leyes parciales) reducían significativamente la probabilidad de empezar a fumar más entre los menores de 21 años que entre los de 21 años o más (edad legal para beber alcohol) en Estados Unidos. Los resultados también indicaban que los impuestos más altos a los cigarrillos reducían significativamente la iniciación diaria del tabaquismo (50).

**Nuevas personas ex fumadoras o cese del hábito tabáquico**

Algunos estudios muestran resultados alentadores en relación al aumento de las personas ex fumadoras o tasas de abandono o cese tabáquico. En un estudio realizado en China mediante dos encuestas antes y después de la ley libre de humo, se halló que las ratios de abandono aumentaron significativamente (de 14,5% a 17,9%), pero se mantuvieron bajas entre las edades 15-44 años (51). En un estudio realizado en Luxemburgo en 2016, se observó que el abandono del hábito de fumar en las personas fumadoras diarias debido a las leyes libres de humo tuvo porcentajes más altos entre los que tenían un nivel socioeconómico más elevado (52).

**Recaída de personas ex fumadoras**

Los datos de la literatura relacionados con la recaída de las personas ex fumadoras son discordantes entre sí. En un estudio de los Estados Unidos en 2010 que comparaba empleados expuestos a una ley libre de humo en hospitales versus empleados no expuestos, se observó que la recaída de las personas ex fumadoras fue similar entre los empleados de los hospitales y los empleados en donde se permitía fumar (53). En cambio, en otro estudio del mismo país en 2015 se halló que las leyes libres humo integrales en bares disuadían significativamente la recaída del hábito de fumar de la abstinencia al tabaquismo diario o al tabaquismo intenso entre personas mayores de 20 años (50).

### 1.7.4 Salud en general

El informe de la IARC del 2009 concluía que a corto plazo ya se observaban mejoras en la salud relacionadas con las restricciones para fumar: reducciones en enfermedades respiratorias agudas y reducciones de un 10-20% de los ingresos hospitalarios por infarto agudo de miocardio (IAM) en el primer año de las leyes sin humo integrales (sin poder distinguir si era por la disminución del tabaquismo activo o pasivo) (36).

Además de estas repercusiones, se han realizado numerosos estudios sobre la afectación en sintomatología sensorial en adultos trabajadores sobre todo del sector de la hostelería, al ser este gremio uno de los más afectados por el humo de segunda mano antes de las implantaciones de las leyes sin humo. La sintomatología sensorial estudiada era irritación ocular ("ojos rojos"), secreción nasal, estornudos, dolor o picor de garganta o cualquiera de estos síntomas en conjunto. Los estudios que valoraban estos ítems ya observaban disminuciones en el periodo más inmediato a la ley (54). Según una revisión Cochrane del 2010, los síntomas disminuían tanto en las personas no fumadoras (en relación con los ojos, la nariz y la garganta) como en las fumadoras (síntomas oculares) (55).

Aparte de las conocidas repercusiones en sintomatología sensorial, salud respiratoria y cardiaca también se han observado en otras variables menos estudiadas. Un meta-análisis que estimaba del impacto de una ley libre de humo integral sobre la tasa de accidentes cerebrovasculares y/o accidentes isquémicos transitorios basado en cinco estudios indicó un RR de 0,81 (Intervalo de Confianza del 95% [IC 95%], 0,70-0,94) en 2014 (6). En España, Galán *et al.* (2017) (56) evaluaron el impacto de las dos leyes sin humo españolas sobre las hospitalizaciones por enfermedades cerebrovasculares (ECV) entre 2003 y 2012. Hallaron un aumento significativo de las ECV tanto en el periodo inmediato como un año después de la Ley parcial. En cambio, tras la Ley integral, las ECV bajaron significativamente un 0,8% inmediatamente tras la ley pero esta reducción no se mantenía al año. Y más recientemente, en un estudio del 2018 se observó una correlación negativa entre el nivel de las políticas de control del tabaco en los países europeos (medido con la TCS*),* particularmente las prohibiciones de fumar en el trabajo y lugares públicos, con la prevalencia de partos prematuros y bajo peso al nacer (57). Un estudio ecológico reciente que correlacionaba las leyes libres de humo con la prevalencia de partos prematuros y bajo peso al nacer en Europa halló que en España (58) bajaron de 8,7% y 15,5%) en 2010 a 7,7% y 6,34% en 2013, respectivamente. Las conclusiones globales exponían una correlación inversa estadísticamente significativa entre el nivel de restricciones para fumar en lugares públicos y la prevalencia de bajo peso al nacer. A similares conclusiones llegaron

Simón *et al*. (2017) (59) en su estudio de evaluación de las dos leyes sin humo españolas sobre riesgo de nacimientos pre-término y bajo peso al nacer.

En relación a mortalidad, la revisión Cochrane del 2016 expuso que había evidencia de una reducción de la mortalidad por enfermedades relacionadas con el tabaquismo a nivel nacional (ocho de 11 estudios detectaron una asociación significativa entre la introducción de las leyes y la reducción de la mortalidad) (40). En población infantil, un estudio suizo del 2016 no observó ningún beneficio de las leyes en términos de mortalidad (60).

### 1.7.5 Función, sintomatología, patología y mortalidad respiratoria

De la misma forma que se ha evaluado el efecto de las leyes sin humo en hábito tabáquico, también existen estudios, revisiones sistemáticas y meta-análisis sobre función pulmonar (medida con espirometrías), sintomatología respiratoria, patología como el asma, EPOC o infecciones respiratorias y mortalidad de causa respiratoria. En los siguientes apartados se detallan algunos estudios al respecto.

**Función pulmonar**

Una revisión Cochrane del 2010 encontró cinco estudios que analizaron la repercusión de la legislación sobre las mediciones de la función pulmonar. La repercusión fue mixta con solo dos estudios que mostraron un aumento significativo en el volumen espiratorio forzado en un segundo, tres estudios con un aumento en la capacidad vital forzada y dos estudios que mostraron una reducción en el flujo espiratorio forzado (55).

**Sintomatología respiratoria**

La revisión Cochrane del 2010 valoró 12 estudios que medían sintomatología respiratoria y encontró que en diez de ellos disminuyeron los síntomas respiratorios en los trabajadores tras la legislación sin humo, algunos de los estudios solo evaluaron a las personas no fumadoras (55). Los síntomas estudiados en estos trabajos eran cualquier síntoma respiratorio, sibilancias, flema, tos matutina, tos durante el resto del día, disnea y opresión en el pecho. En uno de los estudios, se observó que la variable cualquier síntoma respiratorio disminuyó un 42% en el período inmediatamente posterior a la implementación de la ley libre de humo (61).

**Asma en población infantil**

Según la *Royal College of Physicians* (2010), habrían más de 100.000 consultas cada año en Atención Primaria por asma en población infantil atribuibles al tabaquismo pasivo versus 9500 ingresos hospitalarios por esta causa en el Reino Unido (16). Hawkins *et al*. (2016) valoraron la

reducción de visitas a emergencias de asma en población infantil de tres estados de Estados Unidos debidas al efecto de una legislación libre de humo estatal o local (62). No encontraron cambios en la tasa general de visitas por asma. Sin embargo, una interacción con la edad de los niños reveló que entre los 10-17 años de edad, la legislación estatal contra el tabaco se asoció con una reducción del 12% en las visitas por asma (aIRR 0,88; IC95%: 0,83 a 0,95 ). Y fuera del ámbito hospitalario, Been *et al.*(2015) (63) no encontraron ninguna asociación entre la introducción de la ley libre de humo integral en el Reino Unido y el número de nuevos casos de sibilancias o asma entre los niños ≤ 12 años visitados por el médico de cabecera.

**Asma en población adulta**

Revisiones como la de la Cochrane del 2016 y la de Hahn del 2010 concluyen que los resultados en asma son inconsistentes o que son necesarios más estudios sobre indicadores de asma con especial atención a las poblaciones de bajos ingresos, mujeres, minorías étnicas y ancianos (40,64). Posteriormente a estas revisiones, Landers *et al.* (2017) hallaron una reducción significativa de 5,43% de ingresos por asma en adultos en edad laboral tras las leyes de restaurantes y bares libres de humo del bar en condados de Estados Unidos (65).

**Enfermedad Pulmonar Obstructiva Crónica**

Las citadas revisiones de la Cochrane del 2016 y de Hahn (2010) no encuentran consistencia en los estudios que evalúan el efecto de las leyes sin humo en EPOC (40,64). La revisión Cochrane obtuvo seis estudios de 11 con reducciones significativas de los ingresos por EPOC tras la implantación de las leyes (40) y la de Hahn concluye que son necesarios más estudios con análisis en poblaciones especiales (mujeres, minorías étnicas, etc.) (64).

**Infecciones respiratorias de vías altas y bajas**

Un meta-análisis del 2017 (Faber *et al.*) que valoraba el efecto de la implementación de legislaciones libres de humo (66), observó que estas se asociaban a reducciones en las tasas de asistencia hospitalaria para todas las infecciones del tracto respiratorio en población infantil (-3,45%, IC 95% -4,64 a -2,25), sobre todo cuando se implementaron leyes integrales libres de humo (66).

El citado estudio de Hawkins *et al.* (2016) valoró también la reducción de visitas a emergencias de infecciones de vías respiratorias bajas en población infantil (62), encontrando una reducción general del 8% en las visitas por este motivo tras la implementación de la legislación estatal libre de humo en Estados Unidos (aIRR 0.92; IC 95% 0.87, 0.96). Sin embargo, no se encontraron cambios en las misma patologías en adultos en un estudio del 2012 realizado en Irlanda tras la implantación de una ley integral (67).

**Cáncer de pulmón**

El informe de la IARC del 2009 exponía que podrían pasar 10-20 años o más desde la exposición al humo de segunda mano y la aparición de cáncer de pulmón, lo que dificulta la vinculación de los cambios en las tasas de enfermedad con la introducción de leyes sin humo (36). Sin embargo, en un reciente estudio del 2017 ya se observó que los individuos que vivían en municipios con leyes sin humo en Estados Unidos tenían un 7,9% menos probabilidad de tener cáncer de pulmón que aquellos que vivían sin estas leyes protectoras (68).

**Mortalidad por enfermedades respiratorias**

En relación a la mortalidad por cáncer de pulmón, un estudio del 2017 determinó las tendencias en 27 países de la Unión Europea entre 1994 y 2012, sin hallar cambios de tendencias relacionados con la legislación sobre el tabaco a nivel nacional (69).

**Otras patologías respiratorias**

Un artículo que evaluaba los ingresos hospitalarios por neumotórax espontáneo tras la implantación la ley libre de humo integral de Irlanda, no halló cambios significativos en 2012 (67).

### 1.7.6 Patología cardiaca

El informe de *Surgeon General* del 2014 especificaba que dos meta-análisis (70,71) resumían la evidencia sobre los efectos de las leyes libres de humo en las tasas de hospitalización por eventos coronarios agudos, incluido el IAM. La evidencia era suficiente para inferir una relación causal entre la implementación de una ley libre de humo y una reducción en eventos coronarios en personas menores de 65 años y era sugestiva pero no suficiente para inferir una reducción en otros resultados de enfermedad cardíaca, incluyendo angina y muerte coronaria súbita fuera del hospital (6). La magnitud del descenso sería de un 13% de las hospitalizaciones por IAM según un meta-análisis del 2013 (72) o de un 12% de eventos coronarios según otro meta-análisis publicado en 2014 (73). Este último estudio especificaba que los beneficios eran mayores en lugares con legislaciones integrales (14% vs 8%) y con una reducción media mayor al 2,1% en la prevalencia del tabaquismo después de la legislación. En relación a la incidencia de enfermedades cardiacas, la revisión de Lee *et al.* (2014) halló una reducción del 4,2% (IC 95%: 1,8-6,5%) después de una ley sin humo (74).

Estudios aislados recientes observan efectos más discretos en patología cardiaca. Un estudio del 2017, encontró una disminución de -5,8% para la tasa bruta de enfermedad coronaria aguda

después de la ley sin humo parcial portuguesa. Además se observó una tendencia decreciente después de la ley. El efecto de la prohibición fue mayor en hombres y en personas mayores de 65 años (75). El estudio suizo del 2016 citado anteriormente (60) también evaluó los efectos cardiacos tras la prohibición de fumar. Se detectaron reducciones en hospitalizaciones por cardiopatía isquémica del 2,5% (IC95%: -6,2 a 1,3%) para todas las edades y del 5,5% (IC95%: -10,8 a -0,2%) en adultos de 35-64 años posteriormente a la legislación. La mortalidad cardiovascular no cambió después de la introducción de la ley.

Si bien es cierto que en relación con la morbilidad cardiovascular la evidencia es más consistente en reducciones en eventos cardíacos y hospitalizaciones tras la implementación de legislaciones libres de humo, el efecto sobre la mortalidad cardiovascular no es tan claro. Shetty *et al.* (2011) (76) y Rodu *et al*. (2012) (77) no observaron ninguna asociación estadísticamente significativa con las disminuciones a corto plazo en la mortalidad por IAM. Por el contrario, Dove *et al.* (2010) (78) y McAlister *et al.* (2010) (79) estimaron unas 270 menos muertes por IAM por año en Massachusetts, y un cambio de tendencia rápido que conducía a menores tasas de muerte por IAM, respectivamente.

## 1.8. Situación de las leyes libres de humo en España: Implantación y repercusión

### 1.8.1. Leyes libres de humo implantadas en España

En España la aplicación de una legislación libre de humo ha sido un objetivo prioritario de salud debido a la alta prevalencia de exposición al tabaco y de tabaquismo activo existente. Desde finales de los años 1980, el consumo de tabaco en lugares públicos estaba regulado mediante el Real Decreto 192/1988 que lo limitaba a las zonas de personas fumadoras, aunque más de la mitad de estos lugares incumplían la normativa y dejaban desprotegidos a las personas fumadoras pasivas. A principios de los años 1990, diversas organizaciones científico-sanitarias se unieron en coalición y constituyeron el Comité Nacional para la Prevención del Tabaquismo (CNPT) para coordinar diferentes acciones junto a las autoridades sanitarias. En 2003 se aprobó el Plan Nacional de Prevención y Control del Tabaco, con el que se adoptó una agenda integral de prevención común entre las autoridades sanitarias del Ministerio de Sanidad, Servicios Sociales e Igualdad y las comunidades autónomas. Este paso permitió firmar y ratificar el CMCT de la OMS, en junio de 2005, que posibilitó la aprobación de las Leyes 28/2005 y 42/2010 de medidas sanitarias frente el tabaquismo (37).

El 1 de enero del 2006 entró en vigor la Ley de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro, el consumo y la publicidad de los productos del tabaco (Ley 28/2005) (80). Esta ley regulaba tres aspectos del control del tabaquismo: aumentaba la

edad mínima legal para comprar tabaco de 16 a 18 años, prohibía la publicidad y el patrocinio, y establecía ciertas restricciones al consumo. En concreto, prohibía fumar en todos los lugares de trabajo y establecía restricciones en el sector de la hostelería, obligando a los establecimientos mayores de 100 m2 a declararse libres de humo o a habilitar áreas separadas físicamente. Sin embargo, en los establecimientos menores de 100 m2 no establecía ninguna prohibición legal de fumar, pudiendo el dueño del local escoger entre declarar el local libre de humo o permitir fumar. Era, por tanto, una ley libre de humo parcial. Esa ley se vio reforzada 5 años más tarde con una reforma, la Ley 42/2010 (81), con entrada en vigor el 2 de enero del 2011, más estricta que la previa al prohibir completamente fumar en espacios cerrados de restauración (sin restricciones por área de establecimiento), convirtiéndose entonces en una ley integral. En la tabla 1.9 se especifican las características de ambas leyes.

**Tabla 1.9. Comparativa de las políticas de control del tabaquismo en España**

| Tipo de regulación | Ley parcial 28/2005 | Ley integral 42/2010 |
|---|---|---|
| Regulación de los puntos de venta a red de expendedurías de tabaco y timbre o a través de máquinas expendedoras, ubicadas en establecimientos que cuenten con las autorizaciones administrativas oportunas | Sí | Sí |
| Prohibición de venta o entrega de productos del tabaco a personas <18 años, así como cualquier otro producto que le imite e induzca a fumar. En particular, se prohíbe la venta de dulces, refrigerios, juguetes y otros objetos que tengan forma de productos del tabaco y puedan resultar atractivos para la población infantil y adolescente. | Sí | Sí |
| Prohibición de fumar en todos los lugares de uso público y centros de trabajo (excepto los que están al aire libre) | Sí | Sí |
| En el ámbito de la hostelería, se entiende por espacio al aire libre todo espacio no cubierto o todo espacio que estando cubierto esté rodeado lateralmente por un máximo de dos paredes, muros o paramentos | No | Sí |
| Prohibición de fumar en locales de hostelería (bares, cafés, pubs, restaurantes, discotecas y casinos) menores de 100 m2 | Opcional* | Sí |
| Prohibición de fumar en locales de hostelería (bares, cafés, pubs, restaurantes, discotecas y casinos) ≥100 m2 | Sí # | Sí |
| Prohibición de fumar en ascensores, cabinas telefónicas y otros recintos de uso público < 5 $m^2$ | Sí | Sí |
| Prohibición de fumar en vehículos o medios de transporte colectivo urbano e interurbano, vehículos de transporte de empresa, taxis, ambulancias, funiculares y teleféricos, transporte suburbano (vagones, andenes, pasillos, escaleras, estaciones, etc.), medios de transporte ferroviarios y marítimos salvo los espacios que se encuentren por completo al aire libre, aeronaves con origen y destino en territorio nacional y en todos los vuelos de compañías aéreas españolas y estaciones de servicio y similares | Sí | Sí |
| Prohibición de fumar a algunos espacios al aire libre: recintos de parques infantiles y áreas de juego para la infancia, centros docentes y formativos dedicados a personas <18 años, y recintos de centros sanitarios. | No | Sí |
| Se permite fumar en habitaciones de hoteles, hostales y establecimientos análogos habilitadas para ello* (máximo del 30% del total disponible), espacios al aire libre de universidades y centros de formación de adultos, salas cerradas y zonas exteriores en prisiones y centros psiquiátricos de media y larga estancia, y en residencias de personas mayores y de personas con discapacidad. | Sí | Sí |
| Prohibición de la publicidad directa (prohibida en los medios audiovisuales), la promoción y el patrocinio del tabaco | Sí | Sí |
| Se prohíbe en todos los medios de comunicación, incluidos los servicios de la sociedad de la información, la emisión de programas o de imágenes en los que los presentadores, colaboradores o invitados fumen o mencionen o muestren marcas u otros signos identificativos al tabaco | No | Sí |
| Medidas de prevención del tabaquismo, de promoción de la salud y de facilitación de la deshabituación tabáquica en la red asistencial sanitaria, en especial en la atención primaria. Programas de promoción del abandono del consumo de tabaco en instituciones docentes, centros sanitarios, centros de trabajo y entornos deportivos y de ocio. Creación de unidades de deshabituación tabáquica en la red asistencial del Sistema Nacional de Salud. | Sí & | Sí $ |

Fuente: Elaboración propia a partir de Evaluación de las políticas de control del tabaquismo en España (Leyes 28/2005 y 42/2010). Revisión de la evidencia, 2017 (37), del BOE número 309 (80) y del BOE número 318 (81). Abreviaturas: $m^2$ metros cuadrados**.** * el propietario decidía si permitía fumar o no. # el propietario podía habilitar áreas para personas fumadoras. & medidas propuestas pero no bien implantadas. $ con definición de grupos vulnerables, acceso a tratamientos dentro de la cartera de servicios del Sistema Nacional de Salud.

### 1.8.2. Repercusión de las leyes libres de humo españolas

Algunos estudios han evaluado la repercusión de las leyes libres de humo españolas, tanto la parcial como la integral, en exposición al humo de segunda mano, hábito tabáquico, patología respiratoria o cardíaca, mortalidad por enfermedades relacionadas con el tabaco, afectación económica en el sector de la hostelería, etc. En esta tesis se hará hincapié en lo referente a hábito tabáquico y morbilidad respiratoria y cardiaca. En la tabla 1.10 se clasifican algunos estudios españoles relacionados con este tema.

**Tabla 1.10. Estudios españoles que han evaluado la repercusión de las leyes libres de humo en hábito tabáquico, trastornos respiratorios y patología cardíaca**

| Hábito tabáquico | Patología respiratoria | Patología cardíaca |
|---|---|---|
| **Ley parcial** | | |
| Informe de la SEE 2009 (82)<br>Bauzà-Amengual 2009 (83)<br>Villalbí 2009 (84)<br>Martínez-Sánchez 2009 (85)<br>Catalina 2010 (86)<br>Guerrero 2011(87)<br>Regidor 2011 (88)<br>Ariza 2014 (89)<br>Bilal 2015 (90)<br>Regidor 2015 (91)<br>Pinilla and Abásolo, 2017 (92)<br>León-Gómez 2017 (93) | Informe de la SEE 2009 (82)<br>Fernández 2009 (94)<br>Martínez-Sánchez 2009 (85)<br>Galán 2015 (95) | Informe de la SEE 2009 (82)<br>Villalbí 2009 (84)<br>Villalbí 2009 (96)<br>Villalbí 2011 (97)<br>Agüero 2013 (98)<br>Galán 2015 (95) |
| **Ley integral** | | |
| Informe a las Cortes Generales de evaluación del impacto sobre la salud pública de la Ley 42/2010 (2012 y 2016) (99,100)<br>Catalina 2012 (101)<br>García-Villar 2014 (102)<br>Pérez-Ríos 2015 (103)<br>Raña 2016 (104)<br>Martín-Sánchez 2017 | Informe a las Cortes Generales de evaluación del impacto sobre la salud pública de la Ley 42/2010 (2012 y 2016) (99,100) | Informe a las Cortes Generales de evaluación del impacto sobre la salud pública de la Ley 42/2010 (2012 y 2016) (99,100) |
| **Ambas leyes** | | |
| Informe de la SEE 2017 (37)<br>Jiménez- Ruiz 2014 (105)<br>Rojas 2014 (106)<br>Lidón-Moyano 2017 (44)<br>Sureda 2017 (107) | Informe de la SEE 2017 (37)<br>Galán 2017 (108) | Informe de la SEE 2017 (37)<br>Galán 2017 (56) |

Fuente: Elaboración propia a partir de revisión de la bibliografía (28/1/2018). Abreviaturas: SEE, Sociedad Española de Epidemiología.

**Hábito tabáquico**

Los estudios sobre el impacto de las leyes sin humo españolas en hábito tabáquico, tanto en población trabajadora como en la población general, han sido más numerosos que sobre patología derivada del consumo de tabaco.

*Estudios relacionados con la Ley parcial:*

León-Gómez *et al.* (2017) (93) evaluaron el efecto de la ley mediante encuestas del Plan Nacional contra Drogas. Observaron que la prevalencia general de las personas fumadoras diarias españolas disminuyó del 33,5% en 1999 al 30,2% en 2011 (Cambio porcentual anual [CPA] para los hombres: -1,7%, CPA para las mujeres: -1,0%). Las diferencias entre niveles educativos bajos y altos en la prevalencia de personas fumadoras diarias y ex fumadoras diarias aumentaron. Seis años después de la implementación de ley parcial, persistieron las tendencias decrecientes del tabaquismo para hombres y mujeres, mientras que las desigualdades entre los niveles educativos aumentaron entre ambos sexos. Un estudio realizado en pacientes trabajadores activos que se atendían en APS de dos ciudades españolas mediante encuestas, halló una disminución en la prevalencia de fumadores y en el número de cigarrillos fumados en el lugar de trabajo al mes, a los seis meses y a los 18 meses de la implantación de la Ley parcial (83). Otro estudio halló un incremento del 8% en las tasas de cese del hábito tabáquico en los adultos mayores de 20 años al comparar datos de la Encuesta Nacional de Salud del 2006 con la del 2011 (92). En relación a variables incidentes, Guerrero *et al.* (2011) concluyeron que la mayoría de personas que habían dejado de fumar en 2006 no habían recaído en 2009 pero la ley parcial no tuvo efecto sobre la aparición de nuevas personas fumadoras en 2009 (87). Sin embargo, otro estudio del 2017 concluyó que tras la misma ley hubo un 6% de descenso en la tasa de iniciación en el hábito de fumar entre personas jóvenes (92), favoreciendo más los individuos de clases sociales altas.

*Estudios relacionados con la Ley integral:*

Un estudio realizado con datos de encuestas a la población general (Pérez-Ríos *et al.,* 2015) (103) no encontró descensos significativos en la prevalencia de personas fumadoras tras la Ley integral. Pero un estudio que proyectaba el efecto de esta ley para el periodo 2012-2025 preveía un descenso en la prevalencia de tabaquismo en todos los grupos de edad en ambos sexos excepto para mujeres con edades comprendidas entre los 40 y 64 años (109). Respecto a la prevalencia de personas ex fumadoras, Jiménez-Ruiz *et al*. (105) no hallaron aumentos importantes, con una diferencia de tan solo 0,3% entre encuestas poblacionales de 2007 y 2011.

*Estudios relacionados con ambas leyes en conjunto*:

El informe de la SEE del 2017 (37), basado en datos de la Encuesta Nacional de Salud , indicó un descenso absoluto promedio anual del 1,0% en la prevalencia de personas fumadoras en los hombres, mientras que en las mujeres se observó un incremento absoluto promedio anual de la

prevalencia del 0,2% durante el periodo 1987-2005. Durante el periodo de 2006 a 2014, la prevalencia de personas fumadoras disminuyó un 0,7% anual en los hombres y un 0,5% en las mujeres. El estudio de Lidón-Moyano *et al*. (2017) (44) reflejó que tras la implantación de las dos leyes en conjunto, decreció significativamente la prevalencia de personas fumadoras de 34,5% a 26,1%, en los adultos mayores de 15 años de Barcelona (entrevistados en 2004-2005 y seguidos en 2013–2014). Pero un estudio realizado también en adultos mayores de 15 años de Barcelona mediante encuestas obtenidas de dos periodos (2004-2005 y 2011-2012) halló un aumento de consumidores de tabaco de liar del 0,4% al 3,7% (107). En relación a la prevalencia de personas ex fumadoras, estas aumentaron más en las mujeres que los hombres, según el informe de la SEE del 2017 (37). Aquí se mostraba que la proporción de abandono del tabaco en los hombres aumentó un 0,9% anual durante el periodo de 1987 a 2014, mientras que en las mujeres el aumento fue del 1,5% tras la entrada en vigor de la Ley parcial.

**Patología respiratoria**

*Estudios relacionados con la Ley parcial*:

Un estudio que evaluó si los síntomas respiratorios (sibilancias, falta de aliento, tos, etc.) mejoraban tras un año de la aplicación de la ley parcial (Fernández *et al.,* 2009) (94) halló una disminución significativa del 71,9% en los trabajadores del sector de la hostelería en España. En lo referente a patología respiratoria, las tasas de ingresos por asma a cualquier edad en Barcelona y Madrid no cambiaron significativamente entre 2003 y 2006 según un estudio que utilizó modelos totalmente ajustados (Galán *et al*., 2015) (95). Este mismo estudio analizó los ingresos por EPOC observando una disminución significativa del 16% en Barcelona.

*Estudio relacionado con ambas leyes en conjunto:*

Galán *et al*. (2017) (108) encontraron que las tasas de ingreso hospitalario por asma aumentaron no significativamente un 12,1% inmediatamente después de la Ley parcial en cinco regiones españolas, pero disminuyeron en un 7,4% (IC 95%: 0,2, 14,2) inmediatamente después de la Ley integral, aunque la disminución anual solo se mantuvo entre los hombres (9,9%, IC 95%: 3.9, 15,6). En cambio, este mismo estudio observó disminuciones significativas en el periodo posterior a la Ley parcial (-14,3%) pero no tras la Ley integral (-0,9%, IC 95%: -4,4, 2,8) en los ingresos hospitalarios por EPOC.

**Patología cardíaca**

*Estudios relacionados con la Ley parcial:*

Tres estudios evaluaron el efecto de la Ley parcial en ingresos hospitalarios por enfermedad coronaria. Agüero *et al*. (2013) (98) encontraron una disminución significativa del 11% en las

tasas de incidencia de IAM en el período posterior a la prohibición en comparación con el período anterior en Cataluña, especialmente en las mujeres. En la ciudad de Barcelona, Villalbí *et al.* (2009) (96) analizaron las tasas anuales de hospitalización por IAM y encontraron tasas más bajas en 2006 que en 2005 para todos los grupos de edad, excepto en varones menores de 45 años, es decir, una disminución ajustada por edad del 10,68% en hombres y de 8,76% en mujeres en 2006 en comparación con 2004. Usando modelos completamente ajustados, Galán *et al*. (2015) (95) no detectaron cambios significativos en las tasas de ingreso hospitalario para IAM en Barcelona y Madrid en 2006 en comparación con el período anterior. Sin embargo, se observó un cambio significativo en la tasa de porcentaje del IAM de - 8,6% en Barcelona en comparación con el período anterior a la implementación de la Ley libre de humo.

*Estudio relacionado con ambas leyes en conjunto:*
Un estudio realizado en 14 provincias españolas estudió el impacto de las 2 leyes sobre ingresos hospitalarios por IAM y cardiopatía isquémica en personas de 18 años o más, entre 2003 y 2012 (108). Encontraron que al año de la implementación de la Ley parcial el cambio en hospitalizaciones fue -1,2% para IAM y 0,4% para cardiopatía isquémica. No encontraron asociaciones significativas tras un año de la Ley integral aunque sí en el periodo más inmediato a la ley, siendo de mayor magnitud que el cambio hallado inmediatamente tras la ley parcial (-2,3% vs -1,8% para IAM y -2,6% vs 0,1% para cardiopatía isquémica, respectivamente).

### 1.9. Atención Primaria y tabaquismo

Como se ha mencionado en el capítulo 1.2 sobre estrategias para combatir el tabaquismo activo y pasivo y en el capítulo 1.4 sobre el marco conceptual de una ley libre de humo, la APS juega un papel importante en el abordaje de la epidemia del tabaquismo por su accesibilidad, su función de puerta de entrada al sistema sanitario, su continuidad en la atención y por las intervenciones realizadas a la población (individuales, grupales o comunitarias). Un alto porcentaje de la población visita la APS y se estima que las personas que fuman lo hacen con una frecuencia mayor que las que no fuman (110). Estos hechos ofrecen una importante oportunidad para realizar prevención del tabaquismo en las personas no fumadoras, para promover la intención de dejar de fumar y proporcionar ayuda eficaz a quienes han decidido intentarlo (111). La labor de la APS dentro de este abordaje estaría relacionada con ofrecer ayuda para dejar de fumar, la estrategia *offer* (O) del paquete de medidas de reducción de la demanda de MPOWER.

### 1.9.1. Abordaje del tabaquismo desde Atención Primaria de Salud

La APS aborda el tabaquismo desde la prevención del hábito y promoción de la salud y desde el control mediante la deshabituación tabáquica. A su vez, estas dos acciones se pueden realizar mediante una intervención individual (por ejemplo, el consejo antitabaco en la consulta), grupal (talleres para dejar de fumar, paciente experto en tabaco) o comunitaria (educación en las escuelas). Además, los profesionales de APS pueden realizar investigación (112–114) o formación o estar incentivados económicamente en estos aspectos, lo cual favorece una mejor implantación de estas acciones. Algunas de estas intervenciones han surgido en el intervalo alrededor de la Ley integral 42/2010 y pueden haber influido en los cambios en el terreno del tabaquismo y sus consecuencias.

**Intervención individual**

Los profesionales de APS abordan el tabaquismo siguiendo las recomendaciones del Programa de Actividades Preventivas y Promoción de la Salud (PAPPS) (111), el Documento de Consenso para la Atención Clínica al Tabaquismo en España (110) y las guías de práctica clínica vigentes como la del *Institut Català de la Salut* (ICS) del 2009 (115). La promoción de la salud se focalizaría tanto la persona no fumadora reforzando su conducta como en la fumadora aconsejando y promoviendo el cese. En cambio, el control del tabaquismo se centraría en la persona fumadora mediante medidas encaminadas al cese del hábito tabáquico.

Las recomendaciones sobre el estilo de vida del PAPPS (116), proyecto de la Sociedad Española de Medicina de Família y Comunitaria (SEMFYC), aconsejan preguntar en cada visita por el consumo de tabaco a las personas mayores de 10 años y registrar el consumo en la historia clínica. La periodicidad mínima de esta detección debe ser de una vez cada 2 años. No es necesario reinterrogar a las personas mayores de 25 años en las que se tenga constancia en la historia clínica de que nunca han fumado.

El **consejo sanitario antitabaco** sistemático en las consultas de medicina y de enfermería es una actividad sencilla, coste-efectiva, breve, firme, clara y personalizada. Según el PAPPS, todas las personas fumadoras deben recibir consejo para el abandono del tabaco, debe ofrecérseles ayuda para dejar de fumar y se debe fijar un seguimiento mínimo durante las primeas semanas. La estrategia de las 5 Aes es la recomendada por este documento (Tabla 1.11). El **consejo telefónico por personal entrenado** (115) estaría dentro de una intervención mínima como el consejo breve pero su eficacia es similar a la de este último. En algunas regiones se facilita ayuda para la deshabituación tabáquica a personas con dificultades de acceso a las consultas mediante contacto telefónico (***quit-line***) con expertos que valoran la dependencia

y así iniciar una intervención individualizada con seguimiento. A veces estos contactos telefónicos acaban en las consultas de APS para iniciar tratamiento farmacológico o seguimiento por enfermería. Andalucía, Madrid y Cataluña son algunas de las comunidades que han implantado estos servicios (en Cataluña mediante 061 Catsalut respon: http://sem.gencat.cat/es/061CatSalutRespon/que_fem/ajuda_per_deixar_de_fumar/).

**Tabla 1.11. Estrategia de las 5 Aes para intervenir sobre tabaquismo desde Atención Primaria de Salud**

| | |
|---|---|
| **Averiguar** | Preguntar sobre los factores y las conductas de riesgo, así como sobre los aspectos que afectan a la elección o el cambio de la conducta |
| **Aconsejar** | Dar consejos claros, específicos y personalizados, e incluir información sobre los riesgos/beneficios personales |
| **Acordar** | Pactar colaborativamente los objetivos y los métodos más apropiados, basados en los intereses y en la capacidad para el cambio de la persona |
| **Ayudar** | Usar técnicas de modificación de la conducta (autoayuda o asesoramiento) para ayudar a la persona a conseguir los objetivos pactados adquiriendo las habilidades, la confianza y el apoyo social/ambiental que favorece el cambio junto con los tratamientos farmacológicos cuando sean adecuados |
| **Asegurar** | Fijar (asegurar) visitas de seguimiento (en el centro o telefónicas) para ayudar/apoyar y para ajustar el plan terapéutico como se necesite, incluida la derivación a unidades especializadas cuando sea necesario. |

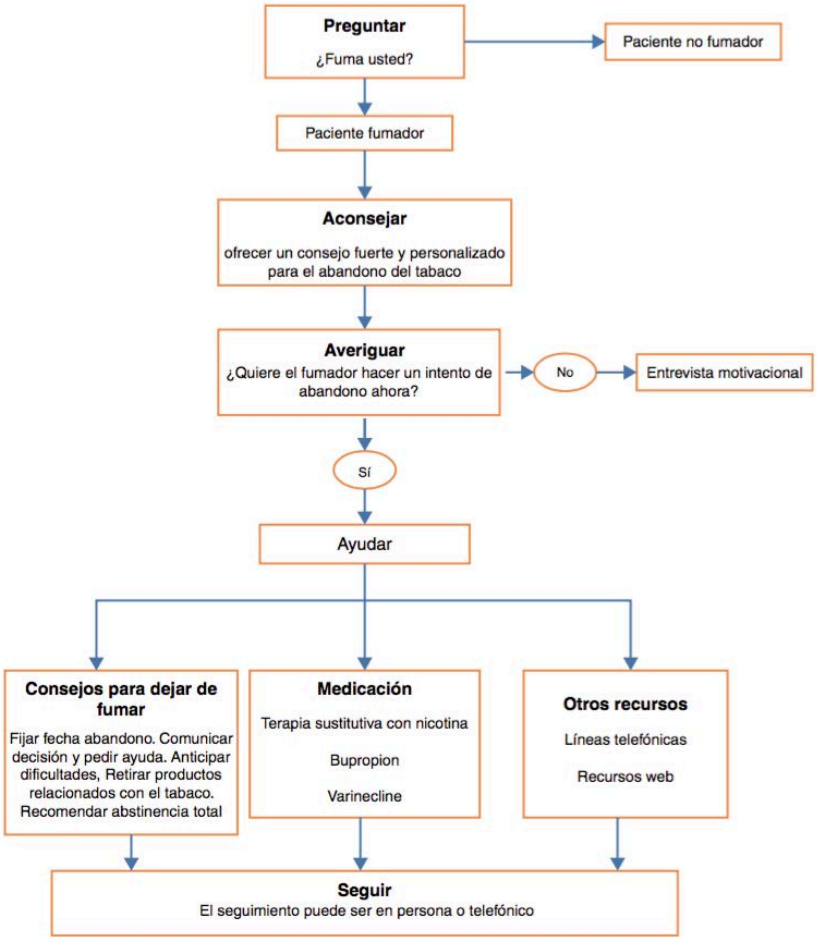
Fuente: Recomendaciones sobre el estilo de vida . Córdoba et al. 2016

La evidencia sobre la mejor manera de recomendar cambios en el estilo de vida en las consultas de APS ha ido aumentando en los últimos años (117). Aunque el grado de eficacia del consejo depende del tipo de cambio propuesto en el estilo de vida, las estrategias cognitivo conductuales han probado ser útiles: las intervenciones específicas más intensivas y las de mayor duración se asocian con mayor magnitud del beneficio y más cambios mantenidos en las conductas saludables. La **entrevista motivacional** es una forma específica de ayudar a las personas que desean realizar un cambio de hábitos y que tienen dudas frente a ello. A partir del diagnóstico de la situación de la persona frente al cambio, se desarrollan una serie de habilidades adaptadas a la situación en la que se encuentra. Para ello se ha de conocer la importancia (motivación) que tiene la persona para dejar de fumar y la confianza (autoeficacia) que tiene en conseguirlo, y de esta manera saber sobre qué aspecto hay que incidir. El elemento fundamental de la entrevista es hacer fuertes los elementos internos favorecedores del cambio de cada persona en una atmósfera positiva y no coercitiva: si está en disposición de hacer un intento serio en ese momento, ayudarle; si ya ha dejado de fumar, felicitarle y reforzarle (116,118).

En las figuras 1.10 y 1.11 se muestran unos esquemas de la intervención en la consulta sobre el paciente fumador según su deseo de abandono del tabaco, siguiendo las recomendaciones del Documento de Consenso para la Atención Clínica al Tabaquismo en España (110). La intervención sistematizada para ofrecer ayuda para dejar de fumar consiste en ofrecer apoyo con

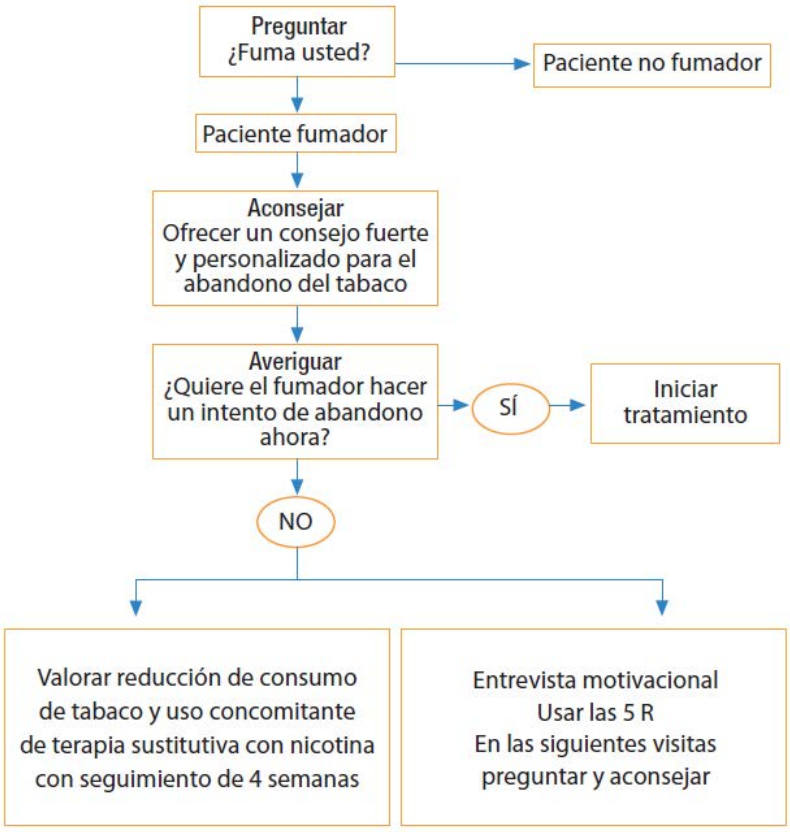
la terapia más adecuada, conductual, farmacológica (terapia sustitutiva de nicotina, bupropion y vareniclina) o una combinación de ambas. La vareniclina tuvo un retraso en su uso debido a comunicados sobre eventos neuropsiquiátricos que después no han sido por una revisión sistemática (119).

**Figura 1.10. Intervenciones en el paciente fumador que quiere hacer un intento de abandono del tabaco en el momento de la visita.**




Fuente: Documento de Consenso para la Atención Clínica al Tabaquismo. Camarelles *et al*. 2013

**Figura 1.11. Intervenciones en el paciente fumador que no quiere hacer un intento de abandono del tabaco en el momento de la visita**




Fuente: Documento de Consenso para la Atención Clínica al Tabaquismo. Camarelles *et al*. 2013. 5 R: Relevancia para el paciente, Riesgos de este paciente, Recompensas personales, Resistencias personales y Repetición del mensaje motivacional.

Otra estrategia novedosa para conseguir el cese del hábito tabáquico es el **uso de las tecnologías de la información y la comunicación** (TIC) como las aplicaciones móviles, el envío de mensajes de texto al móvil y de correo electrónicos que han sido la base de estudios recientes publicados en el ámbito de la APS con resultados esperanzadores (112–114).

**Intervención grupal**

La atención a la demanda de deshabituación tabáquica de la población fumadora también se puede llevar a cabo a través del personal de enfermería o medicina mediante **talleres grupales** de deshabituación en los centros de salud (120). Estos proporcionan la oportunidad de aprender técnicas conductuales para dejar de fumar y obtener el apoyo de otros participantes. Pretenden orientar y reforzar la intervención recibida en la consulta y favorecer la interacción entre personas que comparten un mismo problema. El grupo permite intercambiar conocimientos, opiniones y experiencias. La intervención es un programa multicomponente que comprende tres fases sucesivas: una preliminar de preparación, la fase central de abandono del tabaco y una fase

final de mantenimiento de la abstinencia. Como elementos facilitadores se utilizan técnicas motivacionales y conductuales, tratamiento farmacológico si la dependencia física al tabaco es alta, desarrollo de habilidades conductuales que permitan resistir la presiones sociales que perpetúan el consumo o que incitan a la experimentación y técnicas de mantenimiento de la abstinencia o de prevención de la recaída (121).

Otra modalidad de realizar intervención grupal es mediante la figura del **paciente experto** en tabaco. Estos programas de educación utilizan a personas fumadoras que entienden su dependencia, se responsabilizan de su salud y manejan correctamente las opciones terapéuticas marcadas por sus sanitarios. Si además tienen dotes comunicativas y empatía, una vez formadas y asesoradas, pueden liderar grupos de personas fumadoras de forma eficaz, ya que trasmiten la información con el mismo lenguaje, desde la misma experiencia y con dificultades parecidas para dejar de fumar que otras personas. Los pacientes expertos llevan la iniciativa de su formación y los profesionales sanitarios tienen un papel observador, orientador y resolvente de dudas (122). Al igual que la intervención grupal mencionada anteriormente, esta iniciativa también es multifactorial y multidisciplinaria, basada en la colaboración y en el trabajo de equipo, proponiendo una estrategia proactiva para fomentar la confianza y la motivación de las personas fumadoras (123).

**Intervención comunitaria**

La APS también participa en intervenciones comunitarias de promoción de la salud. Son iniciativas centradas y adaptadas a las características y las necesidades de salud de la comunidad. Esta atención se puede llevar a cabo a través del personal de enfermería o de medicina mediante iniciativas comunitarias, como la Semana sin humo, o información en centros educativos o para la comunidad (124). La promoción de la salud y la prevención de la enfermedad se llevan a cabo mediante la información general de la sustancia consumida y de conductas positivas de salud. Las principales estrategias para prevenir el consumo de tabaco en los jóvenes deben incluir la actuación tanto en la escuela como en la comunidad donde está insertada (125). La SEMFYC, a través del Grupo de abordaje del tabaquismo, ha llevado a cabo dos intervenciones comunitarias como la Semana sin humo y la creación del Programa de Atención Primaria sin humo (126). La Semana sin humo incluye un conjunto de actividades de información a la población, oferta terapéutica y actividades comunitarias en escuelas, centros cívicos, etc. El Programa de Atención Primaria sin humo propone actividades de sensibilización y formación a los profesionales y actuaciones dirigidas a la población.

**Abordaje del tabaquismo en Atención Primaria en Cataluña, Navarra e Islas Baleares**

La implementación de las leyes sin humo ha favorecido que en algunas regiones de España se promocionen servicios de deshabituación a través de la red de los centros de Atención Primaria (CAP). El "Informe a las Cortes Generales de evaluación del impacto sobre la salud pública de la Ley 42/2010" (99) referente a los años 2011-2012 y el "II Informe a las Cortes Generales de evaluación del impacto sobre la salud pública de la Ley 42/2010. Periodo 2011-2014" (100) realizado en 2016 informaron sobre la utilización de los servicios de deshabituación. En la tabla 1.12 se especifican las intervenciones realizadas en deshabituación en APS de Cataluña, Navarra e Islas Baleares por ser las comunidades autónomas que se han evaluado en esta tesis.

**Tabla 1.12. Asistencia y utilización de los servicios de deshabituación tabáquica en Atención Primaria**

| | |
|---|---|
| **2011-2012** | |
| **Cataluña** | Red de Atención Primaria Sin Humo (Programa Atenció Primaria Sense Fum-pAPSF): cubre la totalidad de los centros de salud (357). En cada centro 1 o 2 referentes formadores del resto del equipo (En total, 576 profesionales referentes).<br>Financiación del tratamiento farmacológico para los profesionales y para los pacientes que pertenecen a zonas desfavorecidas, definidas por el programa marco "Salut als barris". www.papsf.cat<br>Entre 2011 y 2012, se han registrado 68.750 nuevas personas ex fumadoras en el último año. [Fuente: extrapolación a partir de datos de Historia Clínica de ICS (80% de la atención primaria).<br>Tratamientos farmacológicos en 2011 en: "Salut als Barris": 371<br>Profesionales sanitarios que recibieron tratamiento farmacológico: 260 |
| **Navarra** | Registros nuevas personas fumadoras 7.708 en 2011.<br>Personas fumadoras que han acudido a los centros de salud 21.384.<br>Personas fumadoras que han recibido cualquier tipo de apoyo (CS/API/APG) 11.251.<br>Personas ex fumadoras registradas 11.862.<br>Personas ex fumadoras que han recibido CS, API o PAG 5.568 |
| **Islas Baleares** | Todos los centros de salud de las Islas Baleares atienden a los pacientes fumadores en los diferentes niveles del tratamiento: intervenciones mínimas, breves y avanzadas o intensivas, individual y grupal. Los criterios de derivación a cualquiera de los tratamientos depende del diagnóstico del paciente fumador y en función del modelo transteórico de la fase o proceso del cambio de Prochaska y DiClemente.<br>No existe financiación de tratamiento farmacológico. |
| **2011-2014** | |
| **Cataluña** | Todos los centros de APS de Catalunya (372 centros) están integrados en el Programa de Atención Primaria sin Humo, y cuentan con un profesional referente en prevención y tratamiento del tabaquismo. Las personas atendidas en estos centros reciben gratuitamente consejo sanitario y eventualmente pueden beneficiarse de otras intervenciones terapéuticas (como el tratamiento farmacológico o la participación en grupos de discusión) para dejar de fumar.<br>Nuevas personas ex fumadoras atendidas en centros de atención primaria: 77.527 en 2013 y 67.070 en 2014. |
| **Navarra** | No informe |
| **Islas Baleares** | No informe |

Fuente: Elaboración propia a partir del Informe a las Cortes Generales de evaluación del impacto sobre la salud pública de la Ley 42/2010 (99) referente a los años 2011-2012 e II Informe a las Cortes Generales de evaluación del impacto sobre la salud pública de la Ley 42/2010 Periodo 2011-2014 (100). Abreviaturas: API Atención Programada Individual; APG Atención Programada Grupal; APS Atención Primaria de Salud; CS Consejo breve Sistematizado; ICS Institut Català de la Salut.

### 1.10. La historia clínica informatizada en Atención Primaria de Salud y su utilidad en la investigación

La informatización de la historia clínica es una herramienta que refleja las tareas asistenciales, administrativas o de gestión, actividades de fármaco-vigilancia, etc. Los registros electrónicos de APS son una fuente fiable de datos como se ha documentado en estudios ingleses de la *General Practice Research Database* (127,128) y estudios españoles (129,130). Por otra parte, la mayoría de centros de APS tienen entre sus estrategias de incentivación anual el seguimiento del hábito tabáquico y codificación de diferentes diagnósticos relevantes (asma, enfermedad coronaria). La inclusión del consumo de tabaco como uno de los signos vitales identifica al 80% o más de las personas fumadoras que visitan las consultas de APS (110). Así pues, la amplia cobertura poblacional, el seguimiento continuado de la población y la visión holística de los procesos asistenciales hacen que la información del hábito tabáquico y de diagnósticos clínicos obtenida en APS sea una buena y actualizada aproximación a la información poblacional.

La APS ofrece un gran sistema de información con datos de la historia clínica informatizada que potencia la investigación de calidad, fomenta la evaluación sanitaria y mejora la gestión clínica mediante la creación de nuevo conocimiento (131). En el caso de Cataluña, la mayoría de los profesionales de APS usan el mismo programa de historia clínica informatizada (e-CAP) desde 2005.

Las bases de datos de APS aportan además seguimientos largos con un coste inferior al de los estudios de cohortes o casos y controles; se relacionan con otras fuentes de información (altas hospitalarias, certificados de mortalidad, datos del censo), que permiten que esta sea más rica y completa; no supone una participación activa del paciente cuando se recoge la información y los datos son muy representativos de la práctica clínica real (131).

### 1.11. Justificación

Al inicio del siglo XXI, algunos gobiernos europeos y americanos, impulsados por el CMCT de la OMS, legislaron acciones concretas para controlar la epidemia del tabaquismo. Entre estas acciones se encontraba la prohibición de fumar en espacios públicos cerrados a fin de proteger la salud de las personas trabajadoras y las personas no fumadoras (33). En España, la aplicación de una legislación libre de humo ha sido un objetivo prioritario de salud debido a la alta prevalencia de exposición al tabaco y de tabaquismo activo existente. En 2006, se aplicó una Ley libre de humo parcial (Ley 28/2005) (80), que prohibía fumar en centros de trabajo y en determinados locales de la hostelería pero en el caso de establecimientos de restauración cerrados, con una superficie útil igual o superior a 100 metros cuadrados, la ley permitía habilitar zonas donde se permitía el consumo de tabaco y en el caso de locales menores a 100 metros cuadrados el propietario decidía si permitía fumar o no. Esta ley se vio reforzada 5 años más tarde con una reforma, la Ley 42/2010 (81) al prohibir completamente fumar en espacios cerrados. Algunos estudios han analizado el impacto de estas dos leyes españolas sobre la prevalencia del tabaquismo. Sin embargo, la mayoría se han basado en encuestas de salud y en encuestas a trabajadores de la hostelería (44,91,93,103). Los resultados de estos estudios a menudo son contradictorios; mientras que algunos concluyen que la legislación libre de humo española 28/2005 no tuvo ningún efecto sobre la tendencia descendente en la prevalencia de personas fumadoras (82,103), otros estudios muestran diferencias en las tasas de abandono tabáquico en estudios antes-después (44,91). Hasta donde sabemos, solo se ha publicado un estudio sobre el impacto en hábito tabáquico en personas adultas atendidas en APS, pero era referente a la Ley parcial y se restringía a población trabajadora activa de nueve zonas básicas de salud de dos ciudades españolas (83). La evaluación de una política desde la APS brinda información relevante al ser uno de los servicios donde se hace mayor hincapié en la promoción de la salud y desempeña un papel clave en el control del consumo de tabaco. Los datos de España muestran que en algunas zonas más del 75% de la población asiste a una consulta de APS una vez al año (110). Además, la implantación de estas leyes produjo el desarrollo de distintas actividades que promovían la cesación del hábito tabáquico en la APS, como la formación a profesionales sanitarios, financiación de los tratamientos farmacológicos para dejar de fumar en los profesionales sanitarios y pacientes, intervenciones comunitarias, etc (100). Estos hechos proporcionan una oportunidad única para la intervención y prevención en un gran número de personas de la población. Por este motivo, el primer objetivo de la tesis será analizar el impacto de la Ley integral en la prevalencia e incidencia del tabaquismo en personas adultas atendidas en APS en tres regiones (Cataluña, Navarra y Baleares).

A consecuencia de la disminución de la exposición del humo de segunda mano y del tabaquismo activo debido a las leyes sin humo se deberían observar disminuciones en ingresos o en la incidencia/prevalencia de enfermedades relacionadas con el tabaco como la enfermedad

coronaria aguda y el asma en la población. Los efectos de las legislaciones libres de humo se han evaluado en enfermedades cardíacas con un claro beneficio tras la implantación de estas leyes (40,72,132). Sin embargo, en salud respiratoria, incluido el asma, la EPOC y la función pulmonar los efectos no son concluyentes según la bibliografía actual (40,63). Tampoco existe una revisión bibliográfica previa que se focalice en sintomatología y patología respiratoria y sensorial en todas las poblaciones con meta-análisis. Por ello, el segundo objetivo de esta tesis será sintetizar la evidencia disponible en los artículos científicos de los efectos de la legislación libre de humo sobre las enfermedades respiratorias, la función respiratoria y los síntomas sensoriales y respiratorios en toda la población mediante una revisión sistemática y meta-análisis.

Los estudios que analizaron el efecto de la Ley parcial 28/2005 en España sobre los ingresos hospitalarios por asma y enfermedad coronaria mostraron una disminución en la incidencia de enfermedad coronaria y resultados no concluyentes para el asma. Según nuestro conocimiento, no se han publicado estudios sobre el impacto de la Ley 42/2010 sobre el asma y la enfermedad cardíaca en el contexto de la APS. En este nivel asistencial se observa frecuentemente el efecto en salud del tabaco en fases más iniciales pero, también, en personas con importante carga de morbilidad. Por ello, el tercer objetivo de esta tesis será evaluar la tendencia en la incidencia y prevalencia de enfermedad asma y coronaria aguda en esta población en relación a la Ley integral.

# 2. HIPÓTESIS

Las tres hipótesis de esta tesis son:

**Hipótesis 1**. La aplicación de la Ley 42/2010 puede influir en disminuir la incidencia y prevalencia de personas fumadoras así como un aumento de la prevalencia e incidencia de personas ex fumadoras atendidas en Atención Primaria de Salud tras tres años de su implantación.

**Hipótesis 2**. La aplicación de las legislaciones libres de humo puede influir en disminuir los ingresos/incidencia o prevalencia de enfermedades y mortalidad respiratorias, además de influir en mejorar la sintomatología respiratoria y sensorial y la función pulmonar en todas las poblaciones (infantil, adulta, general y trabajadora).

**Hipótesis 3.** La aplicación de la Ley 42/2010 puede influir en disminuir la incidencia y prevalencia de enfermedad coronaria aguda y de asma en personas adultas atendidas en Atención Primaria de Salud tras tres años de su implantación.

# 3. OBJETIVOS

El objetivo principal de esta tesis es examinar el impacto de las leyes libres de humo en hábito tabáquico y algunas patologías relacionada con el tabaco centrado en Atención Primaria de Salud. Los tres objetivos secundarios de esta tesis son:

**Objetivo 1**. Analizar el impacto de la Ley 42/2010 en la prevalencia e incidencia del tabaquismo en personas adultas atendidas en Atención Primaria de Salud en tres regiones (Cataluña, Navarra y Baleares) durante el período 2008-2013, en global y estratificado por sexo.

**Objetivo 2**. Sintetizar la evidencia disponible publicada en artículos científicos de los efectos de la legislación libre de humo sobre las enfermedades respiratorias (asma, enfermedad pulmonar obstructiva crónica, infección pulmonar), mortalidad respiratoria y los síntomas sensoriales y respiratorios (tos, flema, ojos rojos, secreción nasal) en todas las poblaciones (infantil, adulta, general y trabajadora).

**Objetivo 3**. Examinar el impacto de la Ley 42/2010 sobre la incidencia y la prevalencia de asma y de enfermedad coronaria en personas adultas atendidas en Atención Primaria de Salud en tres regiones (Cataluña, Navarra y Baleares) durante el período 2007-2013, en global y estratificado por sexo.

Cada objetivo secundario se aborda en un artículo científico diferente.

# 4. ARTÍCULOS CON RESOLUCIÓN FAVORABLE DE LA COMISIÓN ACADÉMICA DEL PROGRAMA DE DOCTORADO EN MEDICINA

## 4.1. Listado de artículos

**Artículo 1**- Pons-Vigués M, Rando-Matos Y, Rodriguez-Blanco T, Ballvé-Moreno JL, Ripoll J, Llobera J, Morán J, López-Jiménez T, Violán C, Bolibar B. Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study. BMJ Open 2019 Mar 3;9(3):e020120. doi:10.1136/bmjopen-2017-020120.

**Artículo 2**- Rando-Matos Y, Pons-Vigués M, López MJ, Córdoba R, Ballve-Moreno JL, Puigdomènech-Puig E, Benito-López VE, Arias-Agudelo OL, López-Grau M, Guardia-Riera A, Trujillo JM, Martin-Cantera C. Smokefree legislation effects on respiratory and sensory disorders: A systematic review and meta-analysis. PLoS One. 2017 Jul 31;12(7):e0181035. doi:10.1371/journal.pone.0181035.

**Artículo 3**- Rando-Matos Y, Pons-Vigués M, Rodriguez-Blanco T, Ripoll J, Llobera J, Morán J, Ballvé-Moreno JL, Violán C, Bolibar B. Effect of comprehensive smoke-free legislation on asthma and coronary disease trends in Spanish primary care patients. Eur J Public Health. 2018 Jun 1:28(3): 553-559. doi: 10.1093/eurpub/cky01.

### 4.1.1. Artículo 1: Effect of the comprehensive smoke-free law on time trends in smoking behaviour in Primary Health Care patients in Spain: a longitudinal observational study

Enlace al artículo:
https://bmjopen.bmj.com/content/9/3/e020120

Pons-Vigués M, Rando-Matos Y, Rodriguez-Blanco T*, et al*. Effect of the comprehensive smoke-free law on time trends in smoking behaviour in primary healthcare patients in Spain: a longitudinal observational study. *BMJ Open* 2019;**9:**e020120. doi: 10.1136/bmjopen-2017-020120

BMJ Open

# Effect of the comprehensive smoke-free law on time trends in smoking behaviour in primary healthcare patients in Spain: a longitudinal observational study

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## ABSTRACT

**Objective** This study aimed to analyse the impact of comprehensive smoke-free legislation (SFL) on the prevalence and incidence of adult smoking in primary healthcare (PHC) patients from three Spanish regions, overall and stratified by sex.

**Design** Longitudinal observational study conducted between 2008 and 2013.

**Setting** 66 PHC teams in Catalonia, Navarre and the Balearic Islands (Spain).

**Participants** Population over 15 years of age assigned to PHC teams.

**Primary and secondary outcomes measures** Quarterly age-standardised 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-standardised prevalence and incidence rates. Trends were expressed as annual percentage change and average annual percent change.

**Results** The overall standardised smoker prevalence rate showed a significant downward trend (higher in men than women) and the overall standardised ex-smoker prevalence rate showed a significant increased trend (higher in women than men) in the three regions. Standardised 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 in smoking behaviour in PHC patients remain unchanged after the implementation of comprehensive SFL. The impact of the comprehensive SFL might have been lessened by the effect of the preceding partial SFL.

## 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 healthcare 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.

## INTRODUCTION

Smoking is the leading worldwide cause of preventable death.[1] According to 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 programmes.[3]

Some studies show a decrease in smoking prevalence since the introduction of smoke-free legislation (SFL).[4–9] A meta-analysis of 26 studies on the effect of the smoke-free workplace in various countries concluded in 2002 that smoke-free workplaces protect non-smokers from the dangers of passive smoking, and they encourage smokers to reduce tobacco consumption. The authors concluded that SFL is associated with a

3%–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 1 January 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 at 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, that is, in bars or restaurants smaller than 100 $m^2$ 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 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 PHC patients evaluates the impact of the Spanish partial SFL, including smoking prevalence in active smoker workers that attended PHC visits; 1 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 hypothesised that Law 42/2010 does reduce exposure to environmental cigarette smoke and its harmful effects and 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

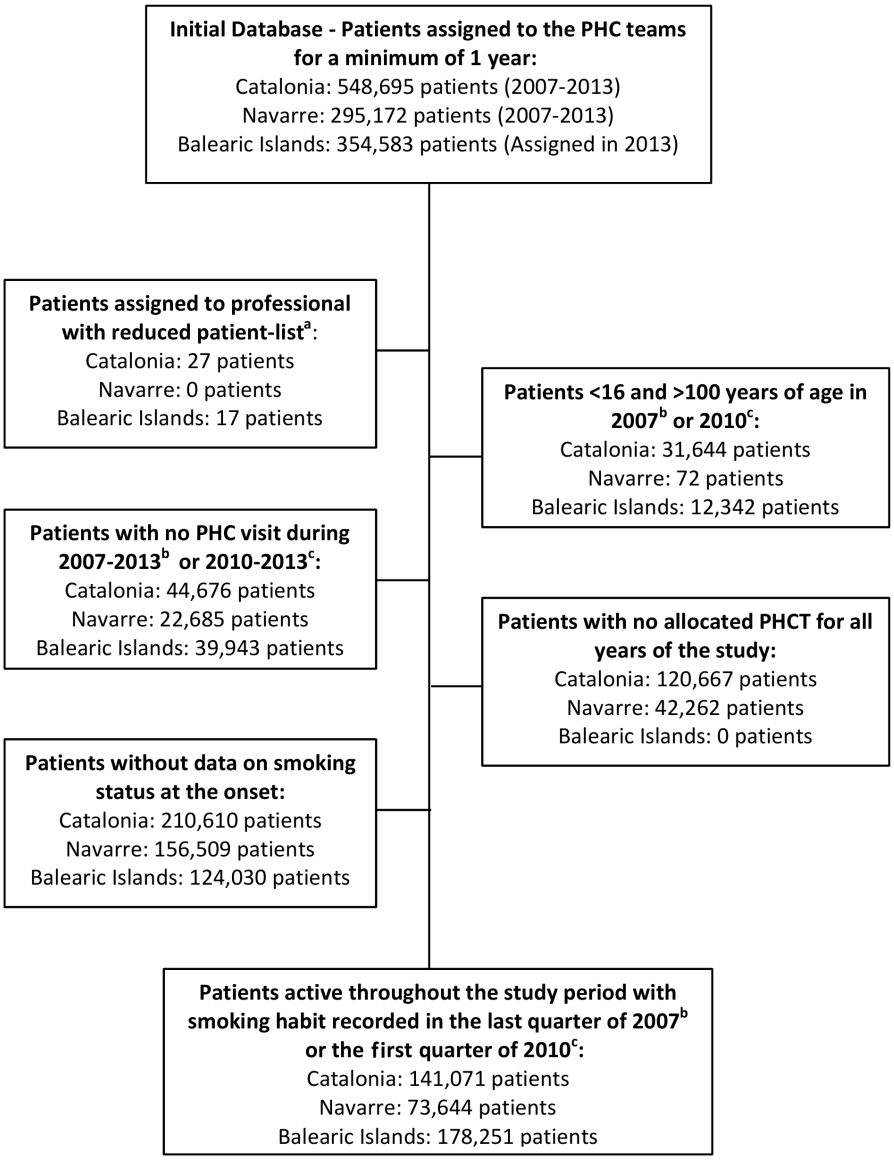
### Design, study participants and information source

Longitudinal observational study of the adult population assigned to 66 PHC teams (PHCTs) in three Spanish regions: Catalonia, Navarre and the Balearic Islands (22 PHCTs per region). Inclusion criteria of the PHCTs were: (1) Computerisation of electronic health records (EHRs) by 1 January 2005 in Catalonia and Navarre, and 2008 in the Balearic Islands. (2) Agreement to participate in the study by over 80% healthcare professionals working in each PHCT. Random cluster sampling was stratified by region, with PHCT as randomisation unit.[26] In each PHCT, general practitioners (GPs) with a patient list between 400 and 3000 were selected. GPs 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 years 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. (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 flow chart of the study.

Data were retrieved from the Registry of Preventive Services in Primary Care (REGIPREV) database,[26] which contains encrypted and anonymised clinical information recorded in the EHR by these 66 PHCTs. 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.




*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 healthcare team*
[b] In Catalonia or Navarre
[c] In the Balearic Islands
PHC: Primary healthcare

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

Codes of the International Classification of Diseases, ninth revision in the Balearic Islands (ICD-9) and tenth in Catalonia (ICD tenth 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 EHRs 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 (online 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. (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 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 the said quarter.

New ex-smoker: the patient was a smoker 2 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 the 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 summarise overall information. Categorical variables were expressed as percentage, and continuous variables as mean (SD) or median (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-standardised 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-standardised 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 summarise and compare these trends over the entire time period. Because the outcomes originate from repeated measurements, control for the autocorrelation errors was used; 95% CIs 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 V.14.2 for Windows (Stata Corp, College Station, Texas, USA). The Joinpoint regression analysis was carried out using the Joinpoint software from the Surveillance Research Programme of the US National Cancer Institute (ref. Joinpoint Regression Program, V.4.6.0. April, 2018; Statistical Research and Applications Branch, National Cancer Institute) (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 in 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 years in Navarre and 47.7 years 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).

The *overall standardised 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 (online supplementary file table 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 and 2013.4 (APC=−1.44) (tables 2, 3 and 4, online supplementary file figure S1).

For the whole period, the *overall standardised 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 standardised

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 (%) | 72 340 (51.28) | 37 898 (51.46) | 94 164 (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) |

Patients belonged to 22 primary healthcare teams in each region.
Abbreviations: SD, standard deviation; IQR, interquartile range.

ex-smoker prevalence rates were higher for men than for women in all regions (online supplementary file table 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 and 4, online supplementary file figure S1).

The *overall new smoker standardised 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 (online supplementary file table 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 and 4, online supplementary file figure S2).

The *overall standardised 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) (online supplementary file table 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 and 4, online supplementary file figure S2).

The *overall standardised 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) (online supplementary file table 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 and 4, online supplementary file figure S2).

## 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 2010.2–2012.2 in the Balearic Islands. Even though the standardised 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 (third quarter) and the Balearic Islands and in 2008 in Navarre, prior to the implementation of the comprehensive SFL (1 January 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

**Table 2** Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse for age-standardised rates. Joinpoints overall and by sex in Catalonia; n=141 071 (2008–2013)

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

Note: 2008.1 represents the first trimester of the year 2008
*p>0.05; †p≤0.01; ‡p≤0.001; §p≤0.05.
APC, annual percentage change; AAPC, average annual percent change estimated by Joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.

**Table 3** Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse for age-standardised rates. Joinpoints overall and by sex in Navarre; n=73 644 (2008–2013)

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

*p≤0.001; †p≤0.05; ‡p≤0.01; §p>0.05
Note, 2008.1 represents the first trimester of the year 2008.
APC, annual percentage change; AAPC, average annual percent change estimated by Joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.

**Table 4** Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse for age-standardised rates. Joinpoints overall and by sex in the Balearic Islands; n=178 251 (2010–2013)

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

*p≤0.001; †p≤0.01; ‡p>0.05; §p≤0.05.
Note, 2010.1 represents the first trimester of the year 2010.
APC, annual percentage change; AAPC, average annual percent change estimated by Joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.

use different methodologies. Two studies that analysed data from surveys of 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 SFLs, 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 years.[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 an 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 computerisation 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 USA observed that relapse was similar between employees in workplaces with SFL and employees where smoking was permitted.[36] In contrast, Shang found that comprehensive SFL in bars significantly deters smoking relapse among people aged 21 years 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] 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 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 are 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 maximise the internal validity of the study. Moreover, young people might be under-represented 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. PHC 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, EHRs portray real life conditions and provide comprehensive, long-term health histories from a large population sample, ensure high representativeness and external validity, and minimise potential recall bias. The results are only generalisable to PHC users. To our knowledge, this study is among the first to show quarterly data from EHRs.

## 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 socioeconomic status and age groups.

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**Competing interests** None declared.

**Patient consent for publication** Not required.

**Ethics approval** 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 anonymisation in agreement with the data confidentiality Law 15/1999.

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**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<br>(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<br>(with entry date)</td><td colspan="3">Smoking habit:<br>0: non-smoker.<br>1: smoker.<br>2: ex-smoker</td></tr>
<tr><td colspan="3">Number of cigarettes per day:<br>0 to 300</td></tr>
<tr><td colspan="3">Smoking cessation advice:<br>1: yes<br>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**

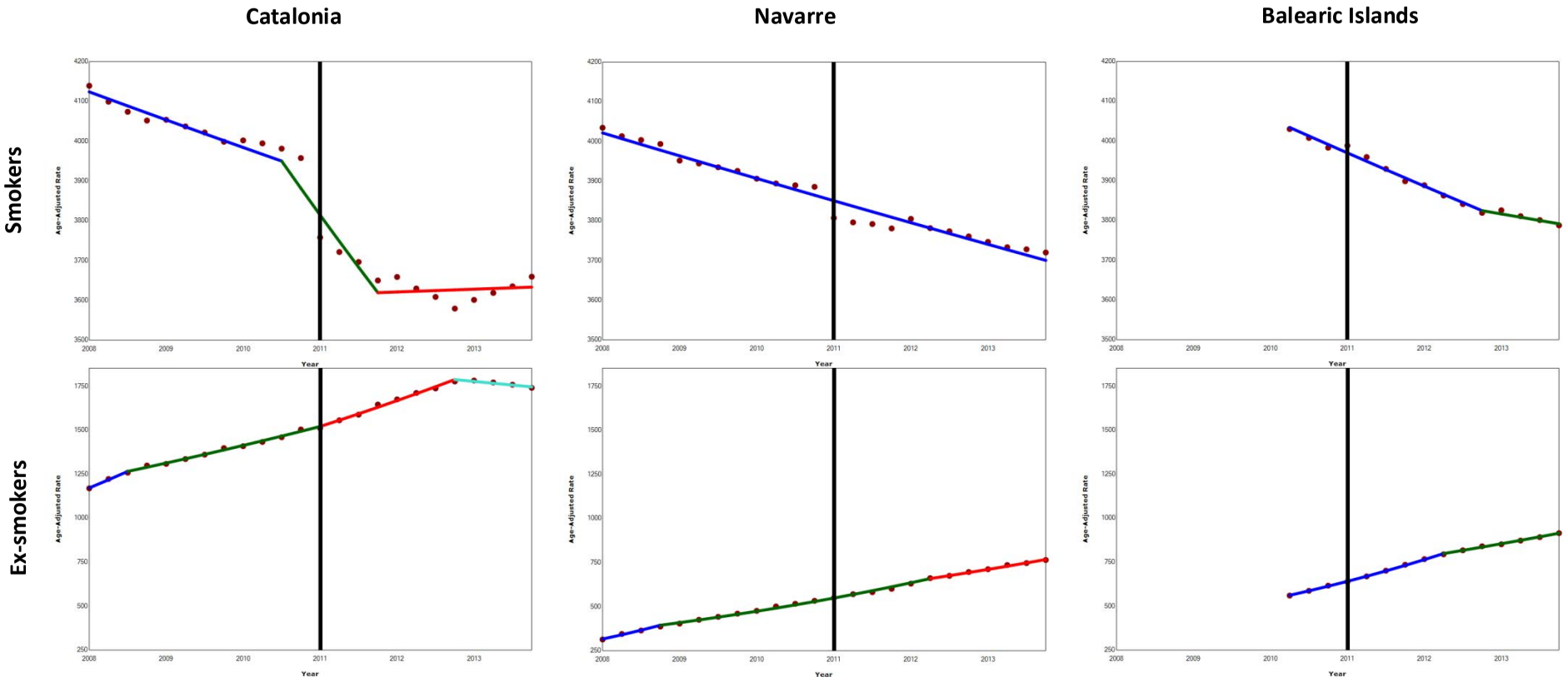


**Figure S1: Overall trends of age-standardized prevalence rates of smoking status in Catalonia, Navarre and the Balearic Islands.**
Solid lines represent the Joinpoint regression lines (each colour is a different trend); circle red points represent the age-adjusted prevalence rates. Black vertical lines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

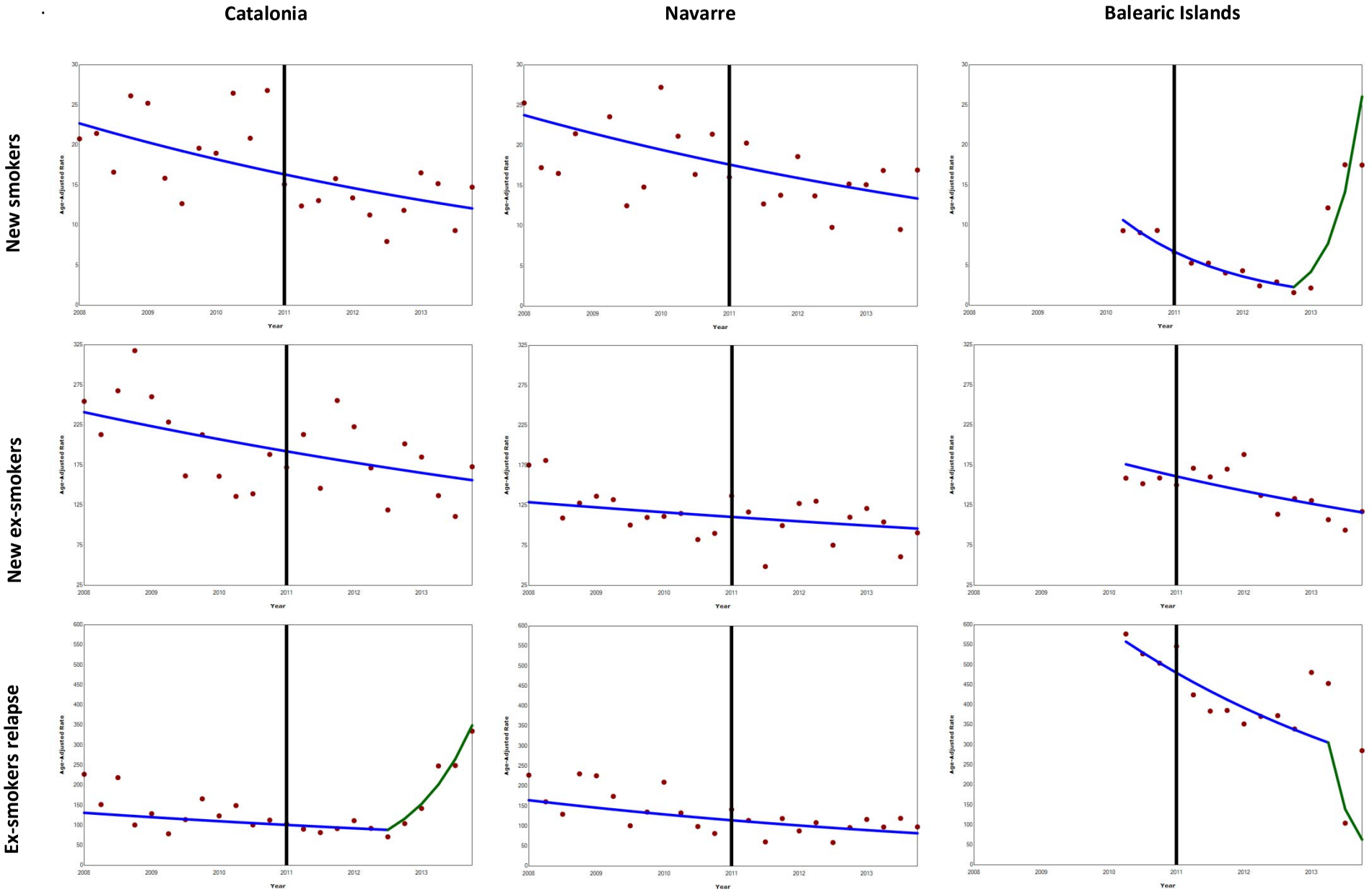


**Figure S2: Overall trends of age-standardized incidence rates of new smokers, ex-smokers and ex-smoker relapse in Catalonia, Navarre and the Balearic Islands.** Solid lines represent the Joinpoint regression lines (each colour is a different trend); circle red points represent the age-adjusted incidence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

### 4.1.2. Artículo 2: Smokefree legislation effects on respiratory and sensory disorders: A systematic review and meta-analysis

Enlace al artículo: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0181035

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PLOS ONE

RESEARCH ARTICLE

# Smokefree legislation effects on respiratory and sensory disorders: A systematic review and meta-analysis

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## Abstract

### Aims

The aim of this systematic review and meta-analysis is to synthesize the available evidence in scientific papers of smokefree legislation effects on respiratory diseases and sensory and respiratory symptoms (cough, phlegm, red eyes, runny nose) among all populations.

### Materials and methods

Systematic review and meta-analysis were carried out. A search between January 1995 and February 2015 was performed in PubMed, EMBASE, Cochrane Library, Scopus, Web of Science, and Google Scholar databases. Inclusion criteria were: 1) original scientific studies about smokefree legislation, 2) Data before and after legislation were collected, and 3) Impact on respiratory and sensory outcomes were assessed. Paired reviewers independently carried out the screening of titles and abstracts, data extraction from full-text articles, and methodological quality assessment.

funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Competing interests:** The authors have declared that no competing interests exist.

## Results

A total number of 1606 papers were identified. 50 papers were selected, 26 were related to symptoms (23 concerned workers). Most outcomes presented significant decreases in the percentage of people suffering from them, especially in locations with comprehensive measures and during the immediate post-ban period (within the first six months). Four (50%) of the papers concerning pulmonary function reported some significant improvement in expiratory parameters. Significant decreases were described in 13 of the 17 papers evaluating asthma hospital admissions, and there were fewer significant reductions in chronic obstructive pulmonary disease admissions (range 1±36%) than for asthma (5±31%). Six studies regarding different respiratory diseases showed discrepant results, and four papers about mortality reported significant declines in subgroups. Low bias risk was present in 23 (46%) of the studies.

## Conclusions

Smokefree legislation appears to improve respiratory and sensory symptoms at short term in workers (the overall effect being greater in comprehensive smokefree legislation in sensory symptoms) and, to a lesser degree, rates of hospitalization for asthma.

## Introduction

Passive exposure to tobacco smoke (also known as exposure to environmental tobacco smoke, second-hand smoke, and passive smoking) multiplies the risk of coronary disease and lung cancer in adults. It also exacerbates asthma and respiratory symptoms, and increases the risk of sudden infant death syndrome amongst other health effects[1]. All of the above has led to legislative measures being adopted in order to protect the population's health in public areas and workplaces[2]. In 1998, in the United States, California was the first to put into practice these measures[3,4], and from 2004 all the members of the European Union have adopted some kind of regulation[5]. There are different types of smokefree legislation (SFL): comprehensive (smoking is prohibited in all closed public areas and workplaces including public transport, bars, and restaurants) and partial (smoking is allowed in some private workplaces, for instance in the hospitality and entertainment sectors)[6]. Numerous studies have been published evaluating the impact of SFL from different perspectives: reduction of exposure to second-hand smoke[7], prevalence of tobacco use (no consistent evidence of a reduction attributable to SFL)[8], cardiovascular mortality (studies related to cardiovascular mortality have conflicting results possibly due to the quality of some of these papers)[9±12], cardiovascular morbidity (consistent evidence of reductions in cardiac events and hospitalizations following implementation of SFL)[13±19], and economic impact (SFL does not adversely affect business revenues or operating costs)[20] amongst others. Most systematic reviews have evaluated cardiovascular effects[15±19], tobacco consumption[8], exposure to second-hand smoke [7], and, in a more heterogeneous manner, respiratory diseases at population levels[8,21]. This last issue is, to the best of our knowledge, the least studied field.

A meta-analysis concerning the impact of banning smoking in the workplace concluded that the measure protected non-smokers from passive exposure and encouraged smokers to reduce their consumption[22]. A Cochrane Review from 2010 with 12 studies found that in ten of them legislation decreased respiratory symptoms in workers, some of the studies only assessed non-smokers[8]. A review of the impact of SFL on health and economic outcomes

[20] concluded that there is a need for further research on indicators such as asthma and chronic obstructive pulmonary disease (COPD) with special attention regarding low-income populations, women, racial/ethnic minorities, and older adults. Tan and Glantz observed in a meta-analysis (2012) a 24% decrease in hospital admissions due to respiratory disease[23]. However, an updated Cochrane Review (2016) with the same inclusion criteria as the first review determined that effects of SFL on respiratory health, including COPD, asthma, and lung function were inconsistent[21].

It is essential to evaluate the impact of SFL on health[24]. In addition, a systematic review of the influence of laws which ban smoking in certain places on respiratory problems (e.g. asthma, COPD, upper and lower respiratory tract infections, and even ear, nose, and throat diseases), and in populations of all ages, irrespective of presenting respiratory diseases, would add greater value to the evidence obtained in other fields. To the best of our knowledge there is no overall, systematic review concerning the effect of SFL on respiratory and sensory symptomatology and disease. For a first approach, gathering data from previous reviews would be of great interest even if the populations differed.

The aim of this study is to synthesize the available evidence published in scientific journals on the effects of SFL on respiratory and sensory symptoms and diseases among all populations. Specifically, the objective is to assess the effects of SFL on admissions and emergency visits at hospital/primary health care centers, treatment use, and mortality in individuals suffering from asthma, COPD, and other respiratory diseases.

## Materials and methods

### Data sources

A systematic review and meta-analysis were carried out to select published papers that assessed respiratory and sensory effects of SFL according to the Preferred Reporting Items for Systematic Reviews and Meta Analysis (PRISMA) guidelines[25]. The study protocol (CRD42015019647) was published in the International Prospective Register of Systematic Reviews (PROSPERO) (http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015019647).

Searches were conducted in: PubMed, EMBASE, Cochrane Library, Scopus, Web of Science, and Google Scholar. S1 Table illustrates the different strategies. Due to the fact that a preliminary Google Scholar search revealed a considerable number of hits, only the first 200 results were scanned as prior bibliography[26±28]. This figure ensures the most relevant articles were obtained[29] and increased the sensitivity of the search[30]. A manual search in the reference lists of systematic reviews was performed. In addition, a national expert in tobacco control and public health was contacted to identify additional studies that might not have been obtained in the process. These sources were combined in order to gather as many relevant data as possible.

Inclusion criteria were: 1) Information concerning SFL (comprehensive or partial) implemented at national, regional, local, and workplace level; 2) Evaluation of SFL with data before and after its implementation; 3) Assessment of the impact of SFL on respiratory diseases (e.g. asthma, COPD and other pulmonary diseases, upper and lower respiratory tract infections, and ear, nose, and throat diseases) and outcomes including hospitalization and mortality/morbidity rate, respiratory (any respiratory symptom, wheezing, phlegm, morning cough, cough during the rest of the day, breathlessness, tightness in chest and asthma symptoms) and sensory symptoms (any sensory symptom, red/irritated eyes, runny nose/sneezing and sore/scratchy throat); 4) All populations irrespective of age, health or smoking status; 5) Original papers in peer-reviewed journals published from January 1, 1995. This date was selected as it is

considered to be the first year a more comprehensive legislation was established with respect to workplaces and restaurants[6]; and 6) Papers written in English, French, Portuguese, Italian, Catalan or Spanish. Exclusion criteria concerning type of study design were editorials, letters to the editor, systematic reviews, conference proceedings, cost studies, and theoretical papers.

## Study selection

Study selection was composed of various stages (Fig 1): First, in February, 2015, the searches were carried out by two authors who identified 2726 papers. Thirty-one additional records were found through non database sources (contact with experts and manual search in the reference lists of the reviews) and 28 from Google Scholar. After removing duplicates 1606 records remained. Second, 12 paired researchers independently screened the titles and abstracts to see whether the papers met the inclusion criteria. Motives for exclusion were recorded. There were two additional reviewers for discrepancies. 1540 records were excluded leaving 66 full-text papers to review. Third, the reviewers read the 66 full-text papers, 46 of which were included in the study and four additional ones were accepted after manual exploration of the bibliography. Finally, 50 papers were selected[31±80] for data extraction and quality assessment.

## Data extraction and quality assessment

The following data were extracted from each full-text paper: Reference (author, year of publication), country, region, aims, type of legislation (i.e. comprehensive SFL banning smoking in virtually all indoor workplaces and public areas, including bars, restaurants and public transport with no designated smoking areas permitted, and partial which covers fewer locations [4,6,81]), study period, study design (following the classification of [a]Evaluative Designs in Public health: Methodological Considerations[o] [82] which groups the main evaluation designs in public health as non-experimental and quasi-experimental, and within each of these there are before-after studies and temporal series), study participants, sample size, respiratory and sensory outcomes, source of information, summary of findings, competing interest, and risk of bias (RoB). The latter was evaluated by a version we adapted of the Suggested Risk of Bias Criteria for the Cochrane Effective Practice and Organization of Care Group[83] (EPOC) reviews for uncontrolled before-and-after studies and interrupted time series. We included some domains/subdomains and some other were discarded others due to their unsuitability for evaluation studies and for the purpose of assessing non-randomized and non-comparative studies as in prior bibliography[84]. Overall methodological quality was rated as low, moderate, or high RoB (S2 Table). Revision of titles and abstracts, data extraction from full-text papers, and quality assessment were performed by two authors (six pairs of reviewers) independently and checked by a third in the case of discrepancies.

## Data analysis

Data were synthesized through a narrative review with summary and quantitative descriptive analysis. IBM SPSS Statistics V21.0 was employed for the descriptive analysis. A meta-analysis was performed using Review Manager (RevMan, version 5.3). The effect of SFL was estimated by mean differences (MD) in continuous outcomes and risk ratios (RR) and risk difference (RD) in dichotomous ones. Pooled effect measures were computed applying the inverse-variance method in a random-effect model. Heterogeneity was quantified with the I2 statistic, which describes the proportion of the total between-study variability due to heterogeneity[85]. If the P-value was less than 0.10 and I2 exceeded 50%, heterogeneity was considered to be substantial. Subgroup analysis was used to evaluate whether results differed according to the

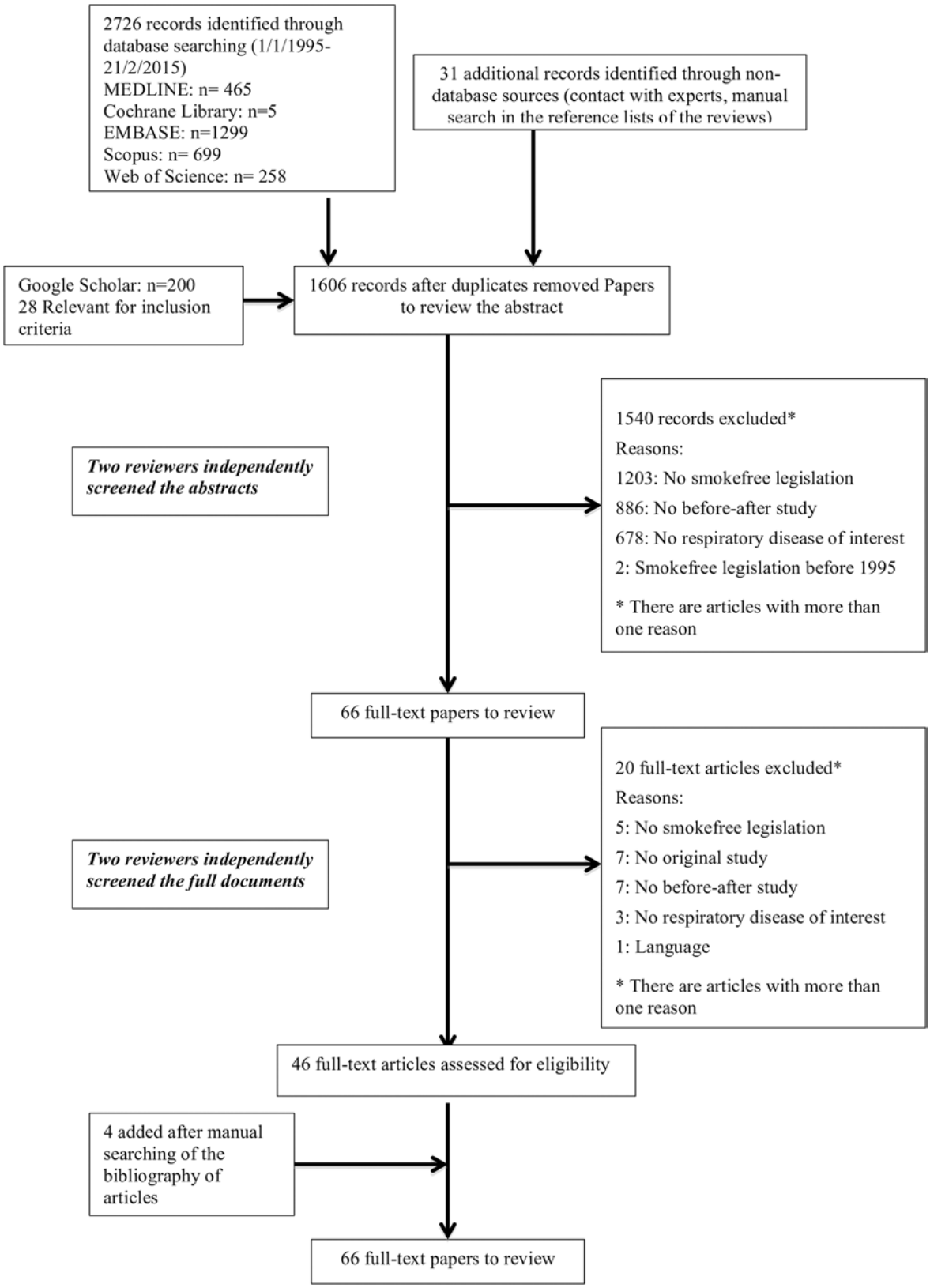


**Fig 1. Flow diagram of literature search and study selection from papers evaluating smokefree legislation effects on respiratory and sensory disorders (1995±2015).**

https://doi.org/10.1371/journal.pone.0181035.g001

outcome (respiratory symptoms, sensory symptoms, spirometry parameters, and asthma, COPD and pneumonia/bronchitis admissions), type of SFL (comprehensive vs partial) and population (general population vs adult vs children). Within these subgroups, further subdivisions by study design (non experimental vs quasi-experimental), the quality of included studies (high vs moderate vs low RoB), and follow-up time ($<$ or $\geq$12 months in the case of outcomes referred to symptomatology and $<$ or $\geq$24 months in those referred to pathology) were carried out. When statistical heterogeneity was detected and there were more than three studies involved, several sensitivity analysis were performed assessing the relative influence of each study on pooled estimates by omitting one study at a time. Further reduced sets of analyzes were continued successively until I2 dropped below the intended threshold 50% (no more than two studies were drawn). Publication bias was assessed by using funnel plots if the meta-analysis included at least ten studies[86].

## Results

### Characteristics of studies

A total number of 1606 papers was identified. Information for each paper is presented in Tables 1, 2 and 3 and papers are classified by type of outcomes. S3 Table shows the characteristics of the 50 included studies[31±80]. The United States was the country with most publications (16 papers, 32.0%), and 24 (48.0%) collectively came from Europe. The hospitality sector represented 44.0% of the studies (22 papers, same percentage for city and regional locations), 33 (66.0%) evaluated comprehensive SFL, 27 (54.0%) presented a non-experimental before-after design (without control group), and 25 (50.0%) had a study population comprising of hospitality workers. The papers that assessed the effect of SFL on lung symptomatology and function had follow-up periods from one month to two years. In contrast, those evaluating diseases had longer periods: from eleven months to seven years. The most evaluated outcomes were respiratory (26 papers, 52.0%; symptoms were any respiratory symptom, wheezing, phlegm, morning cough, cough during the rest of the day, breathlessness, tightness in chest, and asthma symptoms) and sensory (19 papers, 38.0%; symptoms were any sensory symptom, red/irritated eyes, runny nose/sneezing and sore/scratchy throat) symptomatology followed by hospital admissions for asthma (17 papers, 34.0%) and COPD (nine papers, 18.0%).

### SFL effect on respiratory symptoms

Of the 50 papers, 26 (52%) evaluated respiratory symptoms. Of these 26, 23 (88.5%) concerned workers, 22 (84.6%) were non-experimental, and 14 (53.8%) assessed comprehensive SFL. Evaluation periods were from one month to six years. The outcomes included: any respiratory symptom (17 studies, 65.4%), wheezing (16 studies, 61.5%), phlegm (14 studies, 53.8%), morning cough (ten, 38.5%), cough during the rest of the day (17 studies, 65.4%), breathlessness (seven, 26.9%), tightness in chest (four, 15.4%) and asthma symptoms (two, 7.7%)[37,58].

The majority of the outcomes presented a post-ban decrease period in the percentage of adults suffering from them. Those that decreased significantly in most of the studies were [a]any respiratory symptom[o] (range 7.7 to 42.0%), [a]morning cough[o] (4.4 to 30.0%), [a]coughing the rest of the day[o] (2.3 to 41.2%), and phlegm (3.5 to 42.0%). In comparison with partial SFL comprehensive SFL appears to produce the greater decline. Six studies reported post-ban decreases in comprehensive SFL for the outcomes breathlessness (range 6.2 to 25%) [32,40, 67,76] and tightness in chest (10% of decrease)[67], however, along with wheezing (five papers with significant decreases[32,39,40,55,76] and five with non significant decreases[41,43,44,67, 73]) and asthma[58], findings did not indicate a clear decline in these symptoms.

## Table 1. Summary of studies on the impact of smoke-free legislation on symptomatology.

**Respiratory symptoms**

| Aims | Legislation | Study period | Study design | Study participants and size | Variables | Source of information | Summary of findings | Risk of Bias |
|---|---|---|---|---|---|---|---|---|
| **Allwright, 2005. The Republic and Northern Ireland** (three areas in the Republic-Dublin, Cork, and County Galway- intervention- and one area in Northern Ireland -control) [31] | | | | | | | | |
| To compare respiratory health in bar staff in rural and urban areas of the Republic of Ireland before and after the law and to compare these changes with changes observed in Northern Ireland. | Comprehensive. *Ban*: March 2004 | *Pre-ban*: September 2003 *Post-ban*: March 2005 | Pre-posttest quasi-experimental design | 226 participants in the baseline and 213 in the follow-up survey. Of these, 158 were non-smokers. Republic Ireland: Mean age 45.5, 17% women. Northern Ireland: Mean age 36.1, 25% women. | Any symptom, wheezing/ whistlig, shortness of breath cough, morning cough, cough during the rest, production of phlegm in non-smokers | International Union Against Tuberculosis and Lung Disease (IUATLD) Bronchial Symptoms Questionnaire. | At baseline 65% of non-smokers in the Republic reported one or more respiratory symptom. This dropped by 25% to 49% (p 0.001) at follow-up. After the ban, fewer reported cough during the day or night (p 0.004) or production of phlegm (p 0.002). In Northern Ireland, the proportion reporting any respiratory symptom was lower at baseline (45%) than in the Republic and remained at 45% after the ban. The adjusted rate ratio for the number of respiratory symptoms in the Republic dropped (from 1.33 to 0.98), while in Northern Ireland it increased by 16% (from 0.67 to 0.83). | Low |
| **Ayres, 2009. Scotland** [32] | | | | | | | | |
| To examine changes in prevalence of self-reported respiratory and sensory symptoms of bar workers after smoke-free legislation (SFL) was introduced | Comprehensive *Ban*: 26 March 2006 | *Pre-ban*: 7 Jan 2006 *Post-ban*: May-July 2006 and JanuaryÐ March 2007 | Pre-posttest non-experimental design | 371 bar workers, including managers, owners and bar staff non smokers, smokers and ex-smokers. Only 177 at 3 phases. Mean age 29.5, male 51% | Self-reported wheeze, shortness of breath, morning cough, other cough, phlegm, any respiratory symptom. | IUATLD Bronchial Symptoms Questionnaire | Of the 191 (51%) workers seen at 1-year follow- up, any respiratory symptom fell from 69% to 57% (p 0.02), effects being greater at 2 months. The reduction in respiratory symptoms was similar although greater for ``any° sensory symptom (69% falling to 54%, p 0.011). For non-smokers (n = 57) the reductions in reported symptoms were significant for phlegm production (32% to 14%). Wheeze (48% to 31%) and breathlessness (42% to 29%) improved significantly in smokers. | Low |
| **Bannon 2009, North of Ireland.** Belfast [40] | | | | | | | | |
| To assess, before and after the introduction of the SFL, bar workers' self-reported levels of respiratory symptoms | Comprehensive *Ban*: April 2007 | *Pre-ban*: March 2007 *Post-ban*: July 2007 | Pre-posttest non-experimental design | 97 (pre-ban) and101 (post- ban) bar workers of the 35 Belfast bars. Number of female before 39, after 42; Male before 58, after 59. The majority rank of age: 16±25 and 26±35 years | Wheeze/whistling in the chest, shortness of breath, cough first thing in the morning, cough in day or night, at least one respiratory symptoms. | A short self-completing questionnaire similar to IUATLD Bronchial Symptoms Questionnaire. | After SFL, the proportion of bar workers reporting at least one respiratory symptom declined significantly by 18.1% for smokers and 25.1% for non-smokers. The level of wheezing among non-smokers declined significantly by 26.9% but not among smokers (5.9%); this interaction pre/post legislation, occurred also in `cough first thing in the morning' and `cough in day or night'. Smokers had greater odds of reporting `shortness of breath' than non-smokers (Odds ratio (OR) 2.02). There was greater odds of reporting this symptom before the legislation (OR 2.62). | Low |
| **Durham, 2011. Switzerland.** Canton of Vaud [78] | | | | | | | | |
| To assess the ban's impact in non-smokers and smokers by environmental tobacco smoke (ETS) exposure symptoms | Partial *Ban: 15* September 2009 | *Pre-ban*: 30 April 2009 *Post-ban*: 26 Sept 2010 | Pre-posttest non-experimental design | 105 adult hospitality workers. Dropout rate of 37%. Age, mean (before-after): 37.4±41.3. | Cough, wheezing, chest oppression, shortness of breath the four weeks prior. | Self reported questionnaire. | Percentage of reported symptoms pre/post-ban(p-value): cough 14%/16% (p 0.5), wheezing 7.84%/7.84%(p 0.646), chest oppression 5.77%/1.92%(p 0.309), shortness of breath 9.8%/ 7.84% (p 0.5) | Low |
| **Eagan, 2006. Norway.** [76] | | | | | | | | |
| To examine the prevalence of respiratory symptoms among employees in the Norwegian hospitality industry, before and after enacting a SFL | Comprehensive *Ban*: 1 June 2004 | *Pre-ban*: May 2004 *Post-ban*: October 2004 | Pre-posttest non-experimental design | 878 employees of Norwegian hospitality industry | Morning cough, daytime cough, phlegm cough, dyspnoea, wheezing, any symptom. | Medical Research Council questionnaire. Phone interviews | The prevalence of symptoms declined after the ban; for morning cough from 20.6% to 16.2% (p<0.01); for daytime cough from 23.2% to 20.9%; for phlegm cough from 15.3% to 11.8% (p 0.05); for dyspnoea from 19.2% to 13.0% (p 0.01); and for wheezing from 9.0% to 7.8%. The largest decline was seen among workers who gave up smoking, and with a positive attitude towards the law. | Low |
| **Eisner, 1998. California.** San Francisco [39] | | | | | | | | |

(*Continued*)

**Table 1.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To study the respiratory health of bartenders before and after legislative prohibition of smoking in all bars and taverns | Comprehensive *Ban*: 1 January 1998 | *Pre-ban*: December 1997 *Post-ban*: February 1998 | Pre-posttest non-experimental design | Bartenders at a random sample of bars and taverns in San Francisco. 53 of the daytime bartenders. Mean age 42.5. Female 28%. -white 38%. | Wheezing, dyspnoea, morning cough, cough the rest of day, phlegm production and recent upper respiratory tract infections. | IUATLD Bronchial Symptoms Questionnaire | Thirty-nine (74%) of the 53 bartenders reported respiratory symptoms at baseline, while only 17 (32%) were still symptomatic at follow-up. Of the 39 bartenders reporting baseline symptoms, 23 subjects (59%) no longer indicated any respiratory symptoms after prohibition of smoking (p 0.001). | Low |
| **Farrelly 2005, US.** New York State [41] | | | | | | | | |
| To assess the impact of New York's law on respiratory symptoms in the past four weeks on hospitality workers' | Comprehensive Ban: 24 July 2003 | *Pre-ban*: June-July 2003 *Post-ban*: -Oct- Nov 2003 -FebÐMarch 2004 - July- July 2004 | Pre-posttest non-experimental design | 68 workers in restaurants, bars, and bowling facilities. 47% completed the interview at 12 month follow up.Age (years) 18± 26: 37.5%; 27±35: 12.5%; 36±45: 25%; >46: 25%. Male: 29.2% | Self reported respiratory symptoms in the past four weeks (wheeze, shortness of breath, morning cough, cough during the remainder) | IUATLD Bronchial Symptoms Questionnaire | There was no change in the overall prevalence of upper respiratory symptoms (p 0.1). Before the law, approximately 46% of respondents experienced any respiratory symptoms. This dropped by 37% to 29% not significantly. The most common respiratory symptom experienced was coughing during the day or at night (29%). The symptom scale shows that participants reported experiencing an average of 1.1 respiratory symptoms at baseline. By the 12 month follow up, there was a marginally significant change in coughing in the morningÐdropping by 62%, from 21% to 8%. | Moderate |
| **Fernåndez, 2009. Spain.** [77] | | | | | | | | |
| To evaluated self-reported respiratory health in hospitality workers in five regions of Spain before and after SFL. As a control group (without SFL) they studied hospitality workers in Portugal and Andorra. | Partial *Ban*: 1 January 2006 | *Pre-ban*: October 2005 *Post-ban*: December 2006 | Pre-posttest quasi-experimental design | Hospitality workers nonsmokers.117 in Spain and 20 workers in Portugal and Andorra followed up 12 months. Median age: Spain 39.4; Portugal-Andorra 37.1. Women in Spain 39.3% and 70.0% in Portugal-Andorra. | Breathless while wheezing, woken up with chest tightness, shortness of breath at rest, woken up by attack of shortness of breath, cough in the morning, cough during the rest, phlegm, asthma attack | European Community Respiratory Health Study (ECRHS) questionnaire. Face-to-face interviews. | The baseline prevalence of each symptom individually did not significantly change after the ban in Spain regardless of the type of post-ban smoking regulation, except for cough and phlegm among workers in totally smoke-free venues (from 40.6% to15.6% considered together). No changes were observed in the control regions. The prevalence of any respiratory symptom before the law was 32.5% in Spain. After the law, among workers in completely smoke-free venues, declined significantly (-71.9% change), but not in workers in venues where smoking was allowed on part (-57.1% change)or all of the premises (-19.4% change). In Portugal and Andorra, a borderline-significant decrease was observed (-61.9% change). | Moderate |
| **Goodman, 2007. Ireland.** Dublin [43] | | | | | | | | |
| To examine the impact of this legislation on respiratory health effects in bar workers in Dublin. | Comprehensive *Ban*: 29 March 2004 | *Pre-ban*: October 2003Ð March 2004 *Post-ban*: Sept 2004 -March 2005. | Pre-posttest non-experimental design | Bar staff volunteers (n 81), from pubs mostly different. Mean age of 47.9 at the preban assessment. | Respiratory symptoms. | Self reported IUATLD Questionnaire. California Environmental Protection Agency questionnaire | Significant improvements in cough in the morning, cough during the rest of day and phlegm production in nonsmokers (change -48%; -39%, and -41%, respectively). Decrease in any respiratory symptom from 86 to 61%(p<0.01). | Low |
| **Hahn, 2006. US.** Lexington [44] | | | | | | | | |
| To evaluate the association between secondhand smoke (SHS) exposure and respiratory symptoms before and after a SFL on bar and restaurant workers | Comprehensive *Ban*: 27 April 2004 | *Pre-ban*: before the law *Post-ban*: 3 and 6 months after | Pre-posttest non-experimental design | 105 adult restaurant or bar workers, at 3 months postlaw, 71 and at 6 months 60. Female 63%, largely white, mean age 26 | Wheezing, dyspnoea, morning cough, cough during the rest, and phlegm production. | IUATLD Bronchial Symptoms Questionnaire | Significant decrease in symptom prevalence over time for most respiratory symptoms. In particular, for smokers and nonsmokers combined, morning cough, cough at other times during the day, all demonstrated a significant decline in prevalence between the prelaw period and the first postlaw interview, and this decline was maintained at 6 months postlaw. | Low |
| **Ho, 2010. China.** Hong Kong [47] | | | | | | | | |

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**Table 1.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To evaluated the effects of a SFL on the exposure of children to SHS at home and outside home in Hong Kong. | Partial<br>*Ban*: January 2007 | *Pre-ban*: January -March 2006<br>*Post- ban*: JanuaryÐ March 2008 | Pre-posttest non-experimental design | 3243 and 4965 primary 2±4 students in 2006 and in 2008 from 19±24 randomized schools, respectively, smokers excluded. The 2006 survey has 50.3% boys and a mean age of 8.3; the 2008 survey had 52.2% boys and a mean age of 8.6 years. | Frequent cough or phlegm were classified as having respiratory symptoms inside and outside home. | Self-administered questionnaire | The prevalence of respiratory symptoms increased slightly from 36.6% in 2006 to 38.4% in 2008 ($p<0.001$) for follow-up schools. Exposure SHS at home for 4±7 days per week was significantly associated with respiratory symptoms with an adjusted OR of 1.19 in 2008, compared with 1.09 in 2006. The each-day increase in home exposure was associated with 7% excess risk of respiratory symptoms in 2008 but no increased risk in 2006. Association with SHS outside home: for 4±7 days and respiratory symptoms seemed to be weaker in 2008 with OR of 1.54 compared with that of 2.06 in 2006, difference was insignificant. The each-day increase outside home decreased from 35% in 2006 to 20% in 2008 for the respiratory symptoms. | High |
| **Kim, 2015. Republic of Korea**. Seoul [50] | | | | | | | | |
| To determine the effects of Korean smoking ban in restaurants and pubs in terms of air quality, biomarker levels, and health effects on staff. | Partial<br>*Ban*: July 2013 | *Pre-ban*: 29 April -June 2013<br>*Post-ban*: August-Sept 2013 | Pre-posttest non-experimental design | 95 staff members of restaurants or pubs who had never smoked or ex-smokers. 69% female. 19% ex-smokers. Mean age 47.4 | Wheezing/whistling,shortness of breath, morning cough, rest of day or night cough, phlegm production | Self reported questionnaires based on IUATLD questionnaire. | The respiratory symptoms did not significantly differ among staff in any facilities before and after the ban. In < 150 m2 facilities (N = 45), 40% had respiratory symptoms before the law and 26% after the law (p 0.15). In $\geq$ 150 m2 facilities (N = 50), 36% had respiratory symptoms before the law and 26% after the law (p 0.22). | High |
| **Larsson, 2008. Sweden:** Stockholm, Göteborg, Malmö, Uppsala, Västerås, Linköping, Örebro, Östersund, Skövde [52] | | | | | | | | |
| To evaluate the influence of the SFL among hospitality workers by examining the change in the rate of respiratory symptoms before and 12 months after enacting | Partial<br>*Ban*: 1 June 2005 | *Pre-ban*: April-May 2005<br>*Post-ban*: April-May 2006 | Pre-posttest non-experimental design | 91 hospitality workers of bingo halls and casinos. Altogether 71 of 91 (14 daily smokers and 57 nonsmokers) at follow-up: 70% female, 26% smokers | Respiratory symptoms reported | Self reported IUATLD Bronchial Symptoms Questionnaire. | In the 91 workers, all of the reported symptoms declined, and was significant for cough in the morning, cough during the rest of the day (not in nonsmokers). Among the smokers, there was no association between symptoms and period, but there only 14. Among the gaming workers, the OR declined more for cough in the morning (OR 0.23), cough the rest of the day (OR 0.10), and bringing up phlegm (OR 0.19, 0.02 to 1.61). | Moderate |
| **Li, 2013. China.** Shangai[74] | | | | | | | | |
| To evaluate impact of SFL on respiratory symptoms among employees in five kinds of workplaces | Partial<br>*Ban*: March 2010 | *Pre-ban*: August 2009<br>*Post-ban*: September 2010 | Pre-posttest non-experimental design | Employees of schools, kindergartens, hospitals, hotels, and shopping malls. At baseline, 2,254. Females 65.6%. Age mode: 30±49 | Wheezing, dyspnea, morning cough, cough during the rest, phlegm production | IUATLD Bronchial Symptoms Questionnaire. Face-to-face interviews | The prevalence of respiratory and sensory symptoms among employees decreased significantly from 83% to 67%. There were statistically significant differences by type of establishment: shopping malls and schools had a sharp decrease in respiratory and sensory symptoms ($p<0.05$). | Moderate |
| **MacCalman, 2012. Scotland and England** [55] | | | | | | | | |
| To investigate whether changes in self-reported symptoms and attitudes were related to participants' initial attitude towards SFL and to determine the nature of the relationship | Comprehensive<br>*Ban*:<br>-Scotland: March 2006<br>-England: July 2007 | *Pre-ban*<br>*Post-ban*:<br>-2 month after<br>-One year after | Pre-posttest non-experimental design, comparation between 2 studies. | 548 bar workers, at follow-up 253. Age 31.3 (18.4, 66.7). Male 49.8%, 41.1% regular smoking. | Shortness of breath, tight chest, wheezing, phlegm production, morning cough and other cough, sore or dry throat | Self reported IUATLD Bronchial Symptoms Questionnaire. | The proportion of people reporting any symptoms was significantly reduced in both England (76% vs. 49%) and Scotland (67% vs. 87%). The proportion of bar workers in Scotland reporting wheezing reduced from 33 to 22%, while the reduction was from 35 to 10% of bar workers in England. The initial attitude to SFL did not have any effect on the change in respiratory symptoms reported by those in England (p 0.755);it did seem to have an effect in Scotland (p 0.042). | High |
| **Madureira, 2012. Portugal.** Vila Nova de Gaia. *The same data for Madureira, 2014* [56] [57] | | | | | | | | |

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**Table 1.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To assess the impact of ETS exposure on respiratory symptoms among portuguese restaurant workers before and after a SFL | Partial *Ban*: 1 January 2008 | *Pre-ban*: Oct-Dec 2006. *Post-ban*: 2010 | Pre-posttest non-experimental design | 52 restaurant workers. At 2 years of follow-up 47%. Mean age 30.8, 71% men, 46% smokers | Sore or dry throat, cough, tight chest, breathing difficulties such as breathe shortness or wheeze | Questionnaire, self reported symptoms | While 67% of workers reported at least one respiratory and sensory symptom in 2006 (pre-ban phase), only 29% noted the same symptoms in the postban phase. Similarly, self-reported respiratory symptoms decreased markedly 52% from the pre-ban to the post-ban phase | Moderate |
| **Menzies, 2006. Scotland**. Dundee and Perth [58] | | | | | | | | |
| To investigate the association of SFL with symptoms and pulmonary function on bar workers nonsmokers and ex-smokers | Comprehensive *Ban*: 26 March 2006 | *Pre-ban*: February 2006 *Post-ban*: May-June 2006 | Pre-posttest non-experimental design | 105 bar workers, without respiratory disease except asthma or rinitis (n = 23), 77 at follow-up. Mean age: 37.5, male 41%. | Wheeze, shortness of breath, cough, and phlegm | Abbreviated IUATLD Bronchial Symptoms Questionnaire | The percentage of bar workers with respiratory and sensory symptoms decreased from 79.2% before the SFL to 53.2% (p 0.001) and 46.8% (p<0.001) 1 and 2 months afterward. Significant improvements in the percentage of bar workers experiencing respiratory (total reduction, −20.8%, −7.6% to −33.9%; p 0.005) symptoms at 1 month after the ban and at 2 months (−35.1%, −22.2% to −47.9%; p<0.001). | Moderate |
| **Pearson, 2009. US.** Washington [62] | | | | | | | | |
| To test the hypothesis that implementation of the SFL significantly reduces >50% respiratory and sensory symptoms reports | Comprehensive *Ban*: 2 January 2007 | *Pre-ban*: December 2006 *Post-ban*: Febr 2007 | Pre-posttest non-experimental design | 52 bar employees nonsmoker from 41 randomly selected bars, post-ban assessment in 46. Male 89% | Shortness of breath, wheezing, coughing, and phlegm in the past four weeks. | IUATLD Bronchial Symptoms Questionnaire | The difference in respiratory symptom reports was inconclusive. | High |
| **Rajkumar, 2014. Switzerland.** Zurich, Basel City, and Basel County [63] | | | | | | | | |
| To relate workplace SHS exposure in nonsmoking hospitality workers before and 6 to 12 months after a smoking ban to their respiratory health | Partial *Ban*: May 2010 | *Pre-ban*: March 2010 *Post-ban*: 6 and 12 month after (until Dec 2010) | Pre-posttest non-experimental design | 92 nonsmoking hospitality workers. Info baseline: 62% female, mean age 40.3, self-reported asthma 14.1%, allergic 65.2%. | Asthmatic symptoms (breathlessness, wheezing, chest tightness), chronic bronchitis (cough, phlegm), rhinitis (sneezing,running nose) | Computer-based interview adapted from a standardized questionnaire | Respiratory symptoms: Bronchitis symptoms (Cough 29.4%,Phlegm 12.0%); chronic bronchitis 2.2%; asthma symptoms 26.1%; allergy symptoms: rhinitis 22.8%. At baseline,the exposure-response model yielded an OR of 1.25 (1.03 to 1.53) per cigarette/day increase in SHS exposure for cough and 1.13 (0.99 to 1.28) for chronic bronchitis. After SFL, the adjusted OR for cough was 0.59 (0.36 to 0.93) and 0.75 (0.55 to 1.02) for chronic bronchitis compared with the preban period. | Low |
| **Reijula, 2012. Finland** [65] | | | | | | | | |
| To assess the impact of tobacco legislation in bars and restaurants. | Partial *Ban*: June 2007 | *Pre-ban*: *2007* *Post-ban*: June 2009 | Pre-posttest non-experimental design | 1,008 restaurant workers in 2007 and 805 in 2009. 84.5% women. In 2007, 31% of women and 39% of men smokers. In 2009, 31% and 30%, respectively. | [a]has tobacco smoke in your workplace caused you respiratory or eye symptoms?' | Questionnaire surveys, paper form mailed to the participants (self-reported) | The prevalence of respiratory symptoms decreased from 18% to 4% (p < 0.0001) and was highest among bartenders of whom 32% reported respiratory symptoms in 2007 and 6% in 2009 (p < 0.0001). In 2009, the prevalence of respiratory symptoms among those who reported no exposure to ETS at work was 2% while among those who reported exposure to ETS for more than 4 hr a day was 21%. | Low |
| **Schoj, 2010. Argentina**. Neuquén [67] | | | | | | | | |
| To evaluate the impact of SFL on respiratory symptoms and respiratory function among bar and restaurant workers | Comprehensive *Ban*: 15 November 2007 | *Pre-ban*: October 2007 *Post-ban*: March 2008 | Pre-posttest non-experimental design | 134 non-smokers bar and restaurant workers. 80 at follow up: 38.7% women and 6.2% had a history of asthma. Mean age 34.3. | Cough, phlegm production, wheezing and dyspnoea. History of asthma | IUATLD Bronchial Symptoms Questionnaire | An important reduction in respiratory symptoms (from a pre-ban level of 57.5% to a post-ban level of only 28.8%). Respiratory symptoms that declined after prohibition: such as cough, cough at night, dyspnoea on exertion and at rest, and tightness in the chest. | Low |
| **Wilson, 2012. US.** Michigan [73] | | | | | | | | |
| To determine the impact on bar employee's health and exposure to SHS before and after the implementation of a SFL | Comprehensive *Ban*: 1 May 2010 | *Pre-ban*: 6 weeks before *Post-ban*: 6±10 weeks after | Pre-posttest non-experimental design | 40 bar employees ≥ 18 years; never smoked or ex-smokers, lived in a smoke-free household. 70% women, mean age 44.8. 95% whites. | Morning cough, daytime cough, phlegm, shortness of breath, wheezing and allergic symptoms. | A self-administered respiratory questionnaire by the University of Minnesota, Masonic Cancer Center. | There was a significant improvement in all six self-reported respiratory symptoms (p<0.001). Respiratory symptom (p pre-law/post-law): Allergic symptoms (p<0.001), Wheezing (p 0.050), Shortness of breath (p 0.048), Phlegm production (p 0.021), Daytime cough (p .018), Morning cough (p 0.003) | Moderate |
| **Sensory symptoms** | | | | | | | | |
| **Allwright, 2005.The Republic and Northern Ireland** (three areas in the Republic-Dublin, Cork, and County Galway- intervention- and one area in Northern Ireland -control) [31] | | | | | | | | |

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**Table 1.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To compare respiratory health in bar staff in the Republic of Ireland before and after the law and to compare these changes with changes observed in Northern Ireland. | Comprehensive. *Ban*: March 2004 | *Pre-ban*: September 2003 *Post-ban*: March 2005 | Pre-posttest quasi-experimental design | 226 participants at baseline, 213 in the follow-up. Rep Ireland: Mean age 45.5, 17% women. North Ireland: Mean age 36.1, 25% women. | Red eyes, sore throat | IUATLD Bronchial Symptoms Questionnaire. | After the ban, reporting any sensory symptom dropped from 67% to 45% (p < 0.001), reflecting significant declines in reporting red eyes (p < 0.001) and sore throat (p 0.004). In Northern Ireland, the proportion reporting any sensory symptom declined from 75% to 55% (p 0.13). The adjusted RR for the number of sensory symptoms dropped in both regions (by 50% in the Republic and by 44% in Northern Ireland). | Low |
| **Ayres, 2009. Scotland** [32] | | | | | | | | |
| To examine changes in prevalence of self-reported respiratory and sensory symptoms of bar workers after SFL was introduced | Comprehensive *Ban*: 26 March 2006 | *Pre-ban*: 7 Jan 2006 *Post-ban*: -May- July 2006 - Jan -March 2007 | Pre-posttest non-experimental design | 371 bar workers, including managers, owners and bar staff non smokers, smokers and ex-smokers. Only 177 at 3 phases. Age 29.5, male 51% | Self-reported eyes, nose, throat, any sensory symptom | IUATLD Bronchial Symptoms Questionnaire | Of the 191 (51%) workers seen at 1-year follow- up, the percentage reporting any sensory symptoms fell from 75% to 64% (p 0.02), effects being greater at 2 months, probably partly due to seasonal effect. Reduction in ``any° sensory symptom: 69% falling to 54%, p 0.011. For non-smokers (n = 57) the reductions in reported symptoms were significant for red/irritated eyes (44% to 18%). | Low |
| **Bannon 2009, North of Ireland.** Belfast [40] | | | | | | | | |
| To assess, before and after the introduction of the SFL, bar workers' self-reported levels of sensory symptoms | Comprehensive *Ban*: April 2007 | *Pre-ban*: March 2007 *Post-ban*: July 2007 | Pre-posttest non-experimental design | 97 (pre-ban) and101 (post- ban) bar workers of the 35 Belfast bars. Female before 39, after 42; Male before 58, after 59. The majority rank of age: 16±25 and 26±35 years. | Red or irritated eyes, runny nose, sneezing or nose irritation, sore or scratchy throat, at least one sensory symptom | A short self-completing questionnaire similar to IUATLD Questionnaire. | Reductions for sensory symptoms ranged from 7.3% -17.7% for smokers, from 29.6%-46.8% for non- smokers.The proportion of bar workers reporting `at least one sensory symptom' declined by 36% (p 0.001) for non-smokers, not significantly for smokers. Running nose: adjusted OR 2.38, p 0.005. `Sore or scratching throat'; its level declined among non-smokers by 41.5% (p< 0.001),not significant for smokers.Eye irritation for non-smokers:OR 7.72 (p < 0.001);for smokers,OR 2.28, p 0.08. | Low |
| **Durham, 2011. Switzerland.** Canton of Vaud [78] | | | | | | | | |
| To assess the ban's impact in non-smokers as well as smokers on ETS exposure symptoms | Partial *Ban*: *15* September 2009 | *Pre-ban*: 30 April 2009 *Post-ban*: 26 Sept 2010 | Pre-posttest non-experimental design | 105 hospitality workers, 66 after one year. Mean age (before): 37.4. Smoking status (before-after): 61%-54.6%. | Red eyes,irritated eyes, irritated nose, runny nose, sneezing | Self reported questionnaire. | Typical ETS exposure symptoms in the four weeks prior were generally reduced at follow-up. Red and irritated eye symptoms decreased from 26.79% and 31.48% to 12.5% and 11.11% respectively (p 0.047 and 0.009), sneezing also decreased significantly from 23.53% prior to the ban to 7.84% after- wards | Low |
| **Eisner, 1998. California.** San Francisco [39] | | | | | | | | |
| To study the respiratory health of bartenders before and after SFL | Comprehensive *Ban*: 1 January 1998 | *Pre-ban*: Dec 1997 *Post-ban*: Feb 1998. | Pre-posttest non-experimental design | 53 of the daytime bartenders. Mean age 42.5. Female 28%. Nonwhite 38%. | Red or irritated eyes; runny/ irritation nose, sneezing; scratchy throat | IUATLD Bronchial Symptoms Questionnaire. | 51 bartenders (77%) initially reported sensory irritation symptoms. At follow-up, 32 (78%) had resolution of symptoms (p<0.001). After excluding the 8 subjects who reported a recent upper respiratory infection, at follow-up interview, 79% no longer reported any sensory symptoms (p<0.001). | Low |
| **Farrelly 2005, US.** New York State [41] | | | | | | | | |
| To assess the impact of New York's law on sensory symptoms in the past four weeks on hospitality workers' | Comprehensive *Ban*: 24 July 2003 | *Pre-ban*: June-July 2003 *Post-ban*: -15 Oct-19 Nov 2003 - 20 Feb -23 March 2004 - July-July 2004 | Pre-posttest non-experimental design | 68 workers in restaurants, bars, and bowling facilities. 69%, 56% and 47% completed both the interview at the three, six, and 12 month follow up studies, respectively. Age (years) 18±26: 37.5%; 27±35: 12.5%; 36±45: 25%; >46: 25%. Male: 29.2% | Self reported sensory irritation in the past four weeks (eye, nose, throat) | IUATLD Bronchial Symptoms Questionnaire | At baseline, 88%(95% CI 66% to 96%) of respondents experienced any one of three sensory symptoms and reported an average of 1.6 sensory symptoms. By the 12 month follow up, the presence of one or more sensory symptoms decreased by 57% (p 0.01), from 88% to 38%(20% to 59%) (p 0.01), and all individual symptoms declined significantly. Similarly, the total number of sensory symptoms experienced (symptom scale) declined by 69% (p 0.01) from baseline (1.6) to the 12 month follow up (0.5) | Moderate |
| **Goodman, 2007. Ireland.** Dublin [43] | | | | | | | | |

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**Table 1.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To examine the impact of this legislation on respiratory health effects in bar workers in Dublin. | Comprehensive<br>*Ban*: 29 March 2004 | *Pre-ban*: Oct 2003 -March 2004<br>*Post-ban*: Sept 2004 -March 2005. | Pre-posttest non-experimental design | Bar staff volunteers (n 81), from pubs mostly different. Mean age 47.9 years at the preban assessment. | Sensory symptoms. | IUATLD Bronchial Symptoms Questionnaire. California Environmental Protection Agency questionnaire | The results showed significant improvements in sensory irritant symptoms in smokers and non-smokers, but smokers benefited less. | Low |
| **Hahn, 2006. US.** Lexington [44] | | | | | | | | |
| To evaluate the association between SHS exposure and sensory symptoms before and after the SFL | Comprehensive<br>*Ban*: 27 April 2004 | *Pre-ban*: before the law<br>*Post-ban*: 3 and 6 months after | Pre-posttest non-experimental design | 105 adult restaurant or bar workers, at 3 months postlaw, 71 and at 6 months 60. Female 63%, largelly white, Mean age 26 | Red, irritated eyes; runny nose, sneezing, or irritated nose; and scratchy or sore throat | Self reported IUATLD Bronchial Symptoms Questionnaire. | Prevalence of sensory symptoms and comparisons by time, smoking status, for smokers and nonsmokers combined red eyes, and runny nose demonstrated a significant decline in prevalence between the prelaw period and the first postlaw interview, and this decline was maintained at 6 months postlaw. | Low |
| **Kim, 2015. Republic of Korea**. Seoul [50] | | | | | | | | |
| To determine the effects of Korean smoking ban in restaurants and pubs in terms of air quality, biomarker levels, and health effects on staff. | Partial<br>*Ban*: July 2013 | *Pre-ban*: April -June 2013<br>*Post-ban*: August±Sept 2013 | Pre-posttest non-experimental design | 95 staff members of restaurants or pubs who had never smoked or ex-smokers. 69% female. 19% ex-smokers. Mean age 47.4 | Red or irritated eye, runny or sneezing nose, sore or scratchy throat | Self reported questionnaires that were based UATLD Questionnaire. | The self-reported health effects on sensory symptoms were estimated by area regardless of the type of facility due to the low incidence of symptoms in each type of facility. The sensory symptoms among the staff in $\geq$150 $m^2$ facilities (n = 50) significantly decreased from 52% at baseline to 40% after the ban, whereas the staff from <150 $m^2$ facilities (n = 45) did not exhibit a significant change in symptoms | High |
| **Larsson, 2008. Sweden:** Stockholm, Göteborg, Malmö, Uppsala, Västerås, Linköping, Örebro, Östersund, Skövde [52] | | | | | | | | |
| To evaluate the influence of the SFL among hospitality workers by examining the change in the rate of sensory symptoms before and after | Partial<br>*Ban*: 1 June 2005 | *Pre-ban*: April-May 2005<br>*Post-ban*: April-May 2006 | Pre-posttest non-experimental design | 91 hospitality workers of bingo halls and casinos. 71 (14 daily smokers and 57 nonsmokers) at follow-up: 70% female, 26% smokers | Sensory symptoms | Self reported IUATLD Bronchial Symptoms Questionnaire. | In the entire study population, all of the reported symptoms declined, and the decline was statistically significant for questions about eye irritation, nose irritation, and throat symptoms. Among the smokers, there was no notable association between symptoms and period. The sensory symptoms declined somewhat more among no gaming workers. | Moderate |
| **Li, 2013. China.** Shangai [74] | | | | | | | | |
| To evaluate the compliance with the SFL as well as its impact on sensory symptoms among employees in five kinds of workplaces | Partial<br>*Ban*: March 2010 | *Pre-ban*: August 2009<br>*Post-ban*: September 2010 | Pre-posttest non-experimental design | Employees of schools, kindergartens, hospitals, hotels, and shopping malls. At baseline, 2,254. At follow-up 1832. Females 65.6%. Mode age: 30±49 | Red or irritated eyes, runny, sneezing nose, and sore or scratchy throat. | IUATLD Bronchial Symptoms Questionnaire. Face-to-face interviews | The prevalence of respiratory and sensory symptoms among employees decreased from 83% to 67%. There were statistically significant differences by type of establishment: shopping malls and schools had a sharp decrease in respiratory and sensory symptoms. There was no significant change in kindergartens after the legislation. | Moderate |
| **MacCalman, 2012. Scotland and England** [55] | | | | | | | | |
| To investigate whether changes in self-reported symptoms and attitudes were related to participants' initial attitude towards SFL | Comprehensive<br>*Ban*:<br>-Scotland: March 2006<br>-England: July 2007 | *Pre-ban*<br>*Post-ban*:<br>-2 month after<br>-One year after | Pre-posttest non-experimental design, comparation between 2 studies. | 548 bar workers, at follow-up 253. Age 31.3 (18.4, 66.7). Male 49.8%, 41.1% regular smoking. | Runny nose, dry, itching, irritated, wathery eyes, and sore scratchy throat | Self reported IUATLD Bronchial Symptoms Questionnaire. | Initial attitude did not have an effect on the change in symptoms reported by those in England. The proportion of people reporting any symptoms was significantly reduced in both England and Scotland. The proportion of people reporting any symptoms was significantly reduced from pre-ban period to one year after, in both England (76% vs. 49%) and Scotland (67% vs. 87%). The initial attitude to SFL did not have any effect on the change in symptoms reported by those in England. | High |
| **Madureira, 2012. Portugal.** Vila Nova de Gaia. *The same data for Madureira, 2014* [56] [57] | | | | | | | | |

(*Continued*)

**Table 1.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To assess the impact of ETS exposure on respiratory symptoms among portuguese restaurant workers before and after a SFL | Partial *Ban*: 1 January 2008 | *Pre-ban*: Oct-Dec 2006. *Post-ban*: 2010 | Pre-posttest non-experimental design | 52 restaurant workers. At 2 years of follow-up 47%. Mean age 30.8, 71% men, 46% smokers. | Mucosal irritation or dry, itching, irritated, or watery eyes; nasal problems | Self reported questionnaire. | The most common indoor air-related symptoms reported by the participants in the pre-ban phase were dry, itching, irritated, or watery eyes (48%). In the postban phase the most common symptoms were dry, irritated, or watery eyes, fatigue, and headache (21%). Reported at least one respiratory and sensory symptom felled from 67% to 29%. | Moderate |
| **Menzies, 2006. Scotland**. Dundee and Perth [58] | | | | | | | | |
| To investigate the association of SFL with symptoms on bar workers nonsmokers and ex-smokers | Comprehensive *Ban*: 26 March 2006 | *Pre-ban*: Feb 2006 *Post-ban*: May-June 2006 | Pre-posttest non-experimental design | 105 bar workers, without respiratory disease except asthma or rinitis (n = 23), 77 completed the study. Mean age: 37.5, male 41%, | Red or irritated eyes, painful throat and nasal itch, runny nose, and sneeze | Abbreviated IUATLD Bronchial Symptoms Questionnaire | The percentage of bar workers with respiratory and sensory symptoms decreased from 79.2% (n = 61) before the smoke-free policy to 53.2% (p 0.001) and 46.8% (p<0.001) 1 and 2 months afterward. Significant improvements in the percentage of bar workers experiencing sensory (total reduction, −31.2%; −18.1% to −44.3%; p<0.001) symptoms at 1 month after the ban and at 2 months (−35.1%, −21.7% to −48.4%). | Moderate |
| **Pearson, 2009. US.** Washington [62] | | | | | | | | |
| To test the hypothesis that implementation of the SFL reduces >50% respiratory and sensory symptoms reports | Comprehensive *Ban*: 2 January 2007 | *Pre-ban*: Dec 2006 *Post-ban*: Feb 2007 | Pre-posttest non-experimental design | 52 elegible bar employees nonsmoker (94% follow-up), final sample size of 46. Male 89% | Eye, nose, and throat irritation in the past four weeks | IUATLD Bronchial Symptoms Questionnaire | Sensory symptoms reports declined significantly by 70% to 100%, from a median of 2 to a median of 0. | High |
| **Reijula, 2012. Finland** [65] | | | | | | | | |
| To assess the impact of tobacco legislation in bars and restaurants. | Partial *Ban*: June 2007 | *Pre-ban*: 2007 *Post-ban*: June 2009 | Pre-posttest non-experimental design | 1008 restaurant workers in 2007. 84.5% women. Smokers In 2007: 31% of women, 39% of men. | `has tobacco smoke in your workplace caused your eye symptoms?º | Questionnaire surveys, paper form mailed (self-reported) | The prevalence of eye symptoms decreased from 23% to 6% (p < 0.0001). The prevalences of eye symptoms among those who reported no exposure to ETS at work were 2% and among those who reported exposure to ETS for more than 4 hr a day 39%. | Low |
| **Schoj, 2010. Argentina**. Neuquén [67] | | | | | | | | |
| To evaluate the impact of SFL on sensory irritation symptoms among bar and restaurant workers | Comprehensive *Ban*: 15 November 2007 | *Pre-ban*: Oct 2007 *Post-ban*: March 2008 | Pre-posttest non-experimental design | 134 non-smokers bar and restaurant workers. 80 at follow up: 38.7% women Mean age 34.3 | Red or irritated eyes; sore and scratchy throat, sneezing and running nose. | IUATLD Bronchial Symptoms Questionnaire | The reduction of sensory irritation symptoms was even higher than the reduction of respiratory symptoms. From 86.3% of workers who reported at least one sensory irritation symptom in October 2007, only 37.5% reported the same symptoms in March 2008. | Low |
| **Wieslander, 2000. Sweden** [72] | | | | | | | | |
| To determine the influence of a ban on smoking on commercial airlines on nonspecific symptomatology | Labor: smoking ban on intercontinental flights *Ban*: September 1997 | *Pre-ban*: end of august 1997 *Post-ban*: 2 weeks after, Sept 1997 | Pre-posttest non-experimental design | Non asthmatic commercial aircrews. In pre-ban flight n = 39: 35% women, 8% asthmatic, 27% smokers. Post-ban flight n = 41: 0% asthma, 21% smokers | Symptoms (nasal, ocular, dermal and general symptoms). | Medical self-reported questionnaire, medical examination | There were fewer ocular symptoms. A numerical decrease of all types of individual symptoms occurred for the nonasthmatic subjects after the smoking ban. The occurrence of more than 1 ocular symptom was decreased from 55% to 11% (P = 0.004) after the smoking ban. The total symptom score was higher for the smoke conditions (mean 3.9) than for the nonsmoke conditions (mean 1.4) (p 0.05). | High |
| **Spirometry** | | | | | | | | |
| **Durham, 2011. Switzerland.** Canton of Vaud [78] | | | | | | | | |
| To assess the ban's impact in non-smokers as well as smokers on lung functions, ETS exposure symptoms and the perceived impact of the law. | Partial *Ban*: *15* September 2009 | *Pre-ban*: 30 April 2009 *Post-ban*: 26 September 2010 | Pre-posttest non-experimental design | 105 adult hospitality workers, 66 after one year. Age, mean (before): 37.4. Smoking status (before-after): 61%-54.6%. | Lung function by spirometry: forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) | Spirometry with an EasyOne portable spirometer. | Both baseline FEV1 and FVC are reduced to 90% of the predicted value compared to never smoking adults. FEV1 values were lower in men (87.84%) than in women (91.76%) and in smokers (88.68%) than in non-smokers (91.58%), similar values for FVC. At one-year there was a significant increase in FVC from 90.42% to 93.05%, marked in women (+3.07%), non-smokers (+3.91%) and older participants (+4.22%). Asthmatic participants had an almost significant increase in FEV1. | Low |
| **Eisner, 1998. California.** San Francisco [39] | | | | | | | | |

(*Continued*)

**Table 1.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To study the respiratory health of bartenders before and after legislative prohibition of smoking in all bars and tavern | Comprehensive *Ban*: January 1, 1998 | *Pre-ban*: December 1997 *Post-ban*: Feb 1998. | Pre-posttest non-experimental design | 54 of the daytime bartenders (81%) completed spirometry; 98% at follow-up. Mean age 42.5. Female 28%. Nonwhite 38%. | FEV1 and FVC | Spirometry | After prohibition of smoking, the mean FVC and FEV1 both increased at follow-up. Flow rate at midlung volumes (FEF25%-75%), which was highly variable, declined during the study period | Low |
| **Goodman, 2007. Ireland.** Dublin [43] | | | | | | | | |
| To examine the impact of this legislation on respiratory health effects in bar workers in Dublin. | Comprehensive *Ban*: 29 March 2004 | *Pre-ban*: Oct 2003–March 2004 *Post-ban*: Sept 2004 -March 2005. | Pre-posttest non-experimental design | Bar staff volunteers (n 81), from pubs mostly different. Mean age of 47.9 years at the preban assessment. | FEV1, FVC, forced expiratory flow of 25 to 75% (FEF25±75), peak expiratory flow (PEF), and others parameters | Spirometry | FVC increased significantly in never-smokers and ex-smokers, whereas it declined in current smokers. Although FEV1 did not change significantly in any group, it tended to increase in nonsmokers. The TLC increased in never-smokers and ex-smokers but not in smokers. PEF increased significantly in never-smokers, and it tended to decline in current smokers. FEF25±75 decreased in never-smokers and ex-smokers. | Low |
| **Larsson, 2008. Sweden:** Stockholm, Göteborg, Malmö, Uppsala, Västerås, Linköping, Örebro, Östersund, Skövde [52] | | | | | | | | |
| To evaluate the influence of the SFL among hospitality workers by examining the change in the rate of lung function before and 12 months after enacting | Partial *Ban*: 1 June 2005 | *Pre-ban*: April-May 2005 *Post-ban*: April-May 2006 | Pre-posttest non-experimental design | 91 hospitality workers of bingo halls and casinos. 71 (14 daily smokers and 57 nonsmokers) at follow-up 12 months after the ban: 70% female, 26% smokers | FEV1 and FVC | Spirometry | The mean FEV1 for the nonsmokers was defined as 100% at the baseline, after 12 months, it had declined to 99%. Among the smokers, it fell from 93% to 90%. The mean FVC of the nonsmokers was 93% at the baseline and 92% after 12 months, and, among the smokers, it fell from 94% to 92%. The regression analysis produced adjusted coefficients of 0.020 (p 0.566) for the nonsmokers and -0.004 (p 0.957) for the smokers. | Moderate |
| **Menzies, 2006. Scotland**. Dundee and Perth [58] | | | | | | | | |
| To investigate the association of SFL with symptoms and pulmonary function on bar workers | Comprehensive *Ban*: March 26, 2006 | *Pre-ban*: February 2006 *Post-ban*: 1 and 2 months after (May-June) | Pre-posttest non-experimental design | 105 bar workers nonsmokers and ex-smokers, without respiratory disease except asthma or rinitis (n = 23), 77 completed the study. Mean age: 37.5, male 41% | FEV1, PC10, forced exhaled nitric oxide (FENO) | Spirometry with a portable handheld spirometer | FEV1 increased from 96.6% predicted to 104.8% (change, 8.2%, 3.9% to 12.4%; p<0.001) and then 101.7% (change, 5.1%, 2.1% to 8.0%; p 0.002). The greatest gains were in the asthmatic cohort | Moderate |
| **Schoj, 2010. Argentina**. Neuquén [67] | | | | | | | | |
| To evaluate the impact of SFL on respiratory function among bar and restaurant workers | Comprehensive *Ban*: 15 November 2007 | *Pre-ban*: Oct 2007 *Post-ban*: March 2008 | Pre-posttest non-experimental design | 134 non-smokers workers. 80 at follow up: 38.7% women. 6.2% had a history of asthma. Mean age 34.3 | FEV1 and FVC | Spirometric measurements with a portable spirometer. | They found a significant improvement in FVC (mean 96, SD 12 to 88). They did not find any significant differences in FEV1 measurements (mean 90, SD 17 to 70). | Low |
| **Skogstad, 2006. Norway**. Oslo [68] | | | | | | | | |
| To compare cross shift changes in pulmonary function among employees in restaurants and bars before and after enforcement of SFL | Comprehensive *Ban*: 1 June 2004 | *Pre-ban*: May 2004 *Post-ban*: February 2005 | Pre-posttest non-experimental design | 93 subjects employed. At follow up 69 individuals: 35 women, 26 non-smokers and 11 asthmatics. | FVC, FEV1 and FEF 25±75 | Spirometry | The cross shift reduction in FVC not significant changed following the SFL. The reduction FEV1 during a workshift, almost significantly reduced. The reduction in FEF25±75% changed significantly from 199 ml/s to 64 ml/s. Among non-smokers and asthmatics, the reduction in FEV1 and FEF25±75 was significantly larger before compared to after. The mean pre-ban cross shift fall in FEV1 was 120 ml compared to 37ml (p 0.03) post-ban and FEF25±75 decreased from 218 ml/s to 65 ml/s (p 0.01). | Moderate |
| **Vinnikov, 2013. Kyrgyzstan.** Tyan Shan mountain [71] | | | | | | | | |
| To assess whether annual lung function change associated with chronic intermittent hypoxia and smoking exposures differed after a workplace smoking ban | Labor *Ban*: January 2009 | *Pre-ban*: 3 years before (2006±2009) *Post-ban*: 2 years until 2011 | Pre-posttest non-experimental design | 109 high-altitude gold-mine healthy miners at high altitude (4000 m), local subjects, 59% active mine production workers. Women, n = 13 (0 smokers). Males: 55% current smokers at the baseline. Mean age 32.5 years. | FEV1 and FVC, FVC% pred, and the FEV1/FVC ratio | MicroMedical MicroLab (UK) equipment, Smokerlyzer CO (Bedfont, UK). | There was a 115 ± 9 mL annual decline in lung function before the ban but a 178 ± 20 mL per annum increase in the final 2 years (P < 0.001). There was a 2.1 ± 0.3% annual decline in FEV1% pred until the ban and a 4.6 ± 0.5% increase after the ban. FVC, as with FEV1, the magnitude of the change was clinically relevant, lung function declined before the smoking ban and improved after it. For FVC and FVC% pred, annual change was statistically significant in both time periods; for FEV1/FVC, the decline before the ban was statistically significant, but the positive slope after the ban was not statistically significant. | Low |

(*Continued*)

**Table 1.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| **Asthma symptoms** | | | | | | | | |
| **Dove, 2010. US** [37] | | | | | | | | |
| To investigate the association between smoke-free laws and asthma prevalence and severity among nonsmoking youth | Different types of laws and differents locations | From 1999 to 2006, in 2-year cycles | Posttest quasi-experimentaldesign. | Size of 8800, USA nonsmoking children and adolescents participants aged 3±15 years | Asthma prevalence. Asthmatic symptoms | National Health and Nutrition Examination Survey (NHANES). Self reported asthma severity. | SFL were associated with lower odds of asthmatic symptoms (OR: 0.67, 0.48 to 0.93) and trended toward lower odds o f ever having asthma with current symptoms (OR 0.74, 0.53 to 1.03) and asthma attacks (OR 0.66, 0.28 to 1.56) | High |
| **Asthma severity** | | | | | | | | |
| **Kalkhoran, 2014. Uruguay.** Montevideo [79] | | | | | | | | |
| To evaluate the impact of a SFL on non-hospital emergency care visits, hospitalizations for bronchospasm, and bronchodilator use | Comprehensive *Ban*: 1 March 2006 | *Pre-ban*: 3 years before *Post-ban*: 5 years after. February 28, 2011 | Non-experimental time series design | 180,000 people in Montevideo aged ≥ 15 year with a non-hospital emergency visit for bronchospasm | Puffs of salbutamol, and ipratropium, administered per patient per month in the non- hospital emergency setting and during transfer to the hospital. | Electronic medical record of Servicio de Urgencia, Asistencia y Traslado. Medical Emergency Service. | Total monthly puffs of salbutamol and ipratropium administered in the non-hospital emergency setting decreased by 224 (-372 to ±76) and 179 (±340 to ±18.6), respectively, from means of 1,222 and 1,007 before the law | Low |
| **Menzies, 2006. Scotland**. Dundee and Perth [58] | | | | | | | | |
| To investigate the association of SFL with symptoms and pulmonary function on bar workers nonsmokers and ex-smokers | Comprehensive *Ban*: 26 March 2006 | *Pre-ban*: Feb 2006 *Post-ban*: May-June 2006 | Pre-posttest non-experimental design | 105 bar workers, without respiratory disease except asthma or rinitis (n = 23), 77 completed the study. Mean age: 37.5, male 41% | Asthma quality- of-life scores, data on current prescribed asthma medication | Self administration Juniper quality-of-life scores. | Asthmatic bar workers:Juniper quality-of-life scores increased from 80.2 to 87.5 points (7.3 points, 0.1 to 14.6 points; p 0.049). Indeed, a 0.5-point improvement is regarded as a clinically significant change in this tool. | Moderate |
| **Other** | | | | | | | | |
| **Dove, 2010. US** [37] | | | | | | | | |
| To investigate the association between smoke-free laws and persistent ear infection among nonsmoking youth (aged 3±15 years). | Different types of laws in differents settings | From 1999 to 2006, in 2-year cycles | Posttest quasi-experimental design | Size of 8800, USA nonsmoking children and adolescents participants aged 3±15 years | Persistent ear infection (3 or more ear infections in the previous year). | NHANES. Self reported persitent ear infection. | Youth living in smoke-free counties had approximately half the prevalence of persistent ear infections in the previous year (3.4%) compared with youth living in counties without a smoke-free law (6.1%). After adjustment for covariates, this difference no longer persisted. Youth living in the South and Midwest were more likely to have persistent ear infection and were less likely to live in a smoke-free county. The OR adjusted for all covariates except region was 0.64 (0.37 to 1.10) | High |

CI: confidence interval. CO: carbon monoxide. ECRHS: European Community Respiratory Health Study. ETS: environmental tobacco smoke. FEF 25± 75%: forced expiratory flow of 25 to 75%. FENO: forced exhaled nitric oxide. FEV1: forced expiratory volume in one second. FVC: forced vital capacity. ICD: International Classification of Disease. IQR: Interquartile range. IUATLD: International Union Against Tuberculosis and Lung Disease. NHANES: National Health and Nutrition Examination Survey. NS: no significant. OR: odds ratio. PC10: provocative concentration of methacholine causing a 10% decrease in FEV1. PEF: peak expiratory flow. RR: rate ratio. RV: residual volume. SD: standard deviation. SE: standard error. SFL: smokefree law. SHS: secondhand smoke. TLC: total lung capacity

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In addition, two studies focused on children in environments with non strictly comprehensive legislations (one with mixed types of SFL in the same paper[37] and one with partial SFL [47]). They showed discrepant results: an increase of 1.9%[47] in any respiratory symptom in the post-ban period and a decrease in asthmatic symptoms, persistent wheezing, and chronic night cough[37].

Effects regarding ªany respiratory symptomº appeared to be more intense in the period immediately following implementation of the smoking law (maximum decrease of 42.0%[39]) than six months later (maximum 25.0%[43]), particularly in the studies that evaluated comprehensive SFL. In contrast, in partial SFL the declines in percentages of individuals with ªany respiratory symptomº were similiar (around 15.0%[65,74]) irrespective of the moment of evaluation.

Ten studies were included in the meta-analysis for the outcome ªany respiratory symptomº in comprehensive SFL setting (one study was stratified in two due to two regions being

**Table 2. Summary of studies on the impact of smoke-free legislation on admissions.**

| Asthma | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Aims** | **Legislation** | **Study period** | **Study design** | **Study participants and size** | **Variables** | **Source of information** | **Summary of findings** | **Risk of Bias** |
| **Croghan, 2015. US.** Minnesota [34] | | | | | | | | |
| To evaluate the impact of a state- wide clean indoor air law on the frequency of emergency department (ED) visits for asthma. | Comprehensive *Ban*: 16 May 2007. Enacted on 1 October 2007 | *Pre-ban*: 1 January 2005 *Post-ban*: 31 Dec 2009 | Non-experimental time series design | 2013 general population, 147,066 (86.5% white, 51.1% female), median age 37 for asthma; 47 for adults, 6 for children | ED visits for primary diagnosis of asthma (ICD,9th code 493) adjusted by age and sex | Medical records of Mayo Clinic and Olmsted Medical Center | 5,906 ED visits with a primary diagnosis of asthma during the 5-year study period. A significant reduction was detected in asthma-related ED visits (RR 0.814) following the enactment of the SFL. The reduction was observed in both adults (RR 0.840) and children (RR 0.751). | Low |
| **Dove, 2010. US** [37] | | | | | | | | |
| To investigate the association between smoke-free laws and asthma prevalence, and severity among nonsmoking youth | Different types of laws in different settings | From 1999 to 2006, in 2-year cycles | Posttest quasi-experimental design | Size of 8800, USA nonsmoking children and adolescents participants aged 3±15 years | Asthma severity (asthma attack or emergency-department visit for asthma) | NHANES. Self reported asthma severity. | Smoke-free laws were associated with lower odds of emergency-department visits for asthma (OR: 0.55, 0.27 to1.13), although these results were not statistically significant | High |
| **Gaudreau 2013. Canada.** Prince Edward Island (PEI) [42] | | | | | | | | |
| To examine changes in hospital admission rates for respiratory (asthma) conditions were examined before and after a SFL. | Comprehensive *Ban*: 1 June 2003 | *Pre-ban*: April 1995 -May 2003 *Post-ban*: June 2003 ± Dec 2008 | Quasi-experimental time series design | PEI population of 143,000. Province of New Brunswick (NB) population 729,995. | Asthma admissions were divided into pediatric admissions under 15 years of age and adult admissions over 15 years of age (ICD-9 493 and ICD-10 J45-J46) | PEI acute care hospitals registers. Census data from 2001 and 2006 | Crude annual admissions for pediatric (p<0.01) and adult asthma (p<0.01) trended downward from 1995 to 2008. Change in monthly means of admission for respiratory and control conditions after the SFL by sex, per 100,000 population 1995 to 2008: pediatric asthma male 0.97(p 0.89), female 0.91(p 0.81); adult asthma male 1.42 (p 0.42), female 1.45 (p 0.17). | Low |
| **Head, 2012. US.** Beamont (Texas) [45] | | | | | | | | |
| To examine hospital discharge data on 5 tobacco-related diagnoses before and after implementation of a smoking ban | Comprehensive *Ban*: July 2006 | *Pre- Ban*: July 2004-June 2006. *Post Ban*: July 2006-June 2008 | Pre-posttest quasi-experimental design | All residents. Intervention city: Beaumont (≈115,000). Control city: Tyler (≈ 87,600). Mean age: 33 years, Beaumont non-Hispanic black 50% | Hospital discharge rates for asthma (ICD-9 493) | The Texas Department of State Health Services Discharge. Census information | Discharge rates in the intervention city (Beaumont) declined significantly for asthma (RR 0.69; 0.52±0.91) for whites only. Discharge rates for asthma in the control city (Tyler) did not change. | High |
| **Herman, 2011. US.** Arizona [46] | | | | | | | | |
| To examined the impact of a comprehensive statewide smoking ban on hospital admissions for asthma. | Comprehensive *Ban*: May 1, 2007 | *Pre-ban*: Jan 2004- April 2007. *Post-ban*: May 2007 to May 2008. | Quasi-experimental time series design | All Arizona residents (general population). | Primary diagnoses for acute asthma admissions (ICD-9 code: 493). | Hospital admission data gathered by the 87 hospitals in Arizona | The estimated change in admissions for asthma in ban counties is negative and statistically significant. There is evidence that the following reductions (and percentage reductions) in hospital admission cases in the non previous ban counties from May 1, 2007, to May 31, 2008, are attributable to the statewide ban: 249 (22%) fewer asthma cases. | Moderate |
| **Humair, 2014. Switzerland.** Canton of Geneva [48] | | | | | | | | |

(*Continued*)

**Table 2.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To evaluate the effect of the public smoking ban on hospital admissions for acute respiratory diseases | Comprehensive *Ban*: 1 July 2008 | *Pre-ban*: July 2006-July 2008 *Post-ban*: 1rst ban: July 2008- Sept 2008 No ban: Oct 2008- Oct 2009 2nd Ban: Oct 2009-Dec 2010 | Pre-posttest non-experimental design | Patients aged ≥ 16 admitted to University Hospitals of Geneva, with about 450,000 inhabitants. 5345 total admissions: 60% males, mean age of 67. 204 patients with a first hospitalization for acute asthma | First hospitalization for asthma (ICD-10 codes: J45-46). | Hospital database of the University Hospitals of Geneva. Census data of Geneva | Despite variations in the number of admissions, adjusted IRR of hospitalizations for acute asthma did not significantly change throughout the 4 periods (IRR final period 1.17; CI 0.82±1.66; p 0.81 for all patients and IRR final period 1.36; CI 0.91± 2.01, p 0.42 for Geneva residents only) | Moderate |
| **Kalkhoran, 2014. Uruguay.** Montevideo [79] | | | | | | | | |
| To evaluate the impact of Uruguay's national 100% smokefree legislation on non-hospital emergency care visits, hospitalizations for bronchospasm, and bronchodilator use | Comprehensive *Ban*: March 1, 2006 | *Pre-ban*: 3 years before *Post-ban*: 5 years after. February 28, 2011 | Non-experimental time series design | 180,000 people in Montevideo, Uruguay aged ≥ 15 year with a non-hospital emergency visit for bronchospasm | Number of monthly visits for bronchospasm from the non-hospital emergency service, number of individuals subsequently hospitalized (ICD-10 J45) | Electronic record of Servicio de Urgencia, Asistencia y Traslado. | The incidence of non-hospital emergency visits for bronchospasm decreased by 15% (IRR 0.85, 0.76 to 0.94) following implementation of the law. Hospitalizations for bronchospasm did not change significantly (IRR 0.89, 0.66 to 1.21). | Low |
| **Kent, 2012. Ireland** [49] | | | | | | | | |
| To examine the impact of a SFL on emergency hospital admissions with pulmonary illness among individuals of working age | Comprehensive *Ban*: March 2004 | *Pre-ban*: 2002±2003 *Post-ban*: 2005±2006 | Pre-posttest non-experimental design | 286,000 individuals between the ages of 20 and 69 | Emergency medical admissions with acute exacerbations of asthma (ICD-9 and ICD-10) | Hospital In-Patient Enquiry (HIPE) database and census data | Significant reductions were observed in admissions due to asthma (unadjusted RR 0.64; p 0.0001, adjusted by age RR 0.60, in 30±39 years old). These changes remained significant following incorporation of confounding factors into the regression model. The observed changes in admission incidence were influenced by age. | Moderate |
| **Landers, 2014. US**: Arizona, Colorado Florida,Hawaii, Iowa, Maryland, New Jersey, New York, Rhode Island, Utah,Vermont, Washington, Arkansas, Kentucky, Michigan, South Carolina, Wisconsin [51] | | | | | | | | |
| To examine the relationship between SFL and asthma discharges | Comprehensive | 2002±2009 Different locations and different pre and post-ban periods | Pretest-posttest quasi-experimental design | US population (103,000,000 individuals, 35% of the US population). Adults and children admitted for asthma in 17 states (12 state SFL, and 5 states without state SFL as a control group) | Asthma discharges per children or working-age adult. Appendicitis as a control variable. | Healthcare cost and Utilization Project state inpatient data. American Nonsmokers Rights Foundation SFL database | There was a statistically significant relationship (b ±2.44) between the implementation of county laws and reductions in workin-age adult asthma discharges. There was no statistically significant effect of state SFL on working-age adult asthma discharges besides the effect of county laws. There was also a statistically significant relationship between the implementation of county some-free laws and reductions in child asthma discharges (b ± 1.32;) but there was no statistically significant effect of state laws on child asthma discharges besides the effect of county laws. | Low |
| **Mackay, 2010. Scotland** [35] | | | | | | | | |

(*Continued*)

**Table 2.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To determine whether the SFL in Scotland, influenced the rate of hospital admissions for childhood asthma and deaths before arrival at the hospital. | Comprehensive *Ban*: 26 March 2006 | *Pre-ban*: January 2000 ±March 2006 *Post-ban*: March 2006 October 2009 | Non-experimental time series design | Children younger than 15 years. Of the 21,415 admissions for asthma, 11,796 (55.1%) occurred among preschool and 9619 (44.9%) among school-age children | Hospital admissions for asthma (ICD-10 J45 or J46) | Scottish Morbidity Record and death-certificate | Before the SFL, admissions for asthma were increasing at a mean rate of 5.2% per year. Post-ban there was a mean reduction in the rate of admissions of 18.2%, per year relative to the ban (p<0.001), net reduction 13% per year (after adjusting for confounders 15.1%) among both preschool and school-age children. There were no significant interactions between admissions for asthma and age group, sex, urban or rural residence, region, or quintile of socioeconomic status. Only 5 deaths occurred over the study period. | Low |
| **Millet, 2013. England** [59] | | | | | | | | |
| To assess whether the implementation of SFL was associated with a reduction in hospital admissions for childhood asthma and to examine whether changes differed by socioeconomic status (SES). | Comprehensive *Ban*: 1 July 2007 | *Pre-ban*: April 2002 *Post-ban*: November 2010 | Non-experimental time series design | All children (aged ≤14 years) having an emergency hospital admission for asthma. 217381 admissions, 50.1% preschool (49.9% school). 63.4% in boys. 86.5% in urban locations. | All non- planned admissions with a principal diagnosis of asthma (ICD codes: J45 or J46) | Hospital Episodes Sta- tistics data and census data | Before the implementation of the SFL the admission rate for childhood asthma was increasing by 2.2% per year. After SFL, there was a significant immediate change in the admission rate of -8.9% and change in time trend of 23.4% per year. This change was equivalent to 6802 fewer hospital admissions in the first 3 years after SFL. There were similar reductions in asthma admission rates among children from different age, gender, and socioeconomic status groups and among those residing in urban and rural locations. | Low |
| **Moraros, 2010. US.** Delaware [60] | | | | | | | | |
| To examine and determine the effects of a comprehensive SFL on the hospitalization rates of patients due to asthma among residents and non-residents | Comprehensive *Ban*: November 2002 | *Pre-ban*: 1999±2002 *Post-ban*: 2003±2004 | Quasi experimental time series design | Delaware population>18: 783,600 in 2000. 51.4% female. Percentage of smokers: 25.4% in 1999 and 24.4% in 2004. 13.0% ≥65 years. | State and non-state residents discharged with primary discharge diagnosis asthma patients (ICD-9- 410 and 493) | Delaware Department of Health and Social Services. US census data | After adjusting for population growth, the RR for asthma in Delaware residents post-ordinance was 0.95 (0.90 to 0.999), which represented a significant reduction. By comparison, non-Delaware residents had an increased RR for asthma post-ordinance of 1.62 (p< 0.0001). | Low |
| **Naiman, 2010. Canada**. Toronto [61] | | | | | | | | |
| To study rates of hospital admission attributable to asthma after the implementation of smoking bans. | Partial in three phases: *Ban 1*: Oct 1999 *Ban 2*: June 2001 (restaurants) *Ban 3*: June 2004 -March 2006. | *Pre-ban*: 1996 (three years before) *Post-ban*: 1999±2006 | Quasi experimental time series design | Toronto: population of about 2.5 million people. Study population = younger than age 65 years. | Admission to hospital diagnostic for asthma (ICD-9 493 and ICD-10 J45 or J46) Compared to control diseases: acute cholecystitis, bowel obstruction and appendicitis | Canadian Census. Database of the Canadian Institute for Health Information | Reduction in rate of admission for asthma only were significant when they compared smoking ban in restaurant vs in public places and workplaces(-0.354, p<0.001) | Moderate |
| **Rayens, 2008. US.** Kentucky [64] | | | | | | | | |

(*Continued*)

**Table 2.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To evaluate the effects of a smoke-free law on the rate of ED visits for asthma. | Comprehensive *Ban*: 27 April 2004 | *Pre-ban*: 1 January 2001 (40 months before) *Post-ban*: 31 December 2006 | Non-experimental time series design | All 5 Lexington-Fayette County hospitals population. The prelaw cohort (262,186 individuals): mean age 29.5, 63% female, Postlaw: mean age 29.7. 63% female | Asthma ED visits, primary and secondary diagnoses (ICD 9 493) | Hospital registers. The 2000 US Census | A total of 14,839 ED visits for asthma events: 7763 prelaw and 7076 postlaw. 36% of prelaw cases were < 20 years, equivalent to the percentage of pediatric cases postlaw. ED visits for asthma increased frequency of over time, also reflected in the age-adjusted rates. Adjusting for confounders, ED visits for asthma declined 22% from prelaw to postlaw (p<0.0001).The rate of decline was 24% in adults≥20 (p 0.0001), whereas the decrease among children 19 years or younger was 18% (p 0.01) | Moderate |
| **Roberts, 2012. US**. Rhode Island [66] | | | | | | | | |
| To determine whether Rhode Island's SFL reduced hospital admission rates and associated costs for asthma. | Comprehensive *Ban*: March 2005 | *Pre-ban*: 2003±2004 *Post-ban*: Phase I: 2006±2007 Phase II: 2008±2009 | Non-experimental time series design | Adults> = 18 years residents in Rhode Island's. Population size not shown | Admissions to one of Rhode Island's 11 acute care general hospitals for asthma (ICD-9 493), appendicitis as the control condition | Rhode Island's Hospital Discharge Data | There was a significant increase in hospitalization rates for asthma between 2003 (11.3) and 2009 (13.5). | Moderate |
| **Sims, 2013. England** [53] | | | | | | | | |
| To investigate if SFL was associated with an immediate reduction in hospital admissions for asthma in adults and whether any association differs across regions | Comprehensive *Ban*: 1 July 2007 | *Pre-ban*: April 1997 *Post-ban*: December 2010 | Non-experimental time series design | England residents adults ≥ 16 years (43 million individuals). | Emergency admissions for adult asthma (primary diagnosis, ICD-10 code J45 and J46) | Hospital Episode Statistics data | 502 000 emergency admissions had a primary diagnosis of asthma in the period 1997±2010. SFL was associated with an immediate 4.9% (0.6 to 9.0) reduction in emergency admissions for asthma in the adult population. Approximately 1900 emergency admissions for asthma were prevented in each of the first three years after SFL. The reduction in admissions did not vary significantly across regions. | Moderate |
| **Yildiz, 2015. Turkey.** Kocaeli [75] | | | | | | | | |
| To evaluate admissions to ED for smoking-related diseases prior to and following the introduction of SFL in Kocaeli. | Comprehensive *Ban*: 19 July 2009 | *Pre-ban*: Jan 2009 *Post-ban*: June 2010 | Non-experimental time series design | Patients visiting ED of 13 hospitals. Kocaeli. Population size not shown. | Emergency visits for asthma (ICD-10 J45), nasopharyngitis, rinitis, allergic rhinitis (ICD J.30), | Directorate of Health in Kocaeli | Total admissions for smoking-related diseases were 83089 in 2009 and 64314 in 2010, a 22.6% decrease. The number of patients admitted with asthma showed a non-significant increase (Increase nº 6805 to 7895) | Moderate |
| **COPD** | | | | | | | | |
| **Croghan, 2015. US.** Minnesota (Olmsted County) [34] | | | | | | | | |
| To evaluate the impact of the implementation of a SFL on the frequency of ED visits for COPD | Comprehensive Ban: 16 May 2007. Enacted on 1 October 2007 | *Pre-ban*: 1 Jan 2005 *Post-ban*: 31 Dec 2009 | Non-experimental time series design | 2013 population, 147,066 (86.5% white, 51.1% female), median age 75 for COPD; 47 for adults. | ED visits for primary diagnosis of COPD (ICD, 9th codes 491± 492 and 494±496) | Mayo Clinic and Olmsted Medical Center | 5,293 ED visits occurred with a primary diagnosis of COPD during the 5-year study period. Not significant reduction was detected in COPD-related ED visits following the enactment of the SFL. | Low |
| **Dusemund, 2014. Switzerland** [38] | | | | | | | | |

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**Table 2.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To evaluate the effect of the SFL on the incidence of hospital admissions for acute exacerbation of COPD (AECOPD) | Comprehensive *Ban*:1 March 2008 | *Pre-ban*:1 March 2003 2008 *Post-ban*: 28 Feb 2010 | Pretest-posttest quasi-experimental design. | Inhabitants of the canton of Graubünden (GR; 191,988) vs the rest of Switzerland (CH, 7,272,481) | Admissions for AECOPD (ICD-10-codes: J40±44). | Nation-wide database (all hospitalizations in Switzerland) | After the introduction of the SFL and despite clear seasonal variations, the incidence of AECOPD decreased 22.4% in hospitalizations in GR (p <0.001). In the same period, the incidence of AECOPD hospitalizations only slightly decreased by 7.0% in the rest of CH, p<0.001. | Low |
| **Gaudreau 2013. Canada** Prince Edward Island (PEI) [42] | | | | | | | | |
| To examine changes in hospital admission rates for COPD before and after a SFL. | Comprehensive *Ban*: 1 June 2003 | *Pre-ban*: April 1995 -May 2003 *Post-ban*: June 2003Ð December 2008 | Quasi-experimental time series design | PEI population of 143,000. Province of New Brunswick (NB) population 729,995. | Admission for COPD (ICD-9 491, 492, 494, 496 and ICD-10 J41-J44) restricted to ≥35 | PEI acute care hospitals registers. Census data from 2001 and 2006 | Among all hospital admissions for COPD, males were 57.3%. COPD admissions peaked at 75 to 84 years of age (35.7%). COPD admissions showed a non-significant decrease in mean monthly admission rates immediately after the 2003 SFL. Change in monthly rates means of admission after the SFL by sex, per 100,000 population 1995 to 2008: COPD male -11.79 (-32.51, 8.93), female 1.67(-18.84, 22.17). And by age group: COPD 35± 64 years:0.64 (-11.12 to 6.79), 65±104 years: 0.94 (-56.82 to 52.32) | Low |
| **Head, 2012. US.** Beaumont (Texas) [45] | | | | | | | | |
| To examine hospital discharge data on 5 tobacco-related diagnoses before and after implementation of a SFL | Comprehensive *Ban*: July 2006 | *Pre- Ban*: July 2004-June 2006. *Post Ban*: July 2006-June 2008 | Pre-posttest quasi-experimental design | All residents. Intervention city: Beaumont (≈115,000). Control city:Tyler (≈ 87,600). Mean age 33 years, Beaumont non-Hispanic black population 50% | Hospital discharge rates for COPD (ICD-9 491,492, 496) | Texas Department of State Health Services Discharge. Census information | Discharge rates in the intervention city (Beaumont) declined significantly for COPD (RR, 0.64) for whites only. Discharge rates for COPD in the control city (Tyler) did not change. | High |
| **Humair, 2014. Switzerland.** Canton of Geneva [48] | | | | | | | | |
| To evaluate the effect of the public smoking ban on hospital admissions for acute respiratory diseases | Comprehensive *Ban*: 1 July 2008 | *Pre-ban*: 1 July 2006±1 July 2008 *Post-ban*: 1rst ban: 1 July 2008±30 Sept 2008 No ban: 1 Oct 2008±31 Oct 2009 2nd Ban: 30Oct 2009-Dec 2010 | Pre-posttest non experimental design | Patients aged ≥ 16 admitted to University Hospitals of Geneva (≈450,000 inhabitants). 5345 total admissions: 60% males, mean age 67. 436 first AECOPD | First hospitalization for COPD entities among chronic lower respiratory diseases (ICD-10 codes: J40± 44) | Hospital database of the University Hospitals of Geneva. Census data of Geneva | For AECOPD, the weekly number of hospitalizations dropped over the 4 periods from 2.45 to 1.54 (p 0.0001). The adjusted IRR decreased significantly in all periods after the initial smoking ban; it reached 0.54 for all patients and 0.53 for Geneva residents during the 2nd ban. There was a change in the slope of the trend line across the study periods. The reduction started before the legislative smoking ban and became stable in the second part of the period with no ban but partially maintained in practice. The smoking ban could prevent yearly 47 new hospitalizations for AECOPD. | Moderate |
| **Kent, 2012. Ireland** [49] | | | | | | | | |

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**Table 2.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To examine the impact of a SFL on emergency hospital admissions with COPD | Comprehensive *Ban*: March 2004 | *Pre-ban*: 2002±2003 *Post-ban*: 2005±2006 | Pre-posttest non experimental design | 286,00 individuals of working age: 20±69 years | Emergency medical admissions with exacerbations of COPD (ICD-9 and ICD-10) | Hospital In-Patient Enquiry database. Census data | COPD admissions increased in unadjusted analysis (unadjusted RR, 1.21; p 0.04), but significance was lost in adjusted analysis (adjusted RR, 1.18, p.30). The observed changes in admission incidence were markedly influenced by age. | Moderate |
| **Naiman, 2010. Canada**. Toronto [61] | | | | | | | | |
| To study rates of hospital admission attributable to COPD after the implementation of smoking bans. | Partial (3 phases) *Ban 1*: October 1999 *Ban 2*: June 2001 (restaurants) *Ban 3*: June 2004-March 2006 | *Pre-ban*: 1996 (three years before) *Post-ban*: 1999±2006 | Quasi experimental time series design | Toronto: population of about 2.5 million people. Study population = younger than age 65 years. | Admission to hospital diagnostic for COPD (ICD-9 433±436 and ICD-10 I63-66 or G45-46). Compared to control disease: acute cholecystitis, bowel obstruction and appendicitis | Canadian Census. Database of the Canadian Institute for Health Information | Reduction in rate of admission for COPD only were significant when they compared smoking ban in restaurant vs in public places and workplaces(-1.040, p<0.008) | Moderate |
| **Vander, 2012. US** [54] | | | | | | | | |
| To examine effects of 3 types of smoking bans -in restaurants, bars, and workplaces-to determine whether their impact differs according to location and whether there is a relationship between the comprehensiveness and COPD admissions (vs non SHS related diseases) | Different types of laws in different places. 938 laws passed by municipalities, counties, and states to ban smoking in workplaces, restaurants, and bars | 1991±2008. *Pre-ban*: no specified *Post-ban*: 1±3 months after 4±12 months after 13±36 months after >36months after | Pretest-posttest quasi-experimental design | Medicare beneficiaries age $\geq$ 65 for counties that ever or never had a smoking ban as of 2008 ($\approx$ 36.5 millions individuals) | Hospital admissions for COPD (ICD-10) | US Tobacco Control Laws Database. 2000 census. Centers for Medicare and Medicaid Services Denominator | Unadjusted admission rates for COPD during 18-year study period increased. By 2008, mean unadjusted admission rates had increased by 80%.There were no significant differences during 1991 in admission rates between counties that ever or never had a ban. Admission rates fell 11% where workplace smoking bans were in place and 15% where bar smoking bans were present. The increase for counties with a new ban was 5% lower than expected within the first 3 months after the first ban, and 10% and 17% lower within 12 months and after 36 months, respectively. Counties with bans in one, two, or three settings experienced increases in COPD admission rates that were 9%, 14%, and 7% lower than those experienced by counties without bans, respectively (p< 0.001) | High |
| **Yildiz, 2015. Turkey.** Kocaeli [75] | | | | | | | | |
| To evaluate admissions to ED for smoking-related diseases prior to and following the introduction of SFL | Comprehensive *Ban*: 19 July 2009 | *Pre-ban*: Jan 2009 *Post-ban*: June 2010 | Non-experimental time series design | Patients visiting ED of 13 hospitals. Kocaeli. Population size not shown. | Emergency visits for COPD (ICD-10 J.44) | Directorate of Health in Kocaeli | There was a large decrease in the numbers of patients admitted to emergency departments with COPD after the smoking legislation was introduced than before (8342 versus 6571, p>0.05) | Moderate |
| **Pneumoniae/Bronchitis** | | | | | | | | |
| **Humair, 2014. Switzerland.** Canton of Geneva [48] | | | | | | | | |

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**Table 2.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To evaluate the effect of the public smoking ban on hospital admissions for acute respiratory diseases | Comprehensive *Ban*: 1 July 2008 | *Pre-ban*: 1 July 2006±1 July 2008 *Post-ban*: 1rst ban: 1 July 2008- Sept 2008 No ban: Oct 2008±31 Oct 2009 2nd Ban: 30 Oct 2009-Dec 2010 | Pre-posttest non-experimental design | Pacients aged ≥ 16 admitted to University Hospitals of Geneva, (≈450,000 inhabitants).5345 admissions: 60% males, mean age 67. 239 firsts pneumonia | First hospitalization for pneumonia or influenza (ICD-10 codes: J 10± 16) | Hospital database of the University Hospitals of Geneva. Census data of Geneva | Despite variations in the number of admissions, adjusted IRR of hospitalizations for pneumonia did not significantly change throughout the 4 periods. IRR all patients for the final period 1(0.75±1.35) and for Geneva residents only 0.97(0.70±1.35) | Moderate |
| **Kent, 2012. Ireland** [49] | | | | | | | | |
| To examine the potential impact of SFL on emergency hospital admissions with pulmonary illness | Comprehensive *Ban*: March 2004 | *Pre-ban*: 2002±2003 *Post-ban*: 2005±2006 | Pre-posttest non-experimental design | 286,000 individuals of working age:20±69 years. | Emergency medical admissions with acute pneumonia, lower respiratory tract infection-LRTIs (ICD-9 and ICD-10) | Hospital In-Patient Enquiry database. Census data | Significant reductions were observed in admissions due to pneumonia (unadjusted RR, 0.77; 0.64 to 0.93; adjusted 0.71, 0.52± 0.98). These changes remained significant following incorporation of confounding factors into the regression model. The observed changes in admission incidence were markedly influenced by age. | Moderate |
| **Naiman, 2010. Canada**. Toronto [61] | | | | | | | | |
| To study rates of hospital admission attributable to pneumonia or bronchitis after the implementation of smoking bans. | Partial (3 phases) *Ban 1*: October 1999 *Ban 2*: June 2001 (restaurants) *Ban 3*: June 2004 to March 2006). | *Pre-ban*: 1996 (three years before) *Post-ban*: 1999±2006 | Quasi experimental time series design | Toronto: population of about 2.5 million people. Study population = younger than age 65 years. | Admission to hospital diagnostic for pneumonia or bronchitis (ICD-9 266, 480±486 and ICD-10 J12-18, J20). Compared to control disease: acute cholecystitis, bowel obstruction and appendicitis | Canadian Census. Database of the Canadian Institute for Health Information | Crude rates of admission to hospital because of conditions decreased by 33% (32% to 34%) during the ban period affecting restaurant settings (no when affecting other settings). There was a 13.5% overall reduction in admissions for respiratory conditions (p 0.239). Reduction in rate of admission for pneumonia or bronquitis only were significant when they compared smoking ban in restaurant vs in public places and workplaces (-0.598) | Moderate |
| **Yildiz, 2015. Turkey.** Kocaeli [75] | | | | | | | | |
| To evaluate admissions to ED for smoking-related diseases prior to and following the introduction of SFL | Comprehensive *Ban*: 19 July 2009 | *Pre-ban*: January 2009 *Post-ban*: June 2010 | Non-experimental time series design | Patients visiting emergency department of 13 hospitals. Kocaeli. Population size not shown. | Emergency visits for bronchitis (ICD-10 J.20) | Directorate of Health in Kocaeli | Total admissions for smoking-related diseases were 83089 in 2009 and 64314 in 2010, a 22.6% decrease. The number of patients who were admitted to the emergency department with chronic bronchitis was 44141 for the 6-month period in 2009 and 26558 over the same 6-month period in 2010, a reduction of 39.8% (p<0.01). | Moderate |
| **Pneumothorax** | | | | | | | | |
| **Kent, 2012. Ireland** [49] | | | | | | | | |

(*Continued*)

**Table 2.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To examine the impact of SFL on emergency hospital admissions with pulmonary illness | Comprehensive *Ban*: March 2004 | *Pre-ban*: 2002±2003 *Post-ban*: 2005±2006 | Pre-posttest non-experimental design | 286,000 individuals of working age: 20±69 years | Admissions for spontaneous pneumothorax (ICD-9 and ICD-10) | Hospital In-Patient Enquiry database. Census data | No significant change was observed in unadjusted or adjusted analysis with regard to emergency admissions due to spontaneous pneumothorax (RR 0.62). The observed changes in admission incidence were markedly influenced by age. | Moderate |
| **Lower respiratory infection** | | | | | | | | |
| **Kent, 2012. Ireland** [49] | | | | | | | | |
| To examine the potential impact of the Irish smoking ban on emergency hospital admissions with pulmonary illness | Comprehensive *Ban*: March 2004 | *Pre-ban*: 2002±2003 *Post-ban*: 2005±2006 | Pre-posttest non-experimental design | 286,000 individuals of working age: 20±69 years. | Emergency admissions for exacerbations LRTIs (ICD-9 and ICD-10) | Hospital In-Patient Enquiry database. Census data | Admissions due to acute pulmonary illness declined significantly from 439 admissions per 100,000 population per annum in pre-ban period to 396 in post-ban period (unadjusted RR 0.91, adjusted 0.83). This decrease persisted following adjustment for confounding variables (RR, 0.85). No significant change was observed in emergency admissions due to lower respiratory tract infections/acute bronchitis. | Moderate |
| **Yildiz, 2015. Turkey.** Kocaeli [75] | | | | | | | | |
| To evaluate admissions to ED for smoking-related diseases prior to and following a SFL | Comprehensive *Ban*: 19 July 2009 | *Pre-ban*: Jan 2009 *Post-ban*: June 2010 | Non-experimental time series design | Patients visiting ED of 13 hospitals in Kocaeli. Population size not shown. | Emergency visits for bronchitis (J.20), LRTI/ pneumonia (J.22/J.18) | Directorate of Health in Kocaeli | Total admissions for smoking-related diseases were 83089 in 2009 and 64314 in 2010, a 22.6% decrease. Time-series analysis showed that the decreases were significant for bronchitis and lower respiratory tract infections. | Moderate |
| **Respiratory diseases** | | | | | | | | |
| **Dilley, 2012. Washington State** [36] | | | | | | | | |
| To examine health effects associated with 3 tobacco control interventions: a comprehensive state program, a state policy banning smoking in public places, and price increases | Comprehensive *Ban*: December 2005 | *Pre-ban*: 1990 *Post-ban*: December 2008 | Non-experimental time series design | Washington State adults'. Population size not shown. | Hospitalization diagnosis for COPD, emphysema, asthma, chronic bronchitis (ICD-9 490±496), lung, bronchus and trachea cancer(ICD-9 162) | State's Surveillance and Survey. Hospital Reporting System. State's cancer registry | Smoking declines in the state exceeded declines in the nation. The state program had the most consistent and largest effect on trends for respiratory disease. Policy effect was less often negative (4 of 7 hospitalization-incidence models) but infrequently significant (1 of 7 hospitalization-incidence models). Chronic respiratory disease hospitalizations: Policy effect R2 with national adjustment = 2.13, p 0.79, R2 without national adjustment = 1.16, p 0.89 | Low |
| **Kent, 2012. Ireland** [49] | | | | | | | | |
| To examine the impact of SFL on emergency hospital admissions with pulmonary illness | Comprehensive *Ban*: March 2004 | *Pre-ban*: 2002±2003 *Post-ban*: 2005±2006 | Pre-posttest non-experimental design | 286,000 individuals of working age: 20±69 ys. | Emergency admissions for exacerbations LRTIs (ICD-9 and ICD-10) | Hospital In-Patient Enquiry database. Census data | A significant reduction in overall pulmonary admissions was observed in the 20- to 29-year-old age group (adjusted RR, 0.62), with a similar trend in 30- to 39-year-olds (adjusted RR, 0.74). No significant reduction was seen in older age groups. | Moderate |
| **McGhee, 2014. China.** Hong Kong [80] | | | | | | | | |

(*Continued*)

**Table 2.** (*Continued*)

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|---|---|---|---|---|---|---|---|---|
| To examine effects on hospital admissions for conditions associated with SHS following a smoke-free workplace legislation | Partial<br>*Ban*: 27 October 2006. Law extended on 1 January 2007 | *Pre-ban*: 1997±2006<br>*Post-ban*: January 2007 to 2008 | Pre-posttest non-experimental design (with control diseases) | 2013 general population. Population size not shown. | Hospital admissions for respiratory condition (ICD-9-CM 460±519), lung cancer (ICD-9-CM 162) | Hospital Authority Clinical Management System | A seasonal peak in hospital admissions for respiratory disease in all ages was reduced from 12.6% to 10.1% in the first year after intervention; however, there was a rebound to 12.9% in the second year. | Moderate |

AECOPD: acute exacerbated chronic obstructive pulmonary disease. AMI: acute myocardial infarct. ARIMA: Autoregressive Integrated Moving Average. CH: Switzerland. COPD: chronic obstructive pulmonary disease. ED: Emergency department. GR: Graubünden. IRR: incidence rate ratio. LRTIs: lower respiratory tract infections. NHANES: National Health and Nutrition Examination Survey. NB: New Brunswick. PEI: Prince Edward Island. R2: Coefficient. RR: rate ratio. SE: standard error. SES: socioeconomic status. SFL: Smoke free laws/legislation. SUAT: Servicio de Urgencia, Asistencia y Traslado. US: United States

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analyzed[55][56]). The pooled data (Fig 2) showed a decline of 19% in any respiratory symptom after comprehensive SFL (overall RD = -0.19, 95% confidence interval [95%CI]) = -0.26; -0.12) with substantial heterogeneity between studies (I2 = 70%, p = 0.0005). In the sensitivity analysis, the exclusion of individual studies did not substantially modify the estimates, with the pooled RDs of any respiratory symptom ranging from -0.18 to -0.21. One study[76] was the principal origin of heterogeneity and showed a minor magnitude of the effect. After excluding it from the analysis, heterogeneity decreased (I2 = 41%, p = 0.10) and the pooled data remained similar (overall RD = -0.21, 95%CI = -0.27; -0.15) (S4 Table). Subgroup analysis by study design did not significantly reduce heterogeneity. Minor heterogeneity was found in studies with a moderate or high RoB (although there were only two in each case) in contrast with those of low risk. With respect to subgroup analysis by follow-up time, studies with 12 or more months were less heterogeneous and the pool effect was smaller than those with a with shorter follow-up (S5 Table). Regarding to any respiratory symptom in a comprehensive SFL setting, the asymmetric funnel plot suggested publication bias (S1 Fig).

Four studies were included in the meta-analysis for the outcome ªany respiratory symptomº in a partial SFL setting. The pooled data (Fig 2) showed a decline of 20% in any respiratory symptom after the SFL (overall RD = -0.20, 95%CI = -0.31; -0.08) with wide CI and considerable heterogeneity between studies (I2 = 54%, p = 0.09). In the sensitivity analysis, the exclusion of individual studies substantially modified the estimates, with the pooled RDs of any respiratory symptom ranging from -0.14 to -0.25. One study[56] was the principal origin of heterogeneity and had a greater magnitude of the effect in comparison with the rest of the studies. After excluding it from the analysis heterogeneity decreased (I2 = 0%, p = 0.45) and the pooled data was lower than in the previous analysis (overall RD = -0.14, 95%CI = -0.19; -0.10) (S4 Table). Subgroup analysis by study design did not significantly reduce heterogeneity. Minor heterogeneity was found in studies with moderate RoB, (a small number of studies involved only two) than those with low risk. With respect to subgroup analysis by follow-up time, there was only one study with a short follow-up. Studies with 12 or more months were heterogeneous although the pool effect was greater than the initial analysis (S5 Table).

## SFL effect on sensory symptoms

Of the 50 papers, 19 (38.0%) evaluated the presence of sensory symptoms. Of these 19, all solely focused on workers, 17 (89.5%) were non-experimental, and 11 (57.9%) evaluated a comprehensive SFL effect. Periods of evaluation ranged from one month to two years. Outcomes

**Table 3. Summary of studies on the impact of smoke-free legislation on mortality.**

| Aims | Legislation | Study period | Study design | Study participants and size | Variables | Source of information | Summary of findings | Risk of bias |
|---|---|---|---|---|---|---|---|---|
| **Binswanger, 2014. United States (US)** [33] | | | | | | | | |
| To determine whether bans on smoking in prison are associated with reductions in smoking related deaths. | Different types of laws. In 2001, half of states had any smoking ban (n = 25). By 2011, 48 states had a ban on smoking in prison | From 2001 to 2011 | Quasi-experimental time series design | All state prisons in the US. 14,449 individuals. 49.6% of people in 2004 were aged ≥35, and 6.8% were women. Among people of all ages, 75.8% had ever smoked. | Rates of smoking related deaths, including from cancer, cardiovascular disease, and pulmonary disease | Web based searches of state policies and legislation. Bureau of Justice Statistics | Any ban was associated with a reduced incidence of any smoking related death (adjuste IRR 0.91), including significant reductions in pulmonary deaths (0.71). Men had significantly higher rates of death than women for all smoking related causes and cancer. Bans in place for more than nine years were associated with significant reductions in all smoking related deaths (IRR 0.89), cancer deaths (IRR 0.81), and pulmonary deaths (IRR 0.66) compared with places with no ban | Moderate |
| **McGhee, 2014. China.** Hong Kong [80] | | | | | | | | |
| To examine effects on trends in deaths for conditions associated with SHS following a smoke-free workplace legislation | Partial *Ban*: 27 Oct 2006. Law extended on 1 January 2007 | *Pre-ban*: 1997±2006 *Post-ban*: Jan 2007 to 2008 | Pre-posttest non-experimental design (with control diseases) | 2013 general population. Population size not shown. | Deaths for respiratory condition (ICD-9-CM 460±519), lung cancer (ICD-9-CM 162) | Hospital Authority Clinical Management System. Census data | The annual proportional changes in mortality were significant in lung cancer (which decreased among all ages): relative changes -5.65, authors suggested that this is not attributable to the SFL, but to improved treatment and other factors as follow-up | Moderate |
| **Stallings-Smith, 2013. Republic of Ireland** [70] | | | | | | | | |
| To assess the effect of a SFL on all-cause and cause-specific, non-trauma mortality | Comprehensive *Ban*: 29 March 2004 | *Pre-ban*: 1 January 2000 *Post-ban*: 31December 2007 | Non-experimental time series design | Irish population, ages ≥35 years. 1.9 million individuals. | Death for all respiratory diseases (460-519/J0-J99) and COPD (490±492, 494±496/J40±J44, J47). | Mortality data. Irish Health Protection Surveillance Centre for influenza data | Mortality decreases were primarily due to reductions in passive smoking. All respiratory female immediate effects 0.64 (0.42±0.98). Post-ban, a 38% reduction in COPD mortality was observed. Post-ban reductions in COPD mortalities were seen in ages ≥65 years, but not in ages 35±64 years. COPD mortality reductions were found only in females (RR: 0.47), COPD overall 0.62, females immediate effects 0.47, COPD ages 65± 84 immediate effects 0.68, ages≥85 years immediate effects 0.49 | Low |

(*Continued*)

**Table 3.** (*Continued*)

| Aims | Legislation | Study period | Study design | Study participants and size | Variables | Source of information | Summary of findings | Risk of bias |
|---|---|---|---|---|---|---|---|---|
| **Stallings-Smith, 2014. Republic of Ireland** [69] | | | | | | | | |
| To assess the effects of a SFL on COPD mortality by discrete and composite socioeconomic status (SES) indicators to determine impacts on inequalities. | Comprehensive *Ban*: 29 March 2004 | *Pre-ban*: 2000 *Post-ban*: 2010 | Non-experimental time series design | Irish population, ages≥35 years. Population size not shown. | Deaths for COPD (490±492, 494± 496/J40±J44, J47). | Census data. Mortality data. Irish Health Protection Surveillance Centre for the influenza data | From 2000±2010, total deaths due to COPD (n 15192). Post-ban mortality reductions by structural SES indicators were concentrated in the most deprived tertile: RR≈ 0.66 in low education, RR≈0.62 for non-Irish Nationality. RR≈0.75 for population unemployement. RR≈0.72 for rented/ free housing tenure. RR≈0.69 for no car access | Low |

COPD: Chronic obstructive pulmonary disease. IHD: Ischemic heart disease. IRR: incidence rate ratio. RR: rate ratio. SES: Socioeconomic status.US: United States

https://doi.org/10.1371/journal.pone.0181035.t003

were: any sensory symptom (15 studies, 78.9%), red/irritated eyes (15 studies, 78.9%), runny nose/sneezing (14 studies, 73.7%), and sore/scratchy throat (13 studies, 68.4%).

All the 15 studies found significant decreases in the number of individuals who had ªany sensory symptomº in the before-after comparision (range of decrease 11.0±100.0%) irrespective of the kind of legislation. Twelve studies showed statistically significant decreases for the outcomes ªred/irritated eyesº (range 7.5 to 44.0%) and ªrunny nose /sneezingº (6.3 to 45.0%). The outcome ªsore/scratchy throatº decreased non- significantly in four studies[55±57,72], and in the rest of the nine studies it declined in the post-ban period (range 12.0[32] to 48.7% [40]), particularly in those that evaluated comprehensive SFL.

The ªany sensory symptomº outcome showed a greater decrease immediately following implementation of legislation (up to a maximum of 70.0±100.0%[62] at six months versus 50% at longer periods[41]), especially in the case of comprehensive SFL, with even higher percentages than respiratory symptoms in studies assessing both respiratory and sensory symptoms.

Nine studies were included in the meta-analysis for the outcome ªany sensory symptomº in a comprehensive SFL setting (one study was stratified due to having two regions analyzed[55] [56]). The pooled data (Fig 2) showed a decline of 34% in any sensory symptom after the comprehensive SFL (overall RD = -0.34, 95%CI = -0.26; -0.12) with substanial heterogeneity between studies (I2 = 86%, $p < 0.001$). In the sensitivity analysis, the exclusion of individual studies did not substantially modify the estimates, with the pooled RDs of any sensory symptom ranging from -0.31 to -0.37. No study was observed to be the main origin of heterogeneity between studies, I2 remained above 80% in the sensitivity analysis (S4 Table). Subgroup analysis by study design did not significantly reduce heterogeneity, although minor heterogeneity was found in studies with a moderate or high RoB (a small number of studies involved only two) than those with low. Regarding subgroup analysis by follow-up time, the studies with a short follow-up had a greater pool effect than those with 12 or more months, marked heterogeneity being maintained in both cases (S5 Table).

Two studies were included in the meta-analysis for the outcome ªany sensory symptomº in a partial SFL setting. The pooled data (Fig 2) showed a decline of 30% in any sensory symptom after the SFL (overall RD = -0.30, 95%CI = -0.46; -0.13) with wide CI and low heterogeneity between the studies (I2 = 25%, p = 0.25).

## SFL effect on spirometry parameters

Out of the 50 papers, eight studies (16.0%)[39,43,52,58,67,68,71,78] assessed spirometric parameters in workers. Of these eight, all were non-experimental and five (62.5%) were performed in comprehensive SFL settings[39,43,58,67,68]. Evaluation periods ranged from one month to two years. Of the eight studies, four (50.0%) had an increase in forced expired volume in one second (FEV1)[39,58,68,71], although two of these were carried out with non-smokers[39,68] and asthmatic cohorts[68]. Six studies (75.0%) evaluated forced vital capacity (FVC) which increased significantly (range 3±4.2%) in five[39,43,68,71,78] although in one it was only augmented in an asthmatic cohort [68]. Discrepant results were obtained when the effect of comprehensive SFL on forced mid-expiratory flow rate ($FEF_{25-75\%}$)[39,43,68,71] and peak expiratory flow rate (PEF)[43,68] was assessed.

Three studies were included in the meta-analysis for the outcome ªFEV1º in a comprehensive SFL setting. Pooled results indicated a non significant net difference in FEV1 between before and after comprehensive SFL (overall MD = 0.10, 95%CI = -0.04; 0.24; I2 = 87%) (Fig 3). In the sensitivity analysis, the exclusion of individual studies did not substantially modify the estimates, with pooled MDs of FEV1 ranging from non significant values of -0.04 to 0.13.

Only two studies could be included in the meta-analysis for the outcome ªFVCº in a comprehensive SFL setting. Pooled results indicated a significant net difference in FVC between before and after comprehensive SFL (overall MD = 0.19, 95%CI = 0.13; 0.25) with homogeneity (I2 = 0%, p = 0.41) (Fig 3).

Only two studies could be included in the meta-analysis for the outcome ª$FEF_{25-75\%}$º in a comprehensive SFL setting. Pooled results indicated a significant net difference in $FEF_{25-75\%}$ between before and after comprehensive SFL (overall MD = -0.19, 95%CI = -0.26; -0.12) with homogeneity (I2 = 0%, p = 0.82) (Fig 3).

## SFL effect on asthma admissions

Out of the 50 papers, 17 (34%) concerned asthma admissions (all but two in hospital settings). Of these 17, nine (52.9%) were in the general population, five (29.4%) in adults, and three (17.6%) in children. Ten (58.8%) were non-experimental and 15 (88.2%) evaluated comprehensive SFL. One was conerned asthma treatment use (5.9%)[79]. Evaluation periods ranged from 11 months to seven years. Significant decreases were described in 13 of the 17 papers evaluating asthma hospital admissions.

With respect to the nine studies carried out in the general population[34,42,45,46,51,60,61,64,75], six of them (66.7%) were quasi-experimental[42,45,46,51,60,61], and, with the exception of one[61], all were performed in comprehensive SFL locations. In eight studies (88.9%), admission rates for asthma (both hospital and non-hospital admissions) significantly declined with a range of 5.0%[60] to 31.0% (the latter figure was for Caucasians in Texas[45]). In addition, a significant annual rate of reduction of -0.35 [95% confidence interval (CI) -0.53 to -0.018] in hospital asthma admissions was obtained in the sole study on partial SFL[61] when it compared SFL in restaurants versus public areas and workplaces over the ten-year study period. Four stratified studies (44.4%)[34,42,51,64] all reported significant reductions in asthma hospital admissions both in children (range 18.0[64]- 25.0%[34]) and adults (range 16.0[34]-24.0%[64]).

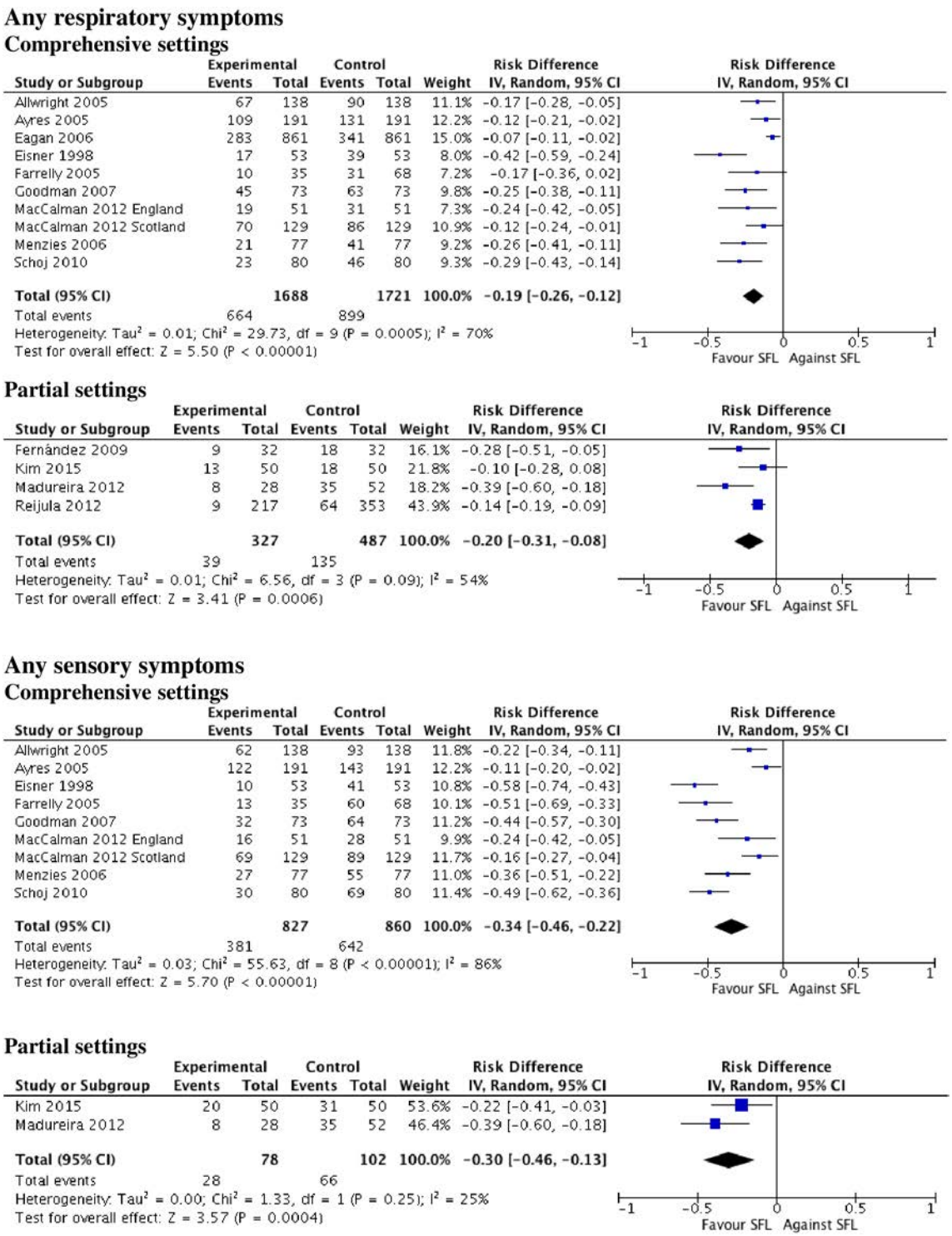


**Fig 2. Risk difference between before and after the smokefree legislation (SFL) in any respiratory/sensory symptom.** Abbreviations: CI, confidence interval; df, degrees of freedom; IV, Inverse Variance method.

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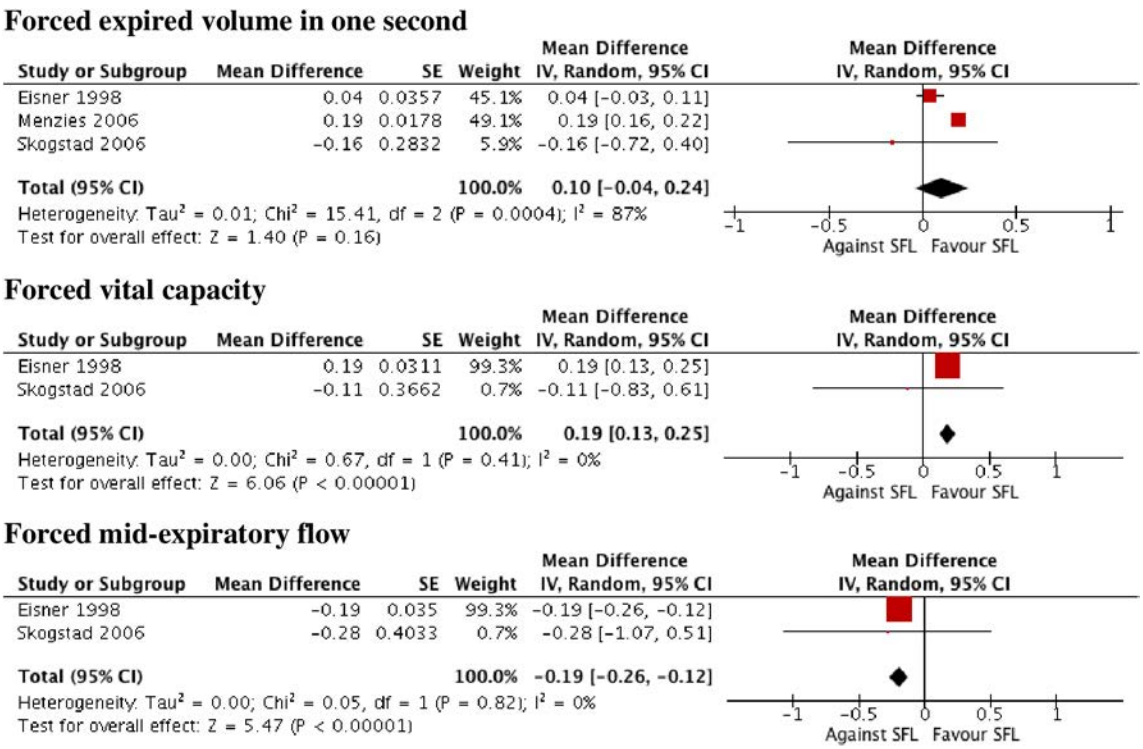



**Fig 3. Mean difference between before and after comprehensive smokefree legislation (SFL) in spirometry parameters.** Abbreviations: CI, confidence interval; df, degrees of freedom; IV, Inverse Variance method.

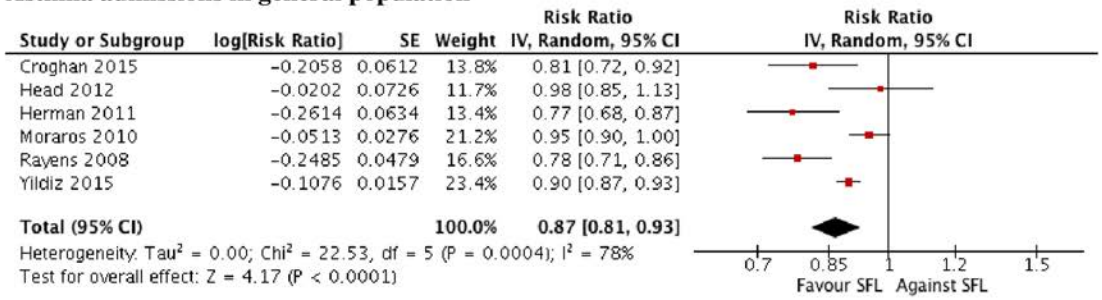
https://doi.org/10.1371/journal.pone.0181035.g003

Six studies were included in a meta-analysis for the outcome ªasthma admissionº in a general population in a comprehensive SFL setting (Fig 4). According to the forest plot, there was a significant decrease of 13% after SFL (overall RR = 0.87; 95%CI = 0.81; 0.93). Heterogeneity was high (I2 = 78%, p <0.001). In the sensitivity analysis, the exclusion of individual studies did not substantially modify the estimates, with pooled RRs of asthma admissions ranging from 0.85 to 0.89. No study was found to be the main origin of heterogeneity between studies, I2 remained above 70% in the sensitivity analysis by omitting one at a time (S4 Table). Subgroup analysis by study design, risk of bias and follow-up time (less than 24 months vs 24 months or more) did not significantly reduce heterogeneity (S6 Table).

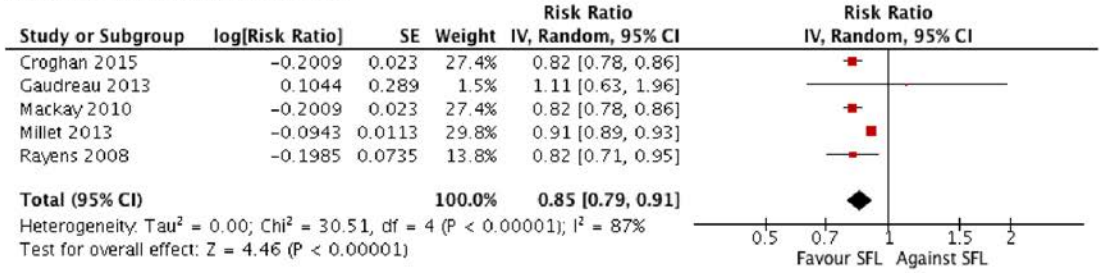
Three studies were focused on children[35,37,59], in two (66.7%) there were significant reductions of hospital asthma admissions in comprehensive SFL locations (declines of 9.0% [59] and 18.2%[35]) whilst in the remaining paper on regions with different types of SFL there was no significant decrease[37].

Five studies were included in the meta-analysis for the outcome ªasthma admissionº in children in comprehensive SFL setting (three focused on children and two were stratified by age) (Fig 4). There was a significant decrease of 15% after SFL (overall RR = 0.85, 95%CI = 0.79; 0.91). Heterogeneity was high (I2 = 87%, p <0.001). In the sensitivity analysis, exclusion of individual studies did not substantially modify the estimates, with pooled RRs of asthma admissions ranging from 0.82 to 0.86. One study, which had the lowest RR, was the main origin of heterogeneity between studies[59]. After excluding it from the analysis, the heterogeneity decreased (I2 = 0%, p = 0.77) and the pooled effect was higher than in the previous analysis (overall RR = 0.82, 95%CI = 0.79; 0.84) (S4 Table). Subgroup analysis by study design and RoB

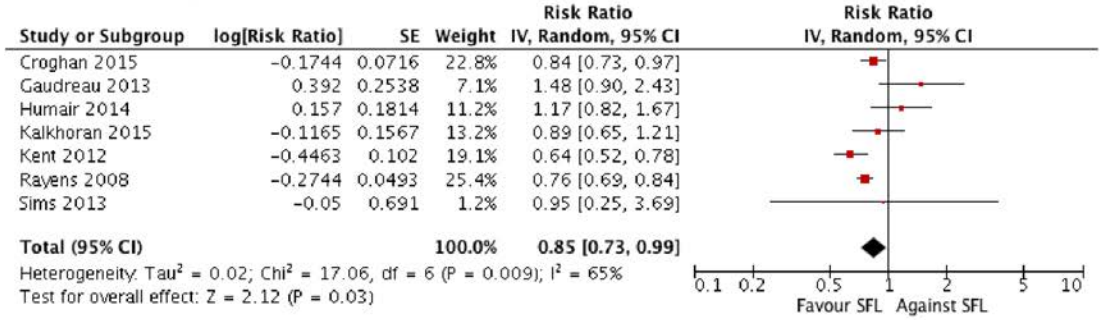
### Asthma admissions in general population



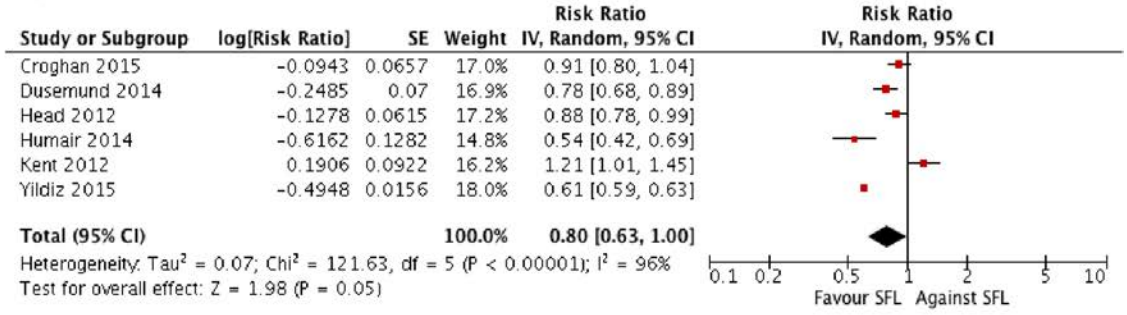

### Asthma admissions in children




### Asthma admissions in adults




### COPD admissions




### Pneumoniae/Bronchitis admissions

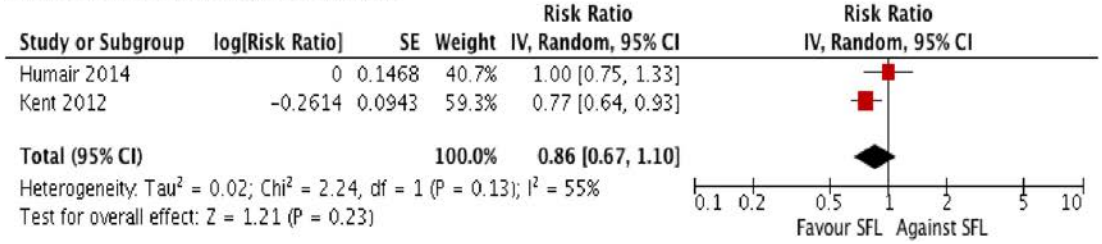


**Fig 4. Risk ratio between before and after comprehensive smokefree legislation (SFL) in asthma, COPD and lung infection admissions.** Abbreviations: CI, confidence interval; df, degrees of freedom; IV, Inverse Variance method.

https://doi.org/10.1371/journal.pone.0181035.g004

did not significantly reduce heterogeneity. All the studies had more than 24 months of follow-up (S6 Table).

Five studies focused on adult populations[48,49,53,66,79], they all evaluated comprehensive SFL and had a non-experimental design. Three of them (60.0%) found significant reduction rates from 4.9%[53] to 36.0%[49] (all except one in hospital admissions[79]). One study reviewed the incidence rate ratio in non-hospital admissions [79] and reported a decrease of 15.0% in admissions after SFL. In the two remaining studies[48,66], results were discordant with no significant differences. With respect to asthma treatment in adults, the use of salbutamol and ipratropium descended in non-hospital emergency settings[79].

Seven studies were included in the meta-analysis for the outcome ªasthma admissionº in adults in comprehensive SFL setting (five focused on adults and two were stratified by age) (Fig 4). There was a significant decrease of 15% after SFL (overall RR = 0.85, 95%CI = 0.73; 0.99). Heterogeneity was considerable (I2 = 65%, p = 0.009). In sensitivity analysis, exclusion of individual studies modified the estimates substantially, with pooled RRs of asthma admissions ranging from 0.80 to 0.90. Two studies were the main origin of heterogeneity between studies[42,48], they had no significant increases of asthma admissions. After excluding them from the analysis, the heterogeneity decreased (I2 = 31%, p = 0.22) and the pooled data was more robust (overall RR = 0.77, 95%CI = 0.70; 0.85) (S4 Table). Subgroup analysis by study design and RoB did not significantly reduce heterogeneity. With respect to subgroup analysis by follow-up time, only one study had less than 24 months of follow-up, and those with longer periods had a greater pool effect than the initial analysis, maintaining high heterogeneity (S6 Table).

## SFL effect on COPD admissions

Nine (18.0%) of the 50 papers reported effects on COPD admissions [34,38,42,45,48,49,54,61,75](all except one in hospital settings): six (66.7%) in a general population and three (33.3%) in adults exclusively. Five (55.5%) were quasi-experimental and eight (88.9%) evaluated comprehensive SFL. Evaluation periods ranged from 11 months to 5.5 years. Significant decreases were described in 6 of the 9 papers evaluating asthma hospital admissions.

In four (66.7%)[38,42,45,61] of the six articles which focused on the general population and had a quasi-experimental design, significant decreases in COPD admissions, ranging from 1.0%[61] (a study that compared the different phases of SFL before becoming comprehensive) to 36.0%[45], were found. The other two studies (33.3%), with non-experimental design [34,75], presented non-signficant declines.

There were three studies that evaluated comprehensive SFL in adults[48,49,54]. In two of them (66.7%), hospital admissions for COPD decreased significantly (from 15.0%[54] to 46.0%[48]) whilst in the other study (33.3%) they increased non significantly (adjusted relative risk 1.18; 95% CI 0.86±1.60[49]).

Six studies were included in the meta-analysis for the outcome ªCOPD admissionº in a comprehensive SFL setting (Fig 4). There was a non significant decrease of 20% after SFL (overall RR = 0.80, 95%CI = 0.63; 1.00). Heterogeneity was high (I2 = 96%, p <0.001). In the sensitivity analysis, the exclusion of individual studies modified the estimates substantially, with pooled RRs of COPD admissions ranging from 0.73 to 0.85. No study was found to be the

main origin of heterogeneity between studies, I2 remained above 80% in the sensitivity analysis (S4 Table). Analysis by subgroup showed significant values in the quasi-experimental studies (overall RR = 0.83, 95% CI = 0.74; 0.94, I2 = 40%, p = 0.20), in the low RoB ones (overall RR = 0.84, 95%CI = 0.73; 0.98, I2 = 61%) and in those with less than 24 months follow-up (overall RR = 0.61, 95%CI = 0.59; 0.63; I2 = 0%, p = 0.35) (S6 Table).

## SFL effect on other respiratory diseases admissions

Six papers evaluated: 1) Respiratory diseases taken together (three studies)[36,49,80] and 2) Other respiratory disease admisions (four studies)[48,49,61,75] such as pneumonia and pneumothorax. One paper fell into both categories[49]. Four (66.7%) of the six were in a general population and two exclusively in adults[48,49], five (83.3%) had a non-experimental design, three (50.0%) evaluated comprehensive SFL[48,49,75], and one (16.7%) different types of SFL [36]. The evaluation period ranged from 11 months to three years.

There were discrepant results in overall respiratory admissions (only one paper out of three reported a significant 15.0% decline in adults[49]) and in respiratory infection (two[49,75] of four papers found significant decreases up to 23.0%[49]).

Only two studies could be included in the meta-analysis for lung infections (pneumonia or bronchitis) in adults in a comprehensive SFL setting (Fig 4). There was a non significant decrease of 14% after SFL (overall RR = 0.86, 95% CI = 0.67; 1.10). The between-study heterogeneity was substantial (I2 = 55%, p = 0.13).

## SFL effect on respiratory mortality

Four (8.0%) of the 50 papers were based on mortality data[33,69,70,80]. These studies were heterogeneous with respect to type of population (one study [25.0%] in prisioners[33], two [50.0%] in adults[69,70], and one [25.0%] in a general population[80]), study design (three [75.0%] were non-experimental), type of SFL evaluated (two comprehensive [50.0%] [69,70], one [25.0%] partial[80], and one [25.0%] of different types) and range of post-ban evaluation (from one to seven years).

Two studies (50.0%) performed in Ireland analysed mortality data on respiratory diseases [69,70], and one focused on effects taking into account socioeconomic status[69]. Decreases in mortality rates were primarily due to reductions in passive smoking (these results were supported in that no observable change in smoking prevalence was seen as a result of the SFL), COPD mortality reduction rate was 0.62 (95% CI 0.46±0.83)[70], especially in women (reduction rate 0.47; 95%CI 0.32±0.70)[70] and in the most deprived areas[69]. In North American prisons[33], pulmonary death declined by 29.0% with men having significantly higher rates of death than women for all smoking-related causes. There was only one study about partial SFL which found no significant results[80].

## Quality assessment of included studies

Methodological quality assessment was classified as summary RoB (S2 Table): low in 23 (46.0%) of the 50 papers, moderate in 19 (38.0%), and high in eight (16.0%). In general, the two main weaknesses were selection and attrition bias, and the highest rated domains were detection and reporting bias. The summary RoB was low in 18 (47.37%) of the 38 non-experimental studies and in five (41.67%) out of 12 of the quasi-experimental ones. The most highly rated domains (with a higher proportion of low RoB) in the non-experimental studies were reporting (92.1%) and detection bias 2 (Was the policy unlikely to affect data collection? [89.5%]). The lowest values (with a higher proportion of high RoB) were selection (28.9%), attrittion (18.4%) and other bias (18.4%). For the quasi-experimental studies the most highly

rated domains were reporting (100%) and attrition (83.3%), and the worst other bias (16.7%) and confounding bias (16.7%). Papers that evaluated spirometric parameters, respiratory mortality, and sensory symptoms were those that presented the greatest percentages of low RoB (62.5, 50.0, and 47.7%, respectively).

## Discussion

SFL beneficial effects were observed in workers with respect to respiratory and sensory symptomatology. The majority of the studies reported a decrease in hospital admissions for asthma and COPD in all populations (overall population or population stratified by age). Regarding other lung diseases, respiratory mortality, and spirometric parameters, the results are heterogeneous and discrepant. Comprehensive SFL was more commonly evaluated than partial, and periods of assessment ranged from one month to seven years. SFL effect appeared to be greater when the legislation was comprehensive. Due to the reduced number of studies involved in the subgroup analysis, the conclusions of the meta-analysis should be considered with caution. We used a random effect model in order to be able to control heterogeneity. Sensitivity analysis of subgroups showed significant decreases in any respiratory symptoms (both in comprehensive and partial SFL settings) and asthma admissions in comprehensive settings (in adults and children). No significant results were found about the effect of SFL on FEV1, COPD and lung infection admissions. In the rest of the outcomes, either the number of studies involved was very low (FVC, FEF25-75% in comprehensive SFL setting and any sensory symptom in partial SFL setting) or heterogeneity was high despite sensitivity analysis (any sensory symptoms and asthma in a general population in comprehensive SLF settings). All of which hinders extrapolation of data to the whole population, and thus limits the strength of the conclusions drawn.

According to this review, SFL effects are more intense in a worker population with respect to sensory symptoms followed by respiratory ones. In contrast, effects on lung function were not so clear. Spirometry parameters could have been conditioned by other factors such as correct performance of the technique, whether the participant was a smoker or asthmatic and, in the case of the latter, whether asthma medication was being taken[87]. In fact, in one of the included studies the authors were unable to analyze the values due to the difficulties in gathering data (participants not fully co-operating in the test)[32]. Overall, asthma and COPD were the diseases most assessed. The majority of the studies reported favourable results for SFL with a maximum decrease in hospital admissions for adults of 46.0%[48] and 36.0%[49] for COPD and asthma, respectively. Few studies have evaluated SFL impact on other respiratory diseases and mortality, and their results have been heterogeneous. Nevertheless, an immediate 38.0% decrease in mortality due to COPD has been reported[70].

Most of the included studies analysed the impact of comprehensive SFL which can cause the greatest decrease in sensory and respiratory symptoms particularly in the immediate post-ban period. It is possible that, at long-term, these effects in worker population are not perceived due to the situation becoming normalized, that is to say, without exposure to second-hand smoke due to SFL. In the studies carried out in all populations, effects were evaluated at eleven months after SFL implementation and better results were observed with respect to decreased admissions due to respiratory diseases in locations with the strictest SFL. Nevertheless, data on respiratory mortality are scarce and from heterogeneous populations. In addition, the maximum time period for SFL implementation to be studied is 6.75 years[69] and differences have not yet been found between the time period immediately after SFL and long-term [70].

Some studies have performed analysis in subgroups and reported a greater decrease in the percentage of sensory and respiratory symptoms in a working, non-smoking population [43,52,76], greater decrease in COPD mortality in women[33,69,70] and in people older than 65 years[69,70], and fewer asthma admissions in a population aged over 20 years[64] and between 30±39 years[49]. Most studies detected a decrease of less intensity in children than in adults for asthma admissions after SFL implementation. However, the few studies that compared both populations reported heterogeneous findings. One explanation is that adults may be exposed to secondhand smoke at both home and work whilst children are only exposed at home[14,64].

In contrast with previous reviews that provided data on respiratory symptomatology and admissions, we identified a considerably larger number of studies (50 papers compared to 21 in the most extensive review by other authors)[21]. The review by Polanska *et al*[87] was limited to respiratory and sensory symptoms in a worker population. They found a reduction in respiratory symptoms in ten out of 12 studies, and in all except one of these ten studies a decline in sensory symptoms. Callinan *et al*[8] arrived at similar conclusions in their systematic review and mentioned, furthermore, a clear reduction in sensory symptoms in smokers and non-smokers. In that review they analyzed spirometer parameters from five studies: in two there were significant increases in FEV1; in three significant increases in FVC; and in three significant reductions in FEF. With respect to symptomatology and lung function the results mentioned concur with those we obtained in our systematic review: 26 papers were identified related to respiratory symptoms, 19 to sensory symptoms, and eight to lung function. In contrast, the 2010 Cochrane[8] identified 12, ten, and six papers, respectively. Self-reported symptoms were excluded from the 2016 up-dated Cochrane Review[21] and symptomatology evidence was not updated with respect to the 2010 edition. In contrast, our review found 12 papers more in the period 2009±2015. The 2016 Cochrane Review selected papers that evaluated effects on health when follow-up was a minimum of six months post-ban (no restriction in our review) and institutional settings were not included. It was concluded that data regarding asthma and COPD admissions were inconsistent. Tan and Glantz[23], in their meta-analysis that included eight articles about respiratory disease admissions with a heterogeneity of 88%, obtained a relative risk of 0.760 (95% CI 0.682±0.846) for decreased asthma and lung infections without any statistically significant association for COPD and spontaneous pneumothorax (fewer studies), and without any follow-up time differences. According to our data, asthma in the general population decreased by 13% and asthma in adults by 23%, with no significant findings for COPD and lung infection. Been *et al*[88] in their meta-analysis based on three studies about asthma admission in children (with moderate bias risk) obtained an overall reduction of 10.10% (95% CI -15.2 to -5), and a non-significant trend towards an annual decrease rate (-7.5% per year, 95% CI -16 to 0.9). In this meta-analysis, a significant overall RR of 0.82 was found. According to the narrative synthesis, we observed that most articles reported a decrease in the number of hospital/non-hospital emergency admissions due to asthma (75.6% of papers) and/or COPD (66.7% of papers). However, as some of these papers only found evidence in population subgroups (children or adults), the results are inconclusive. With respect to the meta-analysis, it seems that SFL has a protective effect nevertheless due to the high heterogeneity between studies of the outcomes analysed the conclusions should be drawn with caution.

Most of the studies in this review had a non-experimental design. The lack of a control group only permits the evaluation of variations before and after SFL implementation; it does not allow the overall observed changes to be attributed to the legislation implemented. We have observed that in some studies significant results were only obtained when comparing

locations with and without SFL or time periods with varying restrictions with respect to smoking bans[61].

The fact that the data source of the included studies with respect to symptomatology (self-administered International Union Against Tuberculosis and Lung Disease questionnaires) and hospital admissions (central registers) has been quite homogenous is a strength as it permits comparison with findings amongst different studies. However, self-reported data have limited validation compared to objective measures. There was a lack of simultaneous adjustment and stratification for confounders in some studies. A few of them stratified confounders such as sex[31,35], location[35,37,77], socioeconomic status[35,59,69], seasonality[64], smoking status[52], secondhand smoke[47,77], influenza/air polution[47], number of symptoms [31,63], comprehensiveness of SFL[54], population growth[60], different policies on tobacco [36], and being resident or not[48,60]. SFL is not the only measure that has had an impact on passive smoking and tobacco-related disease. Other actions that have influenced the consumption of tobacco are control of publicity, tax increases resulting in higher price[89,90], and restrictions on the sale of tobacco products[8].Very often these steps are introduced at the same time as the new legislation comes into being. A policy may be considered ineffective when other components simultaneously occur which cause its impact to be under-rated. It might, therefore, be difficult to know how these different actions could influence the impact observed. As a result, it is important to perform sensitive analysis by subgroups[24].

In general, most articles were classified as low or moderate RoB with the non-experimental ones having a slightly higher percentage. Selection and attrition biases had the worst results, very probably due to convenience sampling (in the case of selection bias) in the studies on symptomatology. Moreover, losses of participants in the hospitality sector are habitual due to the temporal nature of this kind of employment[32,91]. In the twelve quasi-experimental studies (the majority about respiratory diseases in the general population) the confounding bias domain was the worst evaluated. This shows that in even the most robustly designed study it is necessary to analyze confounding factors that could over or underestimate SFL effect. In the systematic review of Frazer *et al*[21], a different assessment tool was used: [a]adequate sequence generation[o], [a]adequate allocation concealments[o], and [a]blinding of personnel/all outcomes[o] (more suitable for randomized clinical trials). These domains were adapted in this systematic review due to the type of studies (evaluating a policy). Papers were rated better in this systematic review than in the up-dated Cochrane Review. However, quality assessment of each paper were performed by two authors independently and checked by a third in the case of discrepancies.

## Strengths and limitations

To the best of our knowledge, this is the first scientific review performed with respiratory outcomes (symptoms, functionality, and hospital admissions) as an effect of SFL, measured in all groups (workers, adults, children, and general populations). The rigorous procedures employed (paired reviewers and a third one in the case of discrepancies) have ensured the validity of the data extraction. A detailed synthesis of sensory and respiratory symptomatology has been done (excluded from the up-dated Cochrane Review). Grey literature was not employed but the combination of heterogeneous sources of data adds value to the results. We tried to identify all the possible papers appearing in scientific journals from six different databases in addition to manually searching the references in the papers and consulting experts. One of the inclusion criteria was that papers were written in English, French, Portuguese, Italian, Catalan or Spanish. This did not have an effect on our results as only one document had to be excluded (Norway)[92].

Although identification and selection biases are common threats to validity in all systematic reviews, they are more likely in the case of non-randomized studies where registration is not standard practice[93]. Particular effort has been devoted to reducing identification bias, as shown by our search strategy which included several databases.

Variability in participants, type of SFL, outcome measures and definition, duration of follow-up and study design may affect the impact of SFL. In addition, the considerable heterogeneity observed hinders the drawing of conclusions about SFL from the meta-analysis. However, the narrative synthesis helps to investigate similarities and differences among studies as well to explore any patterns in the data to better understand the impact of SFL. A possible bias due to authors who may have had a financial conflict of interest arising from the tobacco industry is a complex issue. In fact, with respect to studies on passive smoking there are a number of such authors. Nevertheless, this type of article generally has low quality scores and was probably excluded from selection[94].

### Future lines of study

Building upon the present observations, we would like to underline the need to address several important issues for future research. None of the studies reported sensory/respiratory symptoms and lung function in the general population. Moreover, the effect of SFL with respect to respiratory symptomatology in children was only evaluated in two studies without conclusive results. It is notable that non-hospital setting was monitored in only two studies[34,79]. Neither are there data about respiratory mortality in worker and child populations. There are few, heterogeneous studies regarding lung function, medication use, respiratory infections (both upper and lower tracts), and mortality. In addition, it is essential to better study the mid- to long-term effects of SFL on mortality, COPD, and another chronic respiratory diseases. Finally, we believe there is a need for quasi-experimental design studies comparing locations with and without SFL, and partial versus comprehensive SFL, to better confirm its effects. Moreover, we consider that analysis by age, gender, and socio-economic factors are necessary given that tobacco consumption may vary.

## Conclusions

Results appear to indicate that comprehensive SFL decreases sensory symptomatology more than partial. Almost all the studies reported effectiveness of SFL in respiratory and sensory symptoms in workers and children with significance that decreased in the meta-analysis. There is a majority of studies denoting the effectiveness of SFL in admissions for asthma and COPD in all populations but without statistical significance for the latter in the meta-analysis. There are, however, few studies about respiratory mortality, respiratory infection, and lung function and they do not demonstrate strong effectiveness. It can be concluded, therefore, that it is important to continue conducting research into SFL effectiveness particularly in areas lacking results that can contribute to the available evidence.

## Supporting information

**S1 PRISMA checklist.**
(DOC)

**S1 Table. Search strategy applied in the different databases: SFL effects on respiratory and sensory disorders.**
(PDF)

**S2 Table. Quality assessment of the risk of bias of papers evaluating SFL effects on respiratory and sensory disorders (1995±2015).**
(PDF)

**S3 Table. Descriptive characteristics of the 50 articles obtained for smokefree legislation effects on respiratory disorders (1995±2015).**
(PDF)

**S4 Table. Sensitivity analysis by omitting one or two until I2 dropped below the intented threshold 50% and range.**
(PDF)

**S5 Table. Subgroup analysis by study design and risk of bias among studies relating any respiratory and sensory symptoms.**
(PDF)

**S6 Table. Subgroup analysis by study design and risk of bias among studies relating asthma and COPD admissions in comprehensive SFL setting.**
(PDF)

**S1 Fig. Funnel plot of any respiratory symptom in comprehensive smokefree legislation setting.** Publication bias.
(PDF)

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# Smoking bans' effects on respiratory pathology: a systematic review

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## Review question

Do smoking bans or restrictions reduce admissions and emergency visits at hospital or primary care level among people suffering from asthma, COPD and other respiratory diseases?
Do smoking bans or restrictions reduce morbidity (respiratory symptoms and pulmonary function) among people suffering from asthma, COPD and other respiratory diseases?
Do smoking bans or restrictions reduce treatment use (e.g. pharmacologic treatment, oxygen therapy and respiratory physiotherapy) among people suffering from asthma, COPD and other respiratory diseases?
Do smoking bans or restrictions reduce mortality among people suffering from asthma, COPD and other respiratory diseases?

## Searches

PubMed, EMBASE, Biblioteca Cochrane Plus (Cochrane Library), Scopus, Web of Science, GOOGLE Scholar databases and bibliographies of relevant studies and reviews will be searched for potential original studies published from January 1, 1995 through 21/2/2105.

## Types of study to be included

We will search for uncontrolled pre- and post-ban data evaluating countries, regions, states, cities or workplaces that have implemented laws banning the consumption of tobacco and have evaluated its impact on asthma, COPD and other respiratory diseases in children and / or adults, independently of their smoking habit.

## Condition or domain being studied

Respiratory diseases: asthma, COPD and others

## Participants/population

All populations, without exclusion criteria by age and independently of smoking status,exposed to comprehensive or partial smoking bans

## Intervention(s), exposure(s)

Legislative bans which either ban smoking completely (comprehensive) or restrict it to designated areas (partial). According to Article 8 of the WHO Framework Convention on Tobacco Control we define as comprehensive smoke-free laws that ban smoking in virtually all indoor workplaces and public places, including bars, restaurants and public transport and partial that comprise fewer locations than those described

## Comparator(s)/control

No comparison group except studies that assess geographical contexts (localities, regions, states, countries) with smoking bans versus geographical contexts without it.

## Primary outcome(s)

1. Number of visits to hospital emergency with respiratory disease
2. Number of visits to primary care for asthma
3. Number of hospital admissions for asthma
4. Number of hospital admissions for acute exacerbation of COPD
5. Number of hospital admissions for other lung diseases (lung infection, spontaneous pneumothorax)
6. Number of concerted or spontaneous visits to health centers for respiratory disease

## Secondary outcome(s)

1.Measures of health outcomes relating to morbidity e.g., respiratory health and pulmonary function
2. Measures related to drug use requirements, number of oxygen therapies for respiratory causes, number of patient who have required respiratory physiotherapy.
3. Number of emergency visits for any type of otorhinolaryngology pathology: otitis in children, sinusitis or nasopharyngitis.

## Data extraction (selection and coding)

There will be three stages in the review process:
1. One author will pre-screen all the results (citations and abstracts) to identify studies that may be included or as useful background after removal of duplicate searches.
2. There will be 6 pairs of reviewers who review all of the items. We will obtain the full text of any potentially relevant studies. Two authors independently will assess them to see whether they met the inclusion criteria after reading the title and abstract (the latter if necessary). Reasons for excluding studies will be noted. There will be two additional reviewers to review the discrepancies.
3. Data will be extracted by two authors and checked by a third author if discrepancies.
This stage will include an evaluation of quality, to assess whether the adequacy of follow-up of participants, and whether outcome assessment will be verified.

## Risk of bias (quality) assessment

Two review authors will independently assess the risk of bias in all the included studies by using the STROBE system to examine the quality of the evidence for each outcome. There will be 6 pairs of reviewers who review all of the items.
Disagreements between the review authors over the risk of bias in particular studies will be discussed with involvement of a third review author where necessary.

## Strategy for data synthesis

We will provide a narrative synthesis of the findings from the included studies, structured around the type of legislation(partial or comprehensive smoking ban), target population characteristics, type of outcome and legislation content. If possible, we will provide summaries of legislation effects for each study by calculating risk ratios (for dichotomous outcomes) or standardised mean differences (for continuous outcomes). Because of the considerable heterogeneity in the type of legislations classified as workplace, local or regional level, in study design, participants and outcomes we will do not attempt meta analysis, but we will synthesize the data through narrative review with summary and quantitative descriptive analysis.
However, when studies use the same type of legislation and comparator, with the same outcome measure, we will pool the results using a random-effects meta-analysis, with standardised mean differences for continuous outcomes and risk ratios for binary outcomes, and calculate 95% confidence intervals and two sided P values for each outcome. We will conduct sensitivity analyses based on study quality. We will use stratified meta-analyses to explore heterogeneity in effect estimates according to: study quality; study populations; the logistics of intervention provision; and intervention content. We will also assess evidence of publication bias.

## Analysis of subgroups or subsets

If the necessary data are available, subgroup analyses will be done for:
- Comprehensiveness of smoking ban
- People with asthma and COPD and other respiratory disease separately.

Within each stage, and overall, we also plan to do a subgroup analysis by sex and age (<20, 20-30, 30-40, >40 years).

## Contact details for further information

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## Anticipated or actual start date

03 December 2014

## Anticipated completion date

31 October 2015

## Funding sources/sponsors

Institut d'Investigació en Atenció Primària Jordi Gol (IDIAP Jordi Gol), Barcelona, Spain.
Red de Investigación en Actividades Preventivas y Promoción de la Salud (redIAPP, RD12/0005)

## Conflicts of interest

None known

## Language

English

## Country

Spain

## Stage of review

Review_Completed_published

## Details of final report/publication(s)

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http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0181035

## Subject index terms status
Subject indexing assigned by CRD

## Subject index terms
Humans; Smoking; Tobacco Smoke Pollution

## Date of registration in PROSPERO
25 April 2015

## Date of publication of this version
03 April 2018

## Details of any existing review of the same topic by the same authors

## Stage of review at time of this submission

| Stage | Started | Completed |
|---|---|---|
| Preliminary searches | Yes | Yes |
| Piloting of the study selection process | Yes | Yes |
| Formal screening of search results against eligibility criteria | Yes | Yes |
| Data extraction | Yes | Yes |
| Risk of bias (quality) assessment | Yes | Yes |
| Data analysis | Yes | Yes |

## Versions
25 April 2015
03 April 2018

# PRISMA 2009 Checklist

| Section/topic | # | Checklist item | Reported on page # |
|---|---|---|---|
| **TITLE** | | | |
| Title | 1 | Identify the report as a systematic review, meta-analysis, or both. | 1 |
| **ABSTRACT** | | | |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. | 4-5 |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. | 6-7 |
| Objectives | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | 7 |
| **METHODS** | | | |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. | 8 |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. | 8-9 |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched. | 8 |
| Search | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | 8 and S1 Table |
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis). | 9 and Fig 1 |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. | 9-10 |
| Data items | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. | 9-10 |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. | 10 and S2 Table |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). | |
| Synthesis of results | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$) for each meta-analysis. | 10 |



| Section/topic | # | Checklist item | Reported on page # |
|---|---|---|---|
| Risk of bias across studies | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies). | |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. | |
| **RESULTS** | | | |
| Study selection | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | 11 and Table 1 |

| | | | |
|---|---|---|---|
| Study characteristics | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | 11-19 |
| Risk of bias within studies | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | 19-20 and S2 Table |
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | S3 Table |
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | |
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | |
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | |
| **DISCUSSION** | | | |
| Summary of evidence | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | 21-25 |
| Limitations | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). | 25-26 |
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | 27-28 |
| **FUNDING** | | | |
| Funding | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. | 5 and 29 |

*From:* Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

## Table S1: Search strategy applied in the different databases: SFL effects on respiratory and sensory disorders

| Web of Science | Scopus |
|---|---|
| 1.("Chronic Obstructive Pulmonary Disease" OR "COPD" OR "Chronic Obstructive Lung Disease"OR "Common Cold" OR Bronchitis OR "spontaneous pneumothorax" OR Pneumonia OR otitis OR Nasopharyngitis OR sinusitis OR "Pulmonary Disease, Chronic Obstructive" OR "Common Cold" OR "Bronchitis, Chronic" OR "Bronchitis" OR "Pneumothorax" OR "Pneumonia" OR "Otitis" OR "Nasopharyngitis" OR "Sinusitis" OR "Asthma" OR asthma OR "Respiratory Tract Diseases" OR "Respiration Disorders" OR respiratory) | 1. TITLE-ABS-KEY ( "Chronic Obstructive Pulmonary Disease" OR "COPD" OR "Chronic Obstructive Lung Disease" OR "Common Cold" OR bronchitis OR "spontaneous pneumothorax" OR pneumonia OR otitis OR nasopharyngitis OR sinusitis OR "Pulmonary Disease, Chronic Obstructive" OR "Common Cold" OR "Bronchitis, Chronic" OR "Bronchitis" OR "Pneumothorax" OR "Pneumonia" OR "Otitis" OR "Nasopharyngitis" OR "Sinusitis" OR "Asthma" OR asthma OR "Respiratory Tract Diseases" OR "Respiration Disorders" OR respiratory )<br>AND SUBJAREA ( mult OR medi OR nurs OR vete OR dent OR heal OR envi). Health sciences: Medicine, nursing, veterinary, dentisty, health professions, multidisciplinary. Physical sciences: environement sciences<br>AND PUBYEAR > 1994 hasta 21/2/2015<br>Results: 562.765 records |
| 2.("smoking ban" OR "smoking bans" OR "smokefree law" OR "smokefree laws" OR "smoke-free law" OR "smoke-free laws" OR "smoke-free policy" OR "smoke-free policies" OR "smokefree policy" OR "smokefree policies" OR "Smoke-Free Policy" OR "smoke-free bans" OR "smoke-free ban" OR "smokefree bans" OR "smokefree ban" OR "smoking bans" OR "smoking ban" OR "smoking legislation" OR "legislative smoking" OR "tobacco legislation" OR "tobacco legislations" OR "tobacco laws" OR "smoke-free legislation" OR "smoke-free legislations" OR "smokefree legislation" OR "smokefree legislations" OR "smoking policies" OR "smoking policy" OR anti-tobacco policy OR "Smoking/legislation and jurisprudence" OR "Tobacco Smoke Pollution/legislation and jurisprudence") NOT ("Electronic cigarettes" OR "motivational interviewing" OR "randomized clinical trial" OR Randomized Controlled Trial OR qualitative study OR oxidat* OR economic OR genetic OR motivational) | 2. TITLE-ABS-KEY ( "smoking ban" OR "smoking bans" OR "smokefree law" OR "smokefree laws" OR "smoke-free law" OR "smoke-free laws" OR "smoke-free policy" OR "smoke-free policies" OR "smokefree policy" OR "smokefree policies" OR "Smoke-Free Policy" OR "smoke-free bans" OR "smoke-free ban" OR "smokefree bans" OR "smokefree ban" OR "smoking bans" OR "smoking ban" OR "smoking legislation" OR "legislative smoking" OR "tobacco legislation" OR "tobacco legislations" OR "tobacco laws" OR "smoke-free legislation" OR "smoke-free legislations" OR "smokefree legislation" OR "smokefree legislations" OR "smoking policies" OR "smoking policy" OR anti-tobacco policy OR "Smoking/legislation and jurisprudence" OR "Tobacco Smoke Pollution/legislation and jurisprudence" )<br>AND SUBJAREA ( mult OR medi OR nurs OR vete OR dent OR heal OR envi). Health sciences: Medicine, nursing, veterinary, dentisty, health professions, multidisciplinary. Physical sciences: environement sciences<br>AND PUBYEAR > 1994 until 21/2/2015<br>Results: 1698 records |
| 3. #1 AND #2 | 3. #1 AND #2 |
| 4. Limit from 1995 to 2015 | |
| Results: 258 records | Results: 699 records |

| Cochrane Library | Google Scholar |
|---|---|
| Keywords; smoking ban | With all the words: Smoking ban<br>With at least one of the words: law smokefree asthma respiratory<br>Without the words: randomized “electronic cigarette” myocardial<br>Show articles dated between1995-2015<br>Results: 16900 records. |
| Publication Year from 1995 to 2015, in Cochrane Reviews (Reviews and Protocols) and Other Reviews | A preliminary Google Scholar search showed a large number of hits, so we scanned the first 200 results and we chose 28 for inclusion criteria. |
| Excluding papers from Trials (44) and Economic Evaluations (1) | |
| Results: 5 records | Results: 28 records after reading title of 200 first searches |

## Table S2. Quality assessment of the risk of bias of papers evaluating SFL effects on respiratory and sensory disorders (1995-2015)

Risk of bias was evaluated through the following items: confounding bias, detection bias (only in non-experimental studies- two domains), selection bias, attrition bias, reporting bias, other bias.

- Confounding bias:
  - Quasi-experimental studies: Comparability of groups.
  - Non-experimental studies: Was the policy independent of other changes?
- Detection bias:
  1. Was the shape of the policy effect pre-specified?
  2. Was the policy unlikely to affect data collection?
- Selection bias: Sample representativeness.
- Attrition bias: Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis.
- Reporting bias: State how the possibility of selective outcome reporting was examined by the review authors, and what was found.
- Other bias: State any important concerns about bias not addressed in the other domains in the tool.

We rated the overall methodological quality of the included studies as being at low, moderate, or high risk of bias (RoB). Depending on the type of design:

- Non experimental studies: without control group and seven domains of bias. The articles where there are 5 or more subcategories with low bias are classified as "Low" in the summary risk of bias; the ones with a number of subcategories between 3 and 4 classified as Low are rated as "Moderate"; and the ones with a number of subcategories between 1 and 2 classified as "Low" are rated as "High".
- Quasi-experimental studies: with control group and five domains of bias. The articles where there are 4 or more subcategories with low bias are classified as "Low" in the summary risk of bias; the ones with a 3 subcategories classified as Low are rated as "Moderate"; and the ones with a number of subcategories between 1 and 2 classified as "Low" are rated as "High".

| **Non experimental studies** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Study, year** | **Confounding bias** | **Detection bias 1** | **Detection bias 2** | **Selection bias** | **Attrition bias** | **Reporting bias** | **Other bias** | **Summary risk of bias** |
| Ayres, 2009[1] | Low | Low | Low | Unclear | Low | Low | Low | Low |
| Bannon, 2009[2] | Low | Low | Low | High | Unclear | Low | Low | Low |
| Croghan, 2015[3] | Low | Low | Low | Low | Unclear | Low | Unclear | Low |
| Dilley, 2012[4] | Unclear | Low | Low | Low | Unclear | Low | Unclear | Low |
| Durham, 2011[5] | Low | Low | Low | High | High | Low | High | Low |
| Eagan, 2006[6] | Low | Low | Low | Low | Unclear | Low | Unclear | Low |
| Eisner, 1988[7] | Unclear | Low | Low | Unclear | Low | Low | Low | Low |

| Non experimental studies (continuation) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Study, year** | **Confounding bias** | **Detection bias 1** | **Detection bias 2** | **Selection bias** | **Attrition bias** | **Reporting bias** | **Other bias** | **Summary risk of bias** |
| Farrelly, 2015[8] | Low | Unclear | Low | High | High | Low | Low | Moderate |
| Goodman, 2007[9] | Low | Low | Low | High | Low | Low | Low | Low |
| Hahn, 2006[10] | Low | Low | Low | Low | High | Low | High | Low |
| Ho, 2010[11] | Unclear | Low | Unclear | Unclear | Unclear | Low | Unclear | High |
| Humair, 2014[12] | Unclear | Low | Low | Unclear | Low | Low | High | Moderate |
| Kalkhoran, 2015[13] | Low | Unclear | Low | Low | Low | Low | High | Low |
| Kent, 2012[14] | Unclear | Low | Unclear | Low | Low | Low | Unclear | Moderate |
| Kim, 2014[15] | High | High | Low | High | Unclear | Low | Unclear | High |
| Larsson, 2008[16] | Unclear | Low | Low | High | High | Low | High | Moderate |
| Li, 2013[17] | High | Low | Low | High | Low | Low | High | Moderate |
| MacCalman, 2012[18] | Unclear | Unclear | Unclear | High | High | Low | Unclear | High |
| Mackay, 2010[19] | Low | Low | Low | Low | Unclear | Low | Unclear | Low |
| Madureira,2012[20] | Unclear | Low | Low | High | High | Low | Unclear | Moderate |
| Madureira,2014[21] | Unclear | Low | Low | High | High | Low | Unclear | Moderate |
| McGhee, 2014[22] | Low | Unclear | Low | Low | Unclear | Low | Unclear | Moderate |
| Menzies, 2006[23] | Unclear | Low | Low | Low | Unclear | Unclear | Low | Moderate |
| Millet, 2013[24] | Low | Unclear | Low | Low | Low | Low | Low | Low |
| Pearson, 2009[25] | Unclear | Unclear | Low | Unclear | Unclear | Low | Unclear | High |
| Rajkumar, 2014[26] | Low | Low | Low | Low | Unclear | Low | Unclear | Low |
| Rayens, 2008[27] | Low | Unclear | Low | Low | Unclear | Low | Unclear | Moderate |
| Reijula, 2012[28] | Low | Low | Low | Unclear | Unclear | Low | Low | Low |
| Roberts, 2012[29] | Unclear | Low | Low | Unclear | Low | Low | Unclear | Moderate |
| Schoj, 2010[30] | Low | Low | Low | Unclear | Low | Low | Unclear | Low |
| Sims, 2013[31] | Unclear | Low | Low | Low | Low | Unclear | High | Moderate |
| Skogstad, 2006[32] | High | Low | Low | Unclear | Unclear | Low | Low | Moderate |
| Stallings-Smith, 2013[33] | Low | Low | Low | Low | Low | Low | Unclear | Low |
| Stallings-Smith, 2014[34] | Low | Low | Low | Low | Low | Low | Low | Low |
| Vinnikov, 2013[35] | Low | Low | Low | Unclear | Low | Low | Unclear | Low |
| Wieslander, 2000[36] | Unclear | Low | High | Low | Unclear | Unclear | Unclear | High |
| Wilson, 2012[37] | Unclear | Low | Low | High | Low | Low | Unclear | Moderate |
| Yildiz, 2014[38] | Unclear | Unclear | Low | Low | Unclear | Low | Unclear | Moderate |

| Quasi-experimental studies | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Study, year** | **Confounding bias** | **Detection bias 1** | **Detection bias 2** | **Selection bias** | **Attrition bias** | **Reporting bias** | **Other bias** | **Summary risk of bias** |
| Allwright, 2005[39] | Low | Not applicable | Not applicable | Unclear | Low | Low | Low | Low |
| Binswanger,2014[40] | Low | Not applicable | Not applicable | Low | Unclear | Low | High | Moderate |
| Dove, 2012[41] | Unclear | Not applicable | Not applicable | Low | Unclear | Low | Unclear | High |
| Dusemund, 2013[42] | Low | Not applicable | Not applicable | Low | Low | Low | Unclear | Low |
| Fernández, 2009[43] | Low | Not applicable | Not applicable | Unclear | Low | Low | Unclear | Moderate |
| Gaudreau, 2013[44] | Low | Not applicable | Not applicable | Low | Low | Low | Unclear | Low |
| Head, 2012[45] | High | Not applicable | Not applicable | Unclear | Low | Low | Unclear | High |
| Herman, 2011[46] | Unclear | Not applicable | Not applicable | Low | Low | Low | Unclear | Moderate |
| Landers, 2014[47] | Low | Not applicable | Not applicable | Low | Low | Low | Unclear | Low |
| Moraros, 2010[48] | High | Not applicable | Not applicable | Low | Low | Low | Low | Low |
| Naiman, 2010[49] | Unclear | Not applicable | Not applicable | Low | Low | Low | Unclear | Moderate |
| Vander, 2012[50] | Unclear | Not applicable | Not applicable | Unclear | Low | Low | High | High |

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**Table S3: Descriptive characteristics of the 50 articles obtained for smokefree legislation effects on respiratory disorders (1995-2015)**

| Variable | Category | N | % of the papers included |
|---|---|---|---|
| Continent | Europe | 24 | 48 |
| | America | 21 | 42 |
| | Asia | 5 | 10 |
| Country | United States | 16 | 32 |
| | Ireland | 6 | 12 |
| | Switzerland | 4 | 8 |
| | China | 3 | 6 |
| | Scotland | 3 | 6 |
| | England | 2 | 4 |
| | Canada | 2 | 4 |
| | Norway | 2 | 4 |
| | Portugal | 2 | 4 |
| | Sweden | 2 | 4 |
| | Argentina | 1 | 2 |
| | Finland | 1 | 2 |
| | Korea Rep | 1 | 2 |
| | Kyrgyzstan | 1 | 2 |
| | Scotland & England | 1 | 2 |
| | Spain | 1 | 2 |
| | Turkey | 1 | 2 |
| | Uruguay | 1 | 2 |
| Setting | Hospitality | 22 | 44 |
| | City/region | 22 | 44 |
| | Different workplaces | 3 | 6 |
| | Schools | 2 | 4 |
| | Prisons | 1 | 2 |
| Type of legislation* | Total comprehensive | 33 | 66 |
| | Partial comprehensive | 12 | 24 |
| | Different types of SFL | 3 | 6 |
| | Labor | 2 | 4 |
| Study design | Before-after non-experimental design | 27 | 54 |
| | Non-experimental design: time series | 10 | 20 |
| | Quasi-experimental design: time series | 6 | 12 |
| | Before-after quasi-experimental design | 5 | 10 |
| | Other designs | 2 | 4 |
| Participants | Specifically adult workers | 25 | 50 |
| | Adults + children together (general population) | 12 | 24 |
| | Adults | 8 | 16 |
| | Children | 4 | 8 |
| | Vulnerable population (prisoners) | 1 | 2 |
| Data source/data information | Hospital registers | 19 | 38 |
| | Self-reported questionnaires | 15 | 30 |
| | No self-reported questionnaire | 4 | 8 |
| | Self-reported questionnaires + Spirometry | 4 | 8 |
| | Mortality data | 3 | 6 |
| | Spirometry | 2 | 4 |
| | No self-reported questionnaire + Spirometry | 2 | 4 |
| | Hospital registers + Mortality data | 1 | 2 |

| Variable | Category | N | % of the papers included |
|---|---|---|---|
| Study period before the SFL | 0-1 month | 11 | 22 |
| | 2-6 months | 8 | 16 |
| | 7-12 months | 1 | 2 |
| | >1-2 years | 7 | 14 |
| | >2-3 years | 4 | 8 |
| | >3 years | 13 | 26 |
| | Not specified | 6 | 12 |
| Study period after the SFL | 0-1 month | 4 | 8 |
| | 2-6 months | 6 | 12 |
| | 7-12 months | 13 | 26 |
| | >1-2 years | 11 | 22 |
| | >2-3 years | 4 | 8 |
| | >3 years | 10 | 20 |
| | Not specified | 2 | 4 |
| Respiratory and sensory outcomes † | Respiratory symptoms | 26 | 52 |
| | Sensory symptoms | 19 | 38 |
| | Hospital admissions for asthma | 17 | 34 |
| | Hospital admissions for COPD | 9 | 18 |
| | Spirometric parameters | 8 | 16 |
| | Hospital admissions for other pulmonary diseases | 4 | 8 |
| | Other mortality respiratory diseases | 3 | 6 |
| | Hospital admissions for overall respiratory diseases | 3 | 6 |
| | COPD mortality | 2 | 4 |
| | Persistent ear infection | 1 | 2 |
| Declared Conflict of Interest | Yes | 31 | 62 |
| | No | 19 | 38 |
| Summary Risk of Bias | Low | 23 | 46 |
| | Moderate | 19 | 38 |
| | High | 8 | 16 |

* We classified comprehensive smoke-free legislations as those that banned smoking in virtually all indoor workplaces and public areas, including bars, restaurants and public transport; and parcial as that which comprises fewer locations than those described[6]
All the percentatges of variables add up to100% except: † There are papers with more than one outcome.
COPD=chronic obstructive pulmonary disease.

Reference

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**S4 Table. Sensitivity analysis by omitting one or two until I2 dropped below the intented threshold 50% and range.**

| Subgroup | N. of studies | RD[a], MD[b], RR[c] (95% CI) | I2 (%) | P value I2 | Range |
|---|---|---|---|---|---|
| Any respiratory symptoms in comprehensive SFL setting[a] | | | | | |
| Total | 10 | -0.19 (-0.26, -0.12) | 70 | 0.001 | (-0.18, 0.21) |
| Omitting two [76] | 9 | -0.21 (-0.27,-0.15) | 41 | 0.10 | |
| Any respiratory symptoms in partial SFL setting[a] | | | | | |
| Tota | 4 | -0.20 (-0.31, -0.08) | 54 | 0.09 | (-0.14, -0.25) |
| Omitting one [56] | 3 | -0.14 (-0.19, -0.10) | 0 | 0.45 | |
| Any sensory symptoms in comprehensive SFL setting[a] | | | | | |
| Total | 9 | -0.34 (-0.46, -0.22) | 86 | <0.001 | (-0.31, -0.37) |
| FEV1 in comprehensive SFL setting[b] | | | | | |
| Total | 3 | 0.10 (-0.04, 0.24) | 87 | <0.001 | (-0.04, 0.13) |
| Asthma admissions in general population[c] | | | | | |
| Total | 6 | 0.87 (0.81, 0.93) | 78 | <0.001 | (0.85, 0.89) |
| Asthma admissions in children[c] | | | | | |
| Total | 5 | 0.85 (0.79, 0.91) | 87 | <0.001 | (0.82, 0.86) |
| Omitting one [59] | 4 | 0.82 (0.79, 0.84) | 0 | 0.77 | |
| Asthma admissions in adults[c] | | | | | |
| Total | 7 | 0.85 (0.73, 0.99) | 65 | 0.009 | (0.80, 0.90) |
| Omitting two [42] [48] | 5 | 0.77 (0.70, 0.85) | 31 | 0.22 | |
| COPD admissions[c] | | | | | |
| Total | 6 | 0.80 (0.63, 1.00) | 96 | <0.001 | (0.73, 0.85) |

**Abbreviations: CI, confidence interval; COPD, chronic obstructive pulmonary disease; FEV1, forced expired volume in one second ; MD, mean difference; N, number; RD, risk difference; RR, risk ratio, SFL, smokefree legislation.**

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**S5 Table. Subgroup analysis by study design, risk of bias and follow-up time among studies relating any respiratory and sensory symptoms.**

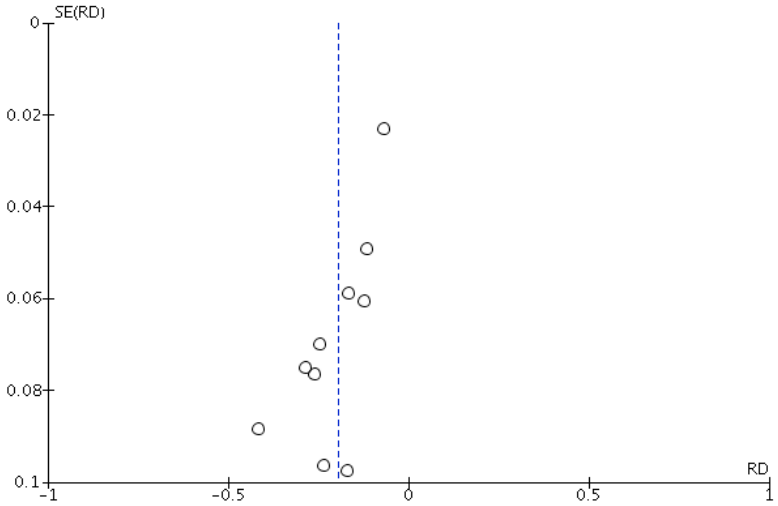
| Subgroup | Number of studies | RD (95% CI) | I2 (%) | P value I2 |
|---|---|---|---|---|
| Any respiratory symptoms in comprehensive SFL setting | | | | |
| Total | 10 | -0.19 (-0.26, -0.12) | 70 | 0.001 |
| Type of study design | | | | |
| Non experimental | 9 | -0.20(-0.28, -0.12) | 73 | <0.001 |
| Quasi-experimental | 1 | -0.17 (-0.28, -0.05) | 90 | 0.005 |
| Risk of bias | | | | |
| Low | 6 | -0.20 (-0.30, -0.10) | 80 | <0.001 |
| Moderate | 2 | -0.23 (-.34, -0.11) | 0 | 0.47 |
| High | 2 | -0.16 (-0.26, -0.06) | 0 | 0.33 |
| Follow-up time | | | | |
| <12 months | 4 | -0.25 (-0.42, -0.07) | 88 | <0.001 |
| ≥12 months | 6 | -0.16 (-0.21, -0.11) | 0 | 0.64 |
| Any respiratory symptoms in partial SFL setting | | | | |
| Total | 4 | -0.20 (-0.31, -0.08) | 54 | 0.09 |
| Type of study design | | | | |
| Non experimental | 3 | -0.19(-0.32, -0.05) | 63 | 0.007 |
| Quasi-experimental | 1 | -0.28 (-0.51, -0.05) | | |
| Risk of bias | | | | |
| Low | 1 | -0.14 (-0.19, -0.09) | | |
| Moderate | 2 | -0.34 (-.50, -0.18) | 0 | 0.51 |
| High | 1 | -0.10 (-0.28, -0.08) | | |
| Follow-up time | | | | |
| <12 months | 1 | -0.10 (-0.28, 0.08) | | |
| ≥12 months | 3 | -0.24 (-0.41, -0.08) | 68 | 0.05 |
| Any sensory symptoms in comprehensive SFL setting | | | | |
| Total | 9 | -0.34 (-0.46, -0.22) | 86 | <0.001 |
| Type of study design | | | | |
| Non experimental | 8 | -0.36(-0.49, -0.22) | 87 | <0.001 |
| Quasi-experimental | 1 | -0.22 (-0.34, -0.11) | | |
| Risk of bias | | | | |
| Low | 5 | -0.36 (-0.54, -0.18) | 91 | <0.001 |
| Moderate | 2 | -0.43 (-.57, -0.29) | 36 | 0.21 |
| High | 2 | -0.18 (-0.28, -0.08) | 0 | 0.48 |
| Follow-up time | | | | |
| <12 months | 3 | -0.48 (-0.60, -0.36) | 52 | 0.12 |
| ≥12 months | 6 | -0.27 (-0.39, -0.15) | 81 | <0.001 |

**Abbreviations: CI, confidence interval; RD, risk difference; SFL, smokefree legislation.**

**S7 Table. Subgroup analysis by study design, risk of bias and follow-up time among studies relating asthma and COPD admissions in comprehensive SFL setting.**

| Subgroup | Number of studies | RD (95% CI) | I2 (%) | P value I2 |
|---|---|---|---|---|
| Asthma admissions in general population | | | | |
| Total | 6 | 0.87 (0.81, 0.93) | 78 | <0.001 |
| Type of study design | | | | |
| Non experimental | 3 | 0.84(0.76, 0.93) | 79 | 0.008 |
| Quasi-experimental | 3 | 0.90 (0.78, 1.03) | 80 | 0.007 |
| Risk of bias | | | | |
| Low | 2 | 0.89 (0.76, 1.03) | 81 | 0.02 |
| Moderate | 3 | 0.82 (0.73, 0.92) | 84 | 0.002 |
| High | 1 | 0.98 (0.85, 1.13) | | |
| Follow-up time | | | | |
| <24 months | 2 | 0.87 (o.68, 1.10) | 84 | 0.01 |
| ≥24 months | 4 | 0.87 (0.81, 0.94) | 80 | 0.002 |
| Asthma admissions in children | | | | |
| Total | 5 | 0.85 (0.79, 0.91) | 87 | <0.001 |
| Type of study design | | | | |
| Non experimental | 4 | 0.85(0.79, 0.91) | 90 | <0.001 |
| Quasi-experimental | 1 | 1.11 (0.63, 1.96) | | |
| Risk of bias | | | | |
| Low | 4 | 0.85 (0.79, 0.92) | 90 | <0.001 |
| Moderate | 1 | 0.82 (0.71, 0.95) | | |
| Asthma admissions in adults | | | | |
| Total | 7 | 0.85 (0.73, 0.99) | 65 | 0.009 |
| Type of study design | | | | |
| Non experimental | 6 | 0.80(0.71, 0.92) | 54 | 0.005 |
| Quasi-experimental | 1 | 1.48 (0.90, 2.43) | | |
| Risk of bias | | | | |
| Low | 3 | 0.95 (0.74, 1.22) | 57 | 0.10 |
| Moderate | 4 | 0.79 (0.63, 0.98) | 65 | 0.04 |
| Follow-up time | | | | |
| <24 months | 1 | 1.17 (0.82, 1.76) | | |
| ≥24 months | 6 | 0.81 (0.70, 0.93) | 59 | 0.03 |
| COPD admissions | | | | |
| Total | 6 | 0.80 (0.63, 1.00) | 96 | <0.001 |
| Type of study design | | | | |
| Non experimental | 4 | 0.78(0.56, 1.09) | 97 | <0.001 |
| Quasi-experimental | 2 | 0.83 (0.74, 0.94) | 40 | 0.20 |
| Risk of bias | | | | |
| Low | 2 | 0.84 (0.73, 0.98) | 61 | 0.11 |
| Moderate | 3 | 0.74 (0.47, 1.16) | 96 | <0.001 |
| High | 1 | 0.88 (0.78, 0.99) | | |
| Follow-up time | | | | |
| <24 months | 2 | 0.61 (0.59, 0.63) | 0 | 0.35 |
| ≥24 months | 4 | 0.92 (0.79, 1.08) | 80 | 0.002 |

**Abbreviations: COPD, chronic obstructive pulmonary disease; CI, confidence interval; RD, risk difference; SFL, smokefree legislation.**




**S6 Fig. Funnel plot of any respiratory symptom in comprehensive smokefree legislation setting. Publication bias**

### 4.1.3. Artículo 3: Effect of comprehensive smoke-free legislation on asthma and coronary disease trends in Spanish primary care patients

**Abstract**

**Background**

To examine the impact of comprehensive smoke-free legislation (SFL) (Law 42/2010) on the incidence and prevalence of adult asthma and coronary disease in primary health care (PHC) patients from three Spanish regions, overall and stratified by sex.

**Methods**

Longitudinal observational study conducted between 2007 and 2013 in the population over 15 years of age assigned to 66 PHC teams in Catalonia, Navarre and the Balearic Islands. Crude rates and age-standardized (truncated: asthma ≥ 16 years and coronary disease ≥ 35 years) incidence and prevalence rates using the direct method based on the European Standard Population were estimated based on data from PHC electronic health records. Joinpoint analysis was used to analyse the trends of age-standardized incidence and prevalence rates. Trends were expressed as annual percentage change and average annual percent change (AAPC).

**Results**

The standardized asthma incidence rate showed a non-significant downward trend and the standardized prevalence rates rose significantly in the three regions. Standardized coronary disease incidence and prevalence rates were considerably higher for men than for women in all regions. The standardized coronary disease incidence rates in Catalonia (AAPC: −8.00%, 95% CI: −10.46; −5.47) and Navarre (AAPC: −3.66%, 95% CI: −4.95;-2.35) showed a significant downward trend from 2007 to 2013, overall and by sex. The standardized coronary disease prevalence trend rate increased significantly in the whole period in Catalonia and the Balearic Islands, although a non-significant downward trend was observed from 2010 in Catalonia.

**Conclusion**

No changes in the trends of adult asthma and coronary disease in PHC Spanish patients were detected after the introduction of comprehensive SFL.

**Cita:** Rando-Matos, Yolanda; Pons-Vigués, Mariona; Rodriguez-Blanco, Teresa; Ripoll, Joana; Llobera, Joan; Morán, Julio; Ballvé-Moreno, Josep Lluís; Violán, Concepció; Bolíbar, Bonaventura. **Effect of comprehensive smoke-free legislation on asthma and coronary disease trends in Spanish primary care patients**, European Journal of Public Health, 1 June 2018; 28(3):553-559. https://doi.org/10.1093/eurpub/cky010.

**Enlace al artículo:** https://academic.oup.com/eurpub/article-abstract/28/3/553/4833567?redirectedFrom=fulltext

# 5. RESUMEN GLOBAL DE LOS RESULTADOS

En el estudio de población atendida en APS de las tres comunidades autonómas, se halló una disminución significativa en la tendencia de las tasas de prevalencia de personas fumadoras (CPAP Cataluña -2,18%; Navarra -1,44%; Islas Baleares -1,75%), mayor en hombres que en mujeres, y un aumento significativo en la tendencia de la prevalencia de personas ex fumadoras en las tres regiones (CPAP Cataluña 7,19%; Navarra 16,67%; Islas Baleares 14,96%), especialmente en las mujeres. Respecto a la incidencia, la tendencia de las tasas de nuevas personas fumadoras disminuyó significativamente en Cataluña (CPAP -10,39%) y Navarra (CPAP -9,49%), similar en hombres y mujeres, pero también disminuyó la tendencia de las nuevas personas ex fumadoras en Cataluña (CPAP -7,27%) y las Islas Baleares (CPAP -11,24%), especialmente entre los hombres. Las tendencias de las tasas de incidencia de recaída de personas exfumadoras mostraron datos contradictorios entre regiones.

En la revisión sistemática y meta-análisis se ha observado efectos beneficiosos de las leyes libres de humo en los trabajadores sobre sintomatología respiratoria (disminución significativa de cualquier síntoma respiratorio después de la ley integral del 19% y 20% [parcial] en el meta-análisis) y sintomatología sensorial (disminución de cualquier síntoma sensorial del 34% [integral] y del 30% [parcial]). También se halló una disminución significativa de los ingresos hospitalarios por asma en población adulta e infantil del 15% tras la legislación. Los rangos de disminución de asma tras las legislaciones integrales según la revisión narrativa eran de entre el 9,0% y el 18,2% para la población infantil y de entre el 4,9 al 36,0% para la población adulta. Hubo una mayoría de estudios que reportaron disminuciones en los ingresos por EPOC en la revisión narrativa (rango de disminución del 1% al 36%) pero sin significación en el meta-análisis. Respecto a otras enfermedades pulmonares, mortalidad respiratoria y parámetros espirométricos, los resultados fueron heterogéneos y discrepantes.

En el ámbito de la APS y en las tres regiones estudiadas, la tendencia de prevalencia de asma aumentó significativamente del 2007 al 2013, en menor medida durante el período 2009-13 en Cataluña (CPA 4,22% vs CPA 7,13% en el periodo 2007-2009) y Navarra (CPA 6,07% vs CPA 9,09% en el periodo 2007-2009), y especialmente en los hombres en todas las regiones. En cambio, las tendencias de las tasas de incidencia de asma no obtuvieron resultados significativos. Las tasas de incidencia de la enfermedad coronaria mostraron una tendencia descendente significativa a lo largo del período en Cataluña (CPAP -8,00%) y Navarra (CPAP -3,66%). Por el contrario, la tendencia de las tasas de prevalencia aumentó significativamente en Cataluña de 2007 a 2010 en global (CPA 1,52%) y en los hombres (CPA 1,90%) y también en las Islas Baleares durante todo el período de estudio (CPAP global 10,01%).

# 6. DISCUSIÓN GLOBAL DE LOS RESULTADOS PRINCIPALES OBTENIDOS

En esta tesis se ha observado una disminución significativa en la tendencia de las tasas de prevalencia de personas fumadoras (mayor en hombres que en mujeres) y en consecuencia, un aumento significativo en la tendencia de la prevalencia de personas ex fumadoras en las tres regiones estudiadas, mayormente en las mujeres, durante todo el periodo de estudio (de 2008 al 2013). Respecto a la incidencia, la tendencia de las tasas de nuevas personas fumadoras disminuyó significativamente en Cataluña y Navarra (similar en hombres y mujeres), pero también disminuyó la tendencia de los nuevas personas ex fumadoras en Cataluña y las Islas Baleares, especialmente entre los hombres de Cataluña, a lo largo de todo el periodo de estudio. A consecuencia del efecto que han tenido las leyes en el aumento de los espacios libres de humo y potencialmente de la disminución de personas fumadoras, es de prever observar un impacto positivo en las patologías relacionadas con el tabaquismo, tanto el pasivo como el activo. En la revisión sistemática y meta-análisis realizados se ha observado efectos beneficiosos de las leyes libres de humo en los trabajadores con respecto a la sintomatología respiratoria y sensorial, tanto con leyes integrales como parciales. También se halló una disminución de los ingresos hospitalarios por asma en adultos y niños, mayor cuando la legislación era integral. En cambio, los resultados para otras enfermedades pulmonares, mortalidad respiratoria y parámetros espirométricos fueron no concluyentes. En el ámbito de la APS y en las tres regiones estudiadas, la tendencia de prevalencia de asma aumentó significativamente, menor durante el período 2009-13 en Cataluña y Navarra, y mayor para los hombres que para las mujeres en todas las regiones. Para la enfermedad coronaria, la otra patología relacionada con el tabaquismo evaluada en esta tesis, las tasas de incidencia mostraron una tendencia descendente significativa a lo largo del período estudiado en Cataluña y Navarra. Por el contrario, la tendencia de las tasas de prevalencia de enfermedad coronaria aumentó significativamente en Cataluña de 2007 a 2010 en global y en los hombres y también en las Islas Baleares durante todo el período de estudio.

El resumen de la discusión de la presente tesis se ha realizado teniendo en cuenta el marco conceptual para la evaluación de políticas libres de humo presentado en la introducción (figura 1.7). El paso inicial para que una ley libre de humo funcione es la aceptación y el cumplimiento de esta. El informe de la SEE del 2017 informó que la aceptación por parte de la población era buena, tanto antes como después de la implantación, y también el cumplimiento excepto en los recintos exteriores de los hospitales, terrazas de bares y cafeterías (37). Se considera muy importante el cumplimiento en estos espacios mencionados para fomentar la desnormalización del consumo del tabaco. En la figura 1.7 se mencionaban otros factores concomitantes que

podían influir en el cumplimiento de la ley, como la influencia de la industria tabacalera, el contexto sociocultural o el nivel socio-económico del territorio. En relación a este último está la coincidencia con la crisis económica del 2008. Un estudio español realizado sobre encuestas nacionales de antes (2005-2007) y después de la crisis (2009-2011) observó que cuando la tasa de desempleo aumentaba 10 puntos porcentuales, la probabilidad de fumar tabaco diariamente aumentaba un 3%, siendo las personas con menor nivel educativo, hombres y el grupo de edad 46-65 años (134) los más vulnerables. Para contrarrestar este efecto, es importante el apoyo a las personas fumadoras que desean dejar de fumar (es decir, asesoramiento individual o grupal, reembolsos para tratamientos farmacológicos para dejar de fumar) y optimizar los efectos de otras políticas de control del tabaco como aumentar los impuestos indirectos al tabaco (135).

**Artículo 1 sobre el efecto de la Ley 42/2010 en hábito tabáquico en Atención Primaria de Salud**

Las leyes libres de humo restringen el fumar en determinados espacios de trabajo y de ocio. Esta restricción podría influir en que las personas fumadoras predispuestas se vean empujadas a abandonar este hábito y quizás desalentar iniciarse en él a posibles nuevos fumadores. Según el artículo 1 de la presente tesis, la ley libre de humo del 2010 no influyó en un cambio de tendencia descendente de la prevalencia de personas fumadoras atendidas en APS (es decir, no ha aumentado la tendencia descendente) con lo que no se ha confirmado la primera hipótesis de esta tesis. Se encontró una disminución anual entre 1,44% y 2,18% en las tres regiones, mayor en los hombres, pero en Cataluña esta disminución fue más acusada entre el tercer trimestre del 2010 y el último trimestre del 2011 (CPAP de -6,75), que podría plantear un posible efecto adelantado a la ley en el hábito tabáquico. Esta ausencia de impacto de la Ley integral está en concordancia con el estudio de Pérez-Ríos *et al.* (2015) (103), que se realizó en población general mayor de 17 años mediante encuestas telefónicas, en su caso la prevalencia bajó no significativamente un 2,7% entre 2006 y 2011. En cambio, el II Informe a las Cortes Generales (100) concluye respecto a la prevalencia de personas fumadoras actuales (diarias y ocasionales) de 15 años o más que hubo una reducción del 2,9% entre los años 2009 y 2011, siendo la reducción del 2,2% en las personas fumadoras diarias, más en hombres que en mujeres al igual que nuestros datos. Este mismo informe resume que entre 2011 y 2014 la prevalencia de personas fumadoras actuales bajó 1,6 puntos porcentuales (del 27% al 25,4%), y al contrario que en el periodo anterior, más en mujeres que en hombres. Aunque se hayan usado análisis estadísticos distintos, vemos porcentajes similares de descenso de prevalencia en la población general (medida mediante encuestas nacionales) y en la atendida en APS.

La coincidencia con la crisis económica y de la implantación de las leyes libres de humo se han relacionado con un desplazamientos hacia otros tipos de consumo de productos del tabaco,

como por ejemplo los cigarrillos de liar y los cigarrillos electrónicos (e-cig) (44,107). Las ventas de cigarrillos bajaron de 888.711.123 a 415.171.239 paquetes de cigarrillos, mientras que las de tabaco de liar aumentaron de 724.353 a 1.281.778 kilogramos desde 2005 a 2017 en Cataluña, según los datos de Comisionado para el Mercado de Tabaco (136). En relación al cigarrillo de liar, Lidón *et al.* (2017) hallaron un aumento del consumo en Barcelona entre 2004 y 2011 especialmente en hombres, grupo de edad de 16-44 años y nivel educativo de secundaria y universitario (107). En la historia clínica electrónica (fuente de datos de la tesis) no se especifica qué tipo de tabaco es el consumido pero se considera persona fumadora aquella que fuma tanto cigarrillos manufacturados como cigarrillos de liar, por tanto, no afectaría a los resultados obtenidos en este artículo. El e-cig es un cigarrillo de atomización electrónico con nicotina que se vendía como sustituto para dejar de fumar, objetivo que no se ha demostrado según la evidencia científica. Es un ejemplo de cómo la industria tabacalera comercializa y promueve estos productos, además de una forma de eludir las leyes libres de humo al permitir a los usuarios "fumar en cualquier lugar" (137). Sin embargo, un estudio realizado en 35 países de Europa no observó una correlación significativa de la TCS (la cual puntúa diferentes medidas legislativas de control del tabaquismo, entre ellas las leyes libres de humo) con la prevalencia del consumo de e-cig (48). Por consiguiente, tampoco debería alterar los resultados del artículo 1 de la presente tesis.

La APS es un ámbito prínceps en la promoción del cese entre las personas fumadoras tal como reporta el II informe a las Cortes Generales. Este informe (100), basado en la Encuesta Nacional de Salud (ENSE) del 2009 y 2011, clasifica el consejo médico como 4º motivo de las personas ex fumadoras para dejar de fumar, por detrás de riesgo para la salud, molestias causadas por el tabaco y otros motivos. La tendencia de la tasa de prevalencia global de personas ex fumadoras aumentó en todo el periodo en las tres regiones examinadas en nuestro estudio, sobretodo en Navarra (CPAP Cataluña 7,19; Navarra 16,67 e Islas Baleares 14,96) pero no cambió en relación a la Ley 42/2010, es decir, no aumentó la tendencia ascendente tras la ley, por lo que tampoco se cumplió la hipótesis de estudio en relación a esta variable. En el estudio de Pérez-Ríos *et al.* (2015) (103) se halló un aumento no significativo del 3,3% entre 2006 y 2011 mediante encuestas telefónicas en dos periodos (de 27,3% en 2006 a 30,6% en 2011) y únicamente se encontró una relación significativa en el subgrupo de población con estudios primarios o menores (aumento del 7,2%, p 0,013). El Informe a las Cortes Generales del 2011 (99) concluyó que la proporción de abandono (ex fumadores/fumadores + ex fumadores) en 2011 era superior a la del año 2009. La proporción de abandono del hábito tabáquico en los hombres aumentó un 0,9% anualmente entre 1984 y 2014 y un 1,5% después de la Ley parcial en las mujeres según el informe de la SEE del 2017 (37), lo que concuerda con la mayor tendencia de mujeres ex fumadoras del artículo 1 de esta tesis, aunque los valores fueron

superiores en este caso (CPAP entre 10,87 y 19,51). Estos porcentajes de CPAP del artículo 1 son mayores que los de las encuestas nacionales, lo que quizás pueda hacer pensar en un probable efecto beneficioso de la APS en la prevalencia de personas ex fumadoras. Por otra parte, también se ha observado que cuando hay una crisis económica hay más abandonos entre las personas fumadoras ocasionales y menos personas inician el hábito tabáquico (135). En el artículo 1 sólo se consideran las personas fumadoras diarias, con lo que no se ha podido analizar el efecto en personas ex fumadoras ocasionales. En relación al registro en la historia clínica electrónica por parte de los profesionales de medicina general, una revisión sistemática del 2010 exponía que aunque el tabaquismo actual (personas fumadoras) generalmente está bien registrado, el tabaquismo previo (personas ex fumadoras) no está tan bien registrado (138), siendo un 29% de lo esperado según la encuesta nacional de hogares en Reino Unido. En el ámbito español, un estudio también observó discordancias entre los registros electrónicos de salud y los datos de REGICOR 2000 para la prevalencia de personas ex fumadoras (139). Sin embargo, en Cataluña, Navarra e Islas Baleares (las tres regiones evaluadas en los artículos 1 y 3) existen objetivos específicos de mejora de registro de variables relacionadas con el tabaquismo y la deshabituación tabáquica (hábito tabáquico, consejo antitabaco, etc.), en los contratos de gestión/cartera de servicios entre las gerencias y los equipos de APS.

Respecto a la incidencia de nuevos fumadores se observa un descenso en la tendencia significativo para todo el periodo de estudio en Cataluña y Navarra (CPAP -10,39 y -9,49, respectivamente) en el artículo 1, no confirmando de nuevo la hipótesis 1 de esta tesis. No se han encontrado estudios españoles que evalúen esta variable respecto a la Ley integral y los que lo hacen respecto a La ley parcial ofrecen resultados contradictorios: sin efecto en el estudio de Guerrero *et al.* (2011) (140) y una disminución del 6% en la tasa de inicio de hábito tabáquico entre jóvenes menores de 21 años en el estudio de Pinilla *et al.*(2017) (92). Las clases sociales más bajas (IV-VI) tuvieron un riesgo relativo mayor de inicio de hábito tabáquico que las clases sociales altas según este último estudio. Como se ha mencionado anteriormente y en relación al nivel socioeconómico del territorio, en momentos históricos de crisis financiera menos personas empiezan a fumar (135). Los porcentajes del artículo 1 son mayores que los hallados tras la Ley parcial, lo que quizás pueda hacer pensar en un probable efecto beneficioso del abordaje desde APS en esta variable pero que no se ha reforzado con la entrada en vigor de la Ley integral.

Los resultados de las incidencias de las dos siguientes variables (nuevas personas ex fumadoras y recaída de ex fumadoras) no son concluyentes y no existen estudios sobre estas en España, según el conocimiento actual. La incidencia de nuevos ex fumadores disminuyó en Cataluña (CPAP -7,27) y en las Islas Baleares (-11,24) a lo largo de todo el periodo estudiado, sobretodo en hombres de Cataluña. Al igual que con la prevalencia de personas ex fumadoras, lo lógico

sería pensar en que aumentaran los nuevos ex fumadores de esta cohorte en el periodo estudiado, el hecho contrario puede deberse a la ausencia de impacto de la ley en este ítem, diferencias socio-económicas de la población (población con nivel socio-económico más bajo ya que según Pinilla *et al.* (2017) (92) el riesgo relativo para dejar de fumar era mayor en clases sociales más altas [I-II]) o a tener poca potencia estadística para detectar cambios, ya que en nuestra cohorte, observamos aumentos y disminuciones aparentemente aleatorios en las tasas ajustadas de las tres regiones a lo largo del estudio. Respecto a la incidencia de recaída de nuevos fumadores, se obtuvieron resultados contradictorios: aumentó en Cataluña (CPAP 18,60) y disminuyó en Navarra (-11,42), sobretodo en mujeres en ambos casos. Estas diferencias entre regiones se pueden explicar por factores concomitantes a la Ley como, de nuevo, la diferente influencia de la crisis económica (tasa de paro de Navarra en 2010 11,6% vs 18% en Cataluña (141)) o medidas complementarias a la Ley (Ley Foral 6/2203 de Navarra (142)) o la prevalencia de ansiedad o depresión de la población (también menor en Navarra que en Cataluña) (143). Así, nuevamente, no se ha observado el impacto de la Ley integral en estas variables como se había previsto en la hipótesis 1.

**Artículo 2 sobre el efecto de las leyes libres de humo en trastornos respiratorios y sensoriales**

En relación a las comorbilidades relacionadas con el tabaquismo, el informe de la *Surgeon General* del 2014 (6) asoció el tabaquismo activo con sobreinfección por virus y bacterias, EPOC, exacerbación de asma en adultos y síntomas respiratorios (tos crónica, producción excesiva de esputo) y el tabaquismo pasivo con infección de vías respiratorias bajas, asma infantil, reducción de función pulmonar y síntomas respiratorios. La segunda hipótesis de esta tesis contemplaba que la aplicación de las legislaciones libres de humo podría influir en disminuir los ingresos/incidencia o prevalencia de enfermedades y mortalidad respiratorias, además de influir en mejorar la sintomatología respiratoria y sensorial y la función pulmonar en todas las poblaciones. Esta hipótesis se ha cumplido parcialmente.

La revisión sistemática incluida en esta tesis halló efectos positivos claros (tanto en la síntesis narrativa como en el meta-análisis) de las leyes libres de humo en sintomatología respiratoria y sensorial (disminución del 19% y del 34% en cualquier síntoma respiratorio o sensorial tras las leyes libres de humo integrales en el meta-análisis, respectivamente) e ingresos por asma en población adulta e infantil (disminución del 15% tras leyes integrales en ambos casos). Sin embargo, respecto a la reducción de la función pulmonar, ingresos por EPOC, infecciones pulmonares y mortalidad de causa respiratoria los resultados fueron no concluyentes o no significativos en el meta-análisis (esto último, en el caso de la EPOC). Como se ha mencionado anteriormente, las leyes libres de humo no son las únicas medidas que contribuyen a que las

personas dejen de fumar y por ende, disminuyan las enfermedades relacionadas con el tabaquismo. Los valores de la espirometría dependen de una realización correcta de la técnica, existencia previa de asma tratado, de asma compensado o de tabaquismo en el participante (144), elementos que a veces no se pueden controlar en los estudios. Es posible que la EPOC necesite de otros factores no legislativos para contribuir a la diminución de los ingresos tales como el buen uso de la medicación de mantenimiento, la educación sobre la importancia de las exacerbaciones, la disminución a la exposición al humo de segunda mano en lugares no regulados por la ley o el status socio-económico personal (145). Un estudio reciente (2017) realizado sobre 14 provincias españolas (Alicante, Asturias, Islas Baleares, Barcelona, Cádiz, La Coruña, Madrid, Málaga, Murcia, Las Palmas, Sevilla, Valencia, Vizcaya y Zaragoza) evaluó los ingresos hospitalarios por EPOC desde el 2003 al 2012, con lo cual estudió el impacto de las dos leyes libres de humo españolas. Halló una disminución inmediata y mantenida al año de los ingresos tras la Ley parcial, sobretodo en las provincias menos desarrolladas económicamente (denotando la fuerte vinculación de esta enfermedad al nivel socio-económico), pero no encontró cambios significativos tras la Ley integral (108). Las infecciones pulmonares como la neumonía, bronquitis o la tuberculosis (esta última no evaluada en los estudios de las leyes libres de humo) también pueden depender, así mismo, de otros elementos como la vacunación o el nivel socio-económico del país. En relación a la mortalidad respiratoria es plausible que se necesiten más años de exposición a la ley libre de humo para que se puedan obtener resultados beneficiosos o que se requieran análisis de subgrupos para ver en qué subtipo de población es más favorable la ley libre de humo (64).

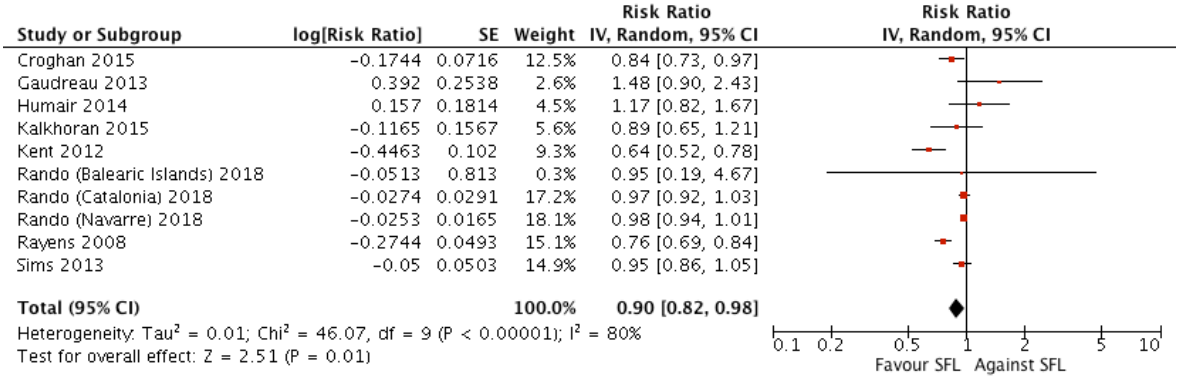
Desde que se han publicado los artículos de esta tesis ha aparecido una nueva revisión sistemática y meta-análisis acerca del impacto de políticas de control del tabaquismo (MPOWER) en ingresos por exacerbaciones de asma y por infecciones del tracto inferior en población infantil. Dicho estudio, de Faber *et al.* (2017) (66), observó que las tasas de asistencia hospitalaria por exacerbaciones de asma disminuyeron significativamente un 9,83% (IC 95% -16,62 a -3,04), las tasas de asistencia hospitalaria para todas las infecciones del tracto respiratorio, un 3,45% (IC 95% -4,64 a -2,25), y para las infecciones del tracto respiratorio inferior, un 18,48% (IC 95% -32,17 a -4,17) tras la implementación de leyes libres de humo (más fuertemente con leyes integrales que parciales). Aunque en nuestro caso no fue posible realizar meta-análisis de las infecciones del tracto respiratorio en población infantil, los ingresos por asma en esta población mostraron una disminución del 15% (IC 95% 0,79 a 0,91, $I^2$ 87%). Los datos administrados por Faber *et al.* son reducciones inmediatas, es decir tras la implantación de la ley. En nuestro estudio no fue posible hacer análisis de subgrupo por tiempo de seguimiento debido al escaso número de estudios (cinco) y la imposibilidad para

combinarlos en el meta-análisis. Además, los estudios analizados en el meta-análisis de Faber *et al.* y los analizados en el meta-análisis de la presente tesis no eran totalmente coincidentes.

**Artículo 3 sobre el efecto de la Ley 42/2010 en asma y enfermedad coronaria en Atención Primaria de Salud**

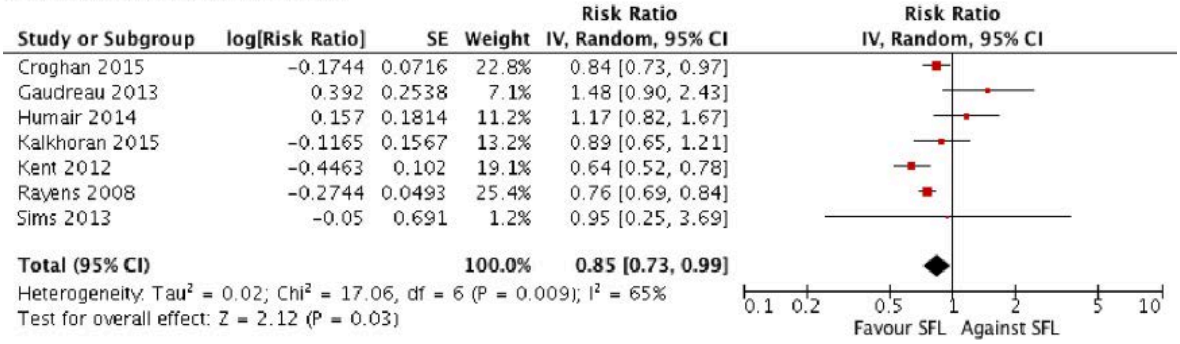
A diferencia del beneficio claro de las leyes libres de humo sobre ingresos por asma encontrado en revisiones, el artículo 3 de la presente tesis que evaluó el impacto de la Ley integral observado desde la APS no obtuvo significación estadística en ninguna de las tres regiones estudiadas, aunque en este caso no se refiere a ingresos hospitalarios. La incidencia de asma en APS disminuyó no significativamente en relación a dicha Ley, no cumpliendo así la hipótesis 3 de esta tesis. En comparación con otros estudios realizados en APS, Been *et al*. (2015) (63) tampoco hallaron cambios en población infantil de APS y Kalkhoran *et al*. (2015) (146) sí observaron una disminución del 15% en la incidencia de asma de adultos extra-hospitalario. El único estudio español que evaluó el efecto de las leyes parcial e integral sobre ingresos hospitalarios por asma de personas de cualquier edad entre 2003 y 2012 observó que disminuyeron significativamente un 7,4% inmediatamente después de la implementación de la Ley integral, aunque la disminución al año solo se mantuvo en hombres (9,9%, IC 95%: 3,9, 15,6) (108). Y el II Informe a las Cortes Generales (2014) (100) expuso que las tasas de hospitalización por asma se redujeron específicamente en 2011 (12,6%) en hombres y en población infantil, pero en los años 2012 y 2013 se detectaron ligeros aumentos no significativos. Por tanto, los resultados del artículo 3 son contradictorios con los de la literatura en relación a la población adulta. Sin embargo, son pocos estudios y diferentes poblaciones (urgencias extra-hospitalarias no necesariamente en el centro de APS (146) e ingresos hospitalarios (108)). De hecho, si hubiesen aparecido los datos de incidencia de asma del artículo 3 en el meta-análisis, en la subpoblación de adultos y separando los datos de cada región, se obtendría la siguiente figura.

**Figura 6.1. Meta-análisis de asma en adultos incluyendo datos del estudio de esta tesis**




La figura original publicada en PloS ONE para esta subpoblación fue la siguiente:

**Figura 6.2. Meta-análisis de asma en adultos del estudio original publicado en PloS ONE**




Dado que los resultados de incidencia del artículo 3 no eran significativos, el hecho de añadirlos al meta-análisis de la tesis hubiera bajado el efecto grupal de las leyes libres de humo (el RR pasaría de 0,85 a 0,90) con un aumento de la heterogeneidad entre estudios (de $I^2$ 65% a 80%) aunque los intervalos de confianza se habrían estrechado, denotando mayor precisión y seguridad de los datos. En el análisis de sensibilidad respecto al meta-análisis original de esta tesis, la inclusión de los datos de Baleares no modificaría substancialmente el efecto (RR 0,87; IC 95% 0,76- 0,99; $I^2$ 73%), en cambio, la inclusión de los datos de Cataluña anularía la significación del efecto (RR 0,88, IC95% 0,78-1,00; $I^2$ 82%) al igual que con Navarra (RR 0,88, IC95% 0,79- 1,00; $I^2$ 84%), lo que traduce que los datos de estas dos regiones hubieran sido causa de heterogeneidad entre estudios. En un análisis de subgrupos incluyendo los resultados del artículo 3, se obtendrían los siguientes resultados:

**Tabla 6.1. Análisis de subgrupos por diseño del estudio, riesgo de sesgo y tiempo de seguimiento de los estudios relacionados con asma en población adulta**

| Subgrupo | Nº estudios | RR (IC del 95%) | $I^2$ (%) | p de $I^2$ |
|---|---|---|---|---|
| **Análisis con los datos añadidos de Cataluña, Navarra e Islas Baleares** | | | | |
| **Total** | 10 | 0,95 (0,92- 0,97) | 80 | <0,001 |
| **Tipo de diseño de estudio** | | | | |
| **No experimental** | 9 | 0,95 (0,92- 0,97) | 81 | <0,001 |
| **Quasi experimental** | 1 | 1,48 (0,90- 2,43) | | |
| **Riesgo de sesgo** | | | | |
| **Bajo** | 6 | 0,96 (0,91- 1,01) | 31 | 0,20 |
| **Moderado** | 4 | 0,79 (0,63- 0,98) | 65 | 0,04 |
| **Tiempo de seguimiento** | | | | |
| **<24 meses** | 1 | 1,17 (0,82- 1,76) | | |
| **≥ 24 meses** | 9 | 0,95 (0,92-0,97) | 82 | <0,001 |
| **Estudio original publicado en PloS ONE** | | | | |
| **Total** | 7 | 0,85 (0,73 - 0,99) | 65 | 0,009 |
| **Tipo de diseño de estudio** | | | | |
| **No experimental** | 6 | 0,80 (0,71- 0,92) | 54 | 0,005 |
| **Quasi experimental** | 1 | 1,48 (0,90- 2,43) | | |
| **Riesgo de sesgo** | | | | |
| **Bajo** | 3 | 0,95 (0,74- 1,22) | 57 | 0,10 |
| **Moderado** | 4 | 0,79 (0,63- 0,98) | 65 | 0,04 |
| **Tiempo de seguimiento** | | | | |
| **<24 meses** | 1 | 1,17 (0,82- 1,76) | | |
| **≥ 24 meses** | 6 | 0,81 (0,70- 0,93) | 59 | 0,03 |

Abreviaturas: IC, Intervalo de confianza; $I^2$, índice de heterogeneidad; RR, riesgo relativo

Con lo que variaría respecto al estudio original es que bajaría el tamaño del efecto en el subgrupo de estudios no experimentales (RR de 0,80 a 0,95) y en el subgrupo de estudios con tiempo de seguimiento de la ley ≥ 24 meses (RR de 0,81 a 0,95). Es posible que el impacto de la ley libre de humo en asma sea más intenso en un nivel asistencial más alto (hospitalario), con exacerbaciones más graves, que en APS, en donde se visitan descompensaciones leves mayormente o que la implementación previa de la Ley parcial haya disminuido el efecto.

En el artículo 3 las tasas de prevalencia de asma de APS aumentaron significativamente (menor durante el período 2009-13 en Cataluña y Navarra, y mayor para los hombres que para las mujeres) en las tres regiones estudiadas a pesar de que la hipótesis inicial para esta variable era que la Ley integral provocaría una disminución. Una posible explicación de este suceso podría ser una mejora en el registro del diagnóstico de asma que podría haber facilitado la prescripción durante el periodo de estudio y no un incremento real en el número de personas con asma.

Respecto al impacto de las leyes libres de humo en la reducción de hospitalizaciones por enfermedad coronaria, la evidencia es fuerte y consistente (40,72,147). Sin embargo y en el artículo 3, la incidencia de enfermedad coronaria disminuyó significativamente en Cataluña (CPAP -8,00) y Navarra (CPAP -3,66) sin un cambio de tendencia debido a la Ley del 2010. Por el contrario, el único estudio español que evaluó IAM y cardiopatía isquémica en relación a

ambas leyes libres de humo (56) sólo observó cambios significativos inmediatamente a la implantación de la Ley integral pero únicamente en personas mayores de 64 años (-5,0% para IAM y -3,9% para cardiopatía isquémica). Y el II Informe a las Cortes Generales (2014) (100) resume que en el caso de infarto agudo de miocardio, especialmente en hombres, se observan dos reducciones importantes en los años de aplicación de la Ley 28/2005 y su modificación (Ley 42/2010), y una destacable reducción global 2005-2013 en ambos sexos, que también se observa en cardiopatía isquémica, sin embargo, expone la existencia de una gran variabiliadd entre provincias y concluye que la investigación del efecto de la Ley en la morbilidad requeriría análisis más completos, con series temporales. En el artículo 3 de esta tesis no se halla cambio de tendencia a pesar de tener una Ley más estricta que la del 2006 y, por tanto, más protectora frente al humo de segunda mano. Otros factores que podrían haber influido en estos resultados son: la informatización incompleta de la HCE en las etapas iniciales de la implementación; incentivos a los proveedores de APS para mejorar el manejo de la hipertensión, la hiperlipidemia y la diabetes; los programas para dejar de fumar previos a la implementación del Ley integral o el hecho de no haber realizado análisis de subgrupos entre población fumadora o no fumadora o por grupos de edad, así como la atenuación del impacto por la Ley parcial previa.

**Limitaciones y fortalezas de la tesis**

En los artículos de esta tesis relacionados con la Ley integral española (artículos 1 y 3), el registro del hábito tabáquico, asma o enfermedad coronaria en la HCE de una persona generalmente es a consecuencia de la presentación de dicha persona en los servicios sanitarios por alguna afección, enfermedad o búsqueda de consejo (sesgo de presencia informada). Por tanto, estas personas eran diferentes de las que no tenían información en los registros electrónicos de salud aunque es conocido que más del 75% de la población visita anualmente su centro de APS. Por otro lado, una parte considerable de los pacientes del artículo 1 fueron excluidos del estudio debido a la falta de registro del hábito tabáquico al inicio del estudio. Sin embargo, al excluirlos se evitaba obtener falsamente casos incidentes de tabaquismo que en realidad eran debidos a la falta de registro previo en la HCE y no a un cambio en el hábito tabáquico durante el periodo de estudio. Así mismo, pudo haber variabilidad en el registro de diagnósticos en cada región que generara diferencias en el número de problemas de salud activos para cada paciente y en las tasas de asma y enfermedad coronaria. Debido a esto y por otros motivos como el diferente periodo de estudio de una de las regiones, se realizaron análisis por región. Además, la población joven está infra-representada al frecuentar menos las consultas de APS. Por otro lado, es plausible pensar en un sesgo de selección debido a que la población atendida estuviera más enferma que la población general. Aunque los datos de los artículos 1 y 3 sólo eran representativos de la población mayor de 15 años que se visita en APS, la frecuentación a este servicio y el tamaño de muestra obtenido fue considerable. Finalmente, en

estos estudio no se contemplaron variables que podrían influir en la incidencia y prevalencia del hábito tabáquico (intervenciones en salud, nivel de educación, posición socioeconómica, estado civil, tener hijos, estar desempleado, patología mental como la esquizofrenia o la ansiedad o presencia de patologías), del asma o de la enfermedad coronaria; se disponía únicamente del sexo, edad, número de visitas y número de diagnósticos activos.

Respecto a la revisión sistemática y meta-análisis, es posible que el hecho de no haber separado el análisis de subgrupos por sistemas de clasificación de diagnóstico haya producido una heterogeneidad más elevada en el meta-análisis. Los estudios sobre problemas respiratorios utilizaban la novena o décima Clasificación Internacional de Enfermedades (CIE-9 o 10) y respecto a la sintomatología, la mayoría de estudios utilizaban *International Union Against Tuberculosis and Lung Disease questionnaire* pero no la totalidad de ellos. Sin embargo, separamos los estudios por variable evaluada, subgrupos de población, tipo de ley libre de humo, riesgo de sesgo, tipo de diseño y tiempo de seguimiento posterior a la implantación de la ley en el meta-análisis. Y en el caso de los estudios que evaluaron la Ley española se hizo una tabla de equivalencias entre los diferentes sistemas de clasificación de las tres provincias.

Aparte de las limitaciones de los estudios propios de la tesis, en el caso de la revisión sistemática se añaden sesgos inherentes a los artículos incluidos dentro de esta. Algunos ejemplos dentro de los estudios que evaluaban sintomatología respiratoria o sensorial son el sesgo del observador (no era posible el cegamiento de la intervención, es decir, la ley), sesgo de recuerdo en estudios retrospectivos (sobretodo en población infantil en la que los cuestionarios eran respondidos por los padres), sesgo voluntario (es posible que los voluntarios no fueran representativos de la población general al tener mayor motivación y mayor nivel educacional) y sesgo de tamaño de la muestra incorrecto (a veces no se alcanzaba antes o después de la implantación de la ley libre de humo y otras se omitía este dato). Además, la tendencia a enviar, aceptar y publicar resultados positivos y el sesgo del idioma (mayor probabilidad de que se publiquen resultados en lengua inglesa cuando son estadísticamente significativos) puede haber contribuido a alterar las conclusiones emitidas. Sin embargo, en el artículo 2 de esta tesis sólo se descartó un artículo en lengua noruega que era concordante con otros artículos que versaban sobre sintomatología respiratoria en trabajadores de la hostelería (reducción tras la ley libre de humo).

Las fortalezas de los estudios relacionados con la Ley libre de humo integral española (artículos 1 y 3) radican en la maximización de validez interna del estudio por los criterios de selección y el diseño longitudinal, la proporción de datos útiles sobre el impacto de la Ley en el hábito tabáquico y enfermedades relacionadas con el tabaquismo de pacientes adultos atendidos en

APS y la inclusión de variables novedosas como la incidencia de nuevos fumadores, nuevos ex fumadores y recaída de ex fumadores, son de gran relevancia en relación con las intervenciones de APS para dejar de fumar. Hasta donde sabemos, el artículo 1 que evaluó el hábito tabáquico es uno de los primeros en mostrar datos trimestrales de la HCE y el artículo 3 que evaluó asma y enfermedad coronaria es el primero que ofrece resultados sobre el efecto de la Ley en estas enfermedades en adultos atendidos en APS. Además, la participación de tres regiones españolas diferentes y el uso de la HCE proporcionó una amplia gama de datos valiosos. Por otra parte, el uso del análisis Joinpoint evaluó tendencias longitudinales en lugar de simplemente comparar dos períodos diferentes, obteniendo un análisis más preciso. Finalmente, la HCE utilizada como herramienta de investigación, retrata las condiciones de la vida real (se recogen durante la puesta en escena de esta) y proporciona datos de salud completos a largo plazo de una gran muestra de población, asegura una alta representatividad y validez externa y minimiza el potencial sesgo de recuerdo a un coste inferior a la de los estudios convencionales. En el caso de las bases de datos utilizadas en esta tesis (SIDIAP/REGIPREV), los datos son validados rutinariamente.

Respecto a la revisión sistemática y según el conocimiento actual, esta es la primera revisión científica realizada con resultados respiratorios (síntomas, funcionalidad e ingresos hospitalarios) por efecto de las leyes libres de humo, medido en todas las poblaciones (trabajadores, adultos, niños y población en general) con meta-análisis. Se combinaron fuentes heterogéneas de datos para agregar valor a los resultados, además de buscar manualmente las referencias en los documentos y consultar a los expertos. Los rigurosos procedimientos empleados (pares de revisores y un tercero en el caso de discrepancias) aseguraron la validez de la extracción de datos. Además se realizó una síntesis detallada de la sintomatología sensorial y respiratoria. La realización del meta-análisis ofreció un efecto más preciso de los resultados y el análisis de sensibilidad permitió que los estudios incluidos fueran suficientemente similares, por población estudiada, tipo de ley libre de humo, tipo de diseño de estudio e intervalo de tiempo post-ley evaluado. Además, los estudios pequeños o no concluyentes que carecían de significación estadística podían contribuir al panorama general.

# 7. CONCLUSIONES

En esta tesis se ha examinado el impacto de la leyes libres de humo en hábito tabáquico y en algunas patologías relacionadas con el tabaquismo en población atendida en APS.

1. La introducción de la Ley libre de humo integral española (Ley 42/2010) no modificó significativamente las tendencias de incidencia y prevalencia del hábito tabáquico de personas adultas atendidas en APS en Cataluña, Navarra y las Islas Baleares tras tres años de su implantación, ni en global ni estratificado por sexos. Del 2008 al 2013, la prevalencia global de personas fumadoras disminuyó y la de personas ex fumadoras aumentó en las tres regiones. En dicho periodo, la incidencia global de nuevas personas fumadoras disminuyó en Cataluña y en Navarra pero se mantuvo estable en Islas Baleares. En cambio, la incidencia de nuevas personas ex fumadoras disminuyó en Cataluña y en Islas Baleares pero no cambió en Navarra. En relación a la incidencia de la recaída de personas ex fumadoras, aumentó en Cataluña disminuyó en Navarra y se mantuvo estable en Islas Baleares.
2. La aplicación de las legislaciones libres de humo disminuyó la sintomatología sensorial y respiratoria en los trabajadores y en población infantil y los ingresos por asma en todas las poblaciones. Sin embargo, los resultados sobre función pulmonar, EPOC, infección respiratoria y mortalidad respiratoria fueron no concluyentes.
3. La introducción de la Ley integral española (Ley 42/2010) no modificó significativamente las tendencias de incidencia y prevalencia de asma y de enfermedad coronaria en personas adultas atendidas en APS en Cataluña, Navarra y las Islas Baleares tras tres años de su implantación, ni en global ni estratificado por sexos. Del 2007 al 2013 y en las tres regiones, la incidencia global de asma se mantuvo estable y la prevalencia global de asma aumentó. En dicho periodo y respecto a la enfermedad coronaria, la incidencia global disminuyó en Cataluña y en Navarra pero no cambió en Islas Baleares. Sin embargo, la prevalencia global de enfermedad coronaria aumentó en Cataluña y en Islas Baleares pero se mantuvo estable en Navarra.

# 8. FUTURAS LÍNEAS DE INVESTIGACIÓN

Sobre la base de los resultados observados, es necesario abordar varios aspectos para las investigaciones futuras como evaluar la efectividad de la Ley libre de humo integral española teniendo en cuenta otros factores específicos asociados con el hábito tabáquico (como el precio de un paquete de cigarrillos o la financiación de los servicios para dejar de fumar, nivel socioeconómico de la persona y los grupos de edad en APS) y asociados con el asma y la enfermedad coronaria (como el consumo de cigarrillos y el nivel socioeconómico de la persona). También serían necesarios estudios que evaluaran dicho impacto en población menor de 15 años o en otros colectivos (grandes consumidores, enfermos psiquiátricos graves) a largo plazo. Además, sería conveniente medir la utilidad de la ley en intervenciones en APS, evaluar si los profesionales sanitarios realizan más consejo breve o entrevista motivacional o más actividades comunitarias a raíz de la ley (y si existen diferencias entre el rol de enfermería y el de medicina) o si baja la prevalencia o incidencia del hábito tabáquico también entre ellos. Al existir diferencias entre las distintas comunidades autónomas en la actuación frente al tabaquismo (como por ejemplo, la financiación de la deshabituación tabáquica en algunas regiones), otras posibles líneas de estudio podrían ser observar el efecto de los incentivos económicos a los profesionales, de la existencia de unidades especializadas en APS o de la formación a los profesionales sobre el hábito tabáquico. Por su proximidad a la población, la APS podría detectar acciones dirigidas a la deshabituación tabáquica no evaluadas previamente contando con la opinión del paciente. También por su accesibilidad, se pueden identificar colectivos vulnerables (pacientes con trastornos mentales, personas en riesgo de exclusión social, pacientes pluripatológicos) y evaluar el efecto de las estrategias adaptadas para la deshabituación en estos colectivos. De cara a impulsar nuevas medidas legislativas en España, podría ser de interés realizar estudios comparativos con países que cuenten con leyes más avanzadas que la nuestra. Así, se podría evaluar el impacto sobre el inicio del hábito tabáquico o la prevalencia o incidencia de personas fumadoras de otras estrategias sinérgicas a las leyes libres de humo, como el empaquetado genérico, la prohibición de fumar en vehículos privados en presencia de menores o embarazadas, la ampliación de la prohibición de fumar en espacios abiertos (playas, establecimientos deportivos y de ocio) y el aumento de la fiscalidad sobre todos los productos del tabaco. Así mismo, se debería continuar investigando la efectividad de las leyes libres de humo en áreas que carecen de resultados concluyentes como en los ingresos por EPOC en todas las poblaciones, en mortalidad respiratoria en población trabajadora e infantil, infecciones respiratorias, sintomatología sensorial o respiratoria y función pulmonar en la población general e infantil, en entornos no hospitalarios o en uso de medicamentos. Hay una necesidad de estudios de diseño cuasi-experimentales que comparen ubicaciones con y sin leyes libres de humo, y leyes parciales versus integrales, para confirmar mejor sus efectos.

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# ANEXOS

## Anexo 1: Difusión en jornadas y congresos: Póster con defensa de 4 minutos presentado al Congreso de la Sociedad Española de Epidemiología 2017

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# 519. SMOKEFREE LEGISLATION EFFECTS ON RESPIRATORY AND SENSORY DISORDERS: A SYSTEMATIC REVIEW

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## CONTENT

### Background

Smokefree laws have been adopted by some countries in order to protect the population's health in public areas and workplaces. Numerous studies have evaluated the impact of this legislations on cardiovascular effects, tobacco consumption, exposure to second-hand smoke. However, effects on respiratory and sensory disorders are not conclusive.

### Aim

To synthesize the available evidence in scientific papers of smokefree legislation effects on respiratory diseases and sensory and respiratory symptoms (cough, phlegm, red eyes, runny nose) among all populations.

### Methods

A systematic review was carried out. A search limited between January 1995 and February 2015 was performed in PubMed, EMBASE, Cochrane Library, Scopus, Web of Science, and Google Scholar databases. PRISMA statement was used to report the review. The study protocol (CRD42015019647) was published in PROSPERO. Inclusion criteria were:

1) Original scientific studies about smokefree legislation.
2) Studies including data before and after legislation.
3) Impact on respiratory and sensory outcomes.

Paired reviewers independently carried out the screening of titles and abstracts, data extraction from full-text articles, and methodological quality assessment.

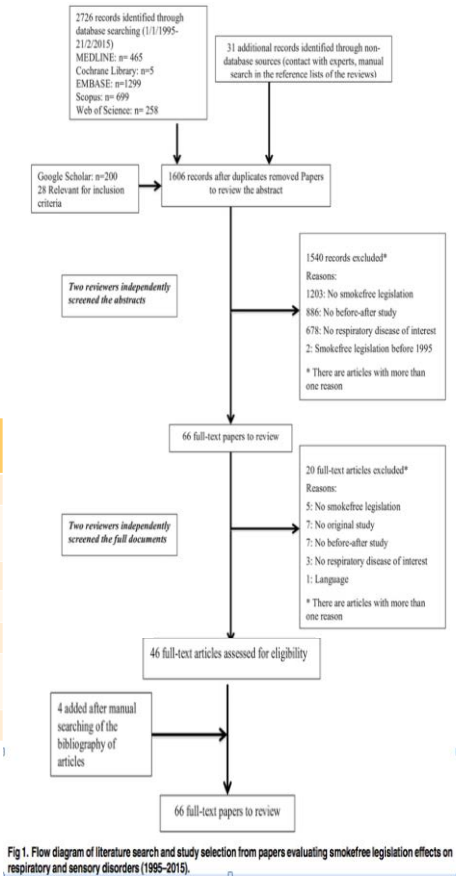


Fig 1. Flow diagram of literature search and study selection from papers evaluating smokefree legislation effects on respiratory and sensory disorders (1995–2015).

### Results

From the 1606 papers identified, 50 followed the inclusion criteria: 26 were related to respiratory or/and sensory symptoms (23 concerned workers).Most outcomes presented significant decreases in the percentage of people suffering from them, especially in locations with comprehensive measures and during the immediate post-ban period (within the first six months). Low risk of bias was present in 46% of the studies.

| Outcome | Total studies N (%) | Articles with decreases N/total | Range of decrease |
|---|---|---|---|
| Respiratory symptoms | 26 (52%) | 13/17(in any symptom) | 7.7-42.0% (any symptom) |
| Sensory symptoms | 19 (38%) | 15/15 (in any symptom) | 11.0-100.0% (any symptom) |
| Pulmonary function | 8 (16%) | 4 (different subvariables) | Not applicable |
| Asthma admissions | 17 (34%) | 13/17 | 5.0-31.0% |
| COPD admissions | 9 (18%) | 6/9 | 1.0-36.0% |
| Other respiratory diseases admissions | 6 (12%) | 2/6 | 15.0-23.0% |
| Mortality | 4 (8%) | 3/4 (Population subgroups) | 29.0-53.0% |

### Conclusions

Smokefree legislation seems to improve respiratory and sensory symptoms at short term in workers (the overall effect being greater in comprehensive smokefree legislation) and, to a lesser extent, rates of hospitalization for asthma.

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