Impacto de las leyes de medidas sanitarias de control del tabaquismo: cambios en la exposición al humo ambiental del tabaco, en el consumo de tabaco y creencias de la población

Francisca Sureda Llull

Programa de Doctorat en Medicina
Departament de Ciències Clíniques
Facultat de Medicina, Universitat de Barcelona

IMPACTO DE LAS LEYES DE MEDIDAS SANITARIAS DE CONTROL DEL TABAQUISMO:

CAMBIOS EN LA EXPOSICIÓN AL HUMO AMBIENTAL DEL TABACO, EN EL CONSUMO DE TABACO, Y CREENCIAS DE LA POBLACIÓN.

Xisca Sureda Llull

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Tesis presentada por

Xisca Sureda Llull

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Director:
Dr. Esteve Fernández Muñoz

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"The primary determinants of disease are mainly economic and social, and therefore its remedies must also be economic and social. Medicine and politics cannot and should not be kept apart"

Geoffrey Rose

Agraïments

Han passat uns quants anys de quan vaig començar a treballar en la present tesis doctoral durant els quals m'han acompanyat moltes persones a les que vull agrair part d'aquest treball, per la seva participació en ell, bé de manera directa, indirecte o d'ambdues maneres.

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RESUMEN

Antecedentes

El tabaco mata a casi 6 millones de personas cada año. De ellos, más de 5 millones son o han sido consumidores del producto. En España, se han cuantificado además entre 1.200 y 3.200 muertes anuales en la población no fumadora atribuibles a la exposición al humo ambiental del tabaco. Desde que España ratificara el Convenio Marco de la Organización Mundial de la Salud para el Control del Tabaquismo se han implementado dos leyes de medidas sanitarias frente al tabaquismo. La Ley 28/2005 entró en vigor el 1 de enero de 2006 y prohibía fumar en todos los espacios públicos cerrados con importantes excepciones en el sector de la hostelería. El 2 de enero de 2011 entró en vigor la Ley 42/2010 que extiende la anterior ley a todos los espacios públicos cerrados, incluyendo los locales de restauración y hostelería, y algunos al aire libre, como parques y lugares de ocio infantil, colegios y recintos hospitalarios.

Hipótesis

1.- La implementación de medidas sanitarias frente al tabaquismo disminuye tanto la exposición percibida al humo ambiental del tabaco como la concentración de cotinina en saliva de la población adulta no fumadora.

2.- El consumo de tabaco entre la población fumadora se verá levemente reducido después de la implementación de medidas sanitarias.

3.- Se observarán niveles de exposición al humo ambiental del tabaco por encima de los mínimos anuales permitidos por las guías de calidad del aire de la Organización Mundial de la Salud (10 µg/m^3 para las $PM_{2.5}$) en las zonas de fumadores al aire libre y en las localizaciones interiores adyacentes a estas zonas.

4.- Existen zonas al aire libre dónde coincide que la población no fumadora se siente especialmente expuesta y los fumadores declaran fumar. La población apoya la implementación de espacios exteriores libres de humo en determinadas localizaciones.

Objetivos

1.- Evaluar el impacto de las medidas sanitarias para la prevención y control del tabaquismo implementadas a nivel nacional (Ley 28/2005 y Ley 42/2010) en la población adulta no fumadora mediante la medición de la exposición al humo ambiental del tabaco (referida y mediante cotinina en saliva) antes y después su implementación.

2.- Evaluar los cambios de prevalencia de consumo de tabaco y el patrón de consumo de tabaco entre la población fumadora antes y después de la implementación de la Ley 28/2005 y la Ley 42/2010.

3.- Revisar la literatura científica que mide objetivamente la exposición al humo ambiental del tabaco en espacios abiertos y semiabiertos mediante el uso de marcadores biológicos y ambientales del tabaco.

4.- Caracterizar el consumo de tabaco y la exposición al humo ambiental del tabaco en lugares al aire libre y analizar las opiniones y creencias de la población hacia las políticas de control del tabaquismo en estos lugares.

Metodología

Para conseguir los objetivos propuestos se realiza un estudio antes-después mediante 2 encuestas transversales de muestras representativas de la población adulta (≥16 años) de la ciudad de Barcelona. La primera encuesta se realizó en 2004-05 y la segunda en 2011-12, siguiendo la misma metodología. Se analiza la exposición al humo ambiental del tabaco percibida en el hogar, en el lugar de trabajo y/o centro de estudios, durante el tiempo libre y en el transporte (cuestionario administrado) y medida objetivamente mediante cotinina en saliva. Se analizan los cambios de prevalencia de consumo de tabaco y las características de consumo entre la población fumadora. Se evalúan las percepciones y creencias de la población hacia las políticas libres de humo en espacios exteriores mediante cuestionario. Finalmente se realiza una revisión sistemática de la literatura que ha medido la exposición al humo ambiental del tabaco en espacios exteriores mediante marcadores ambientales y/o biológicos del tabaco.

Resultados

Globalmente, se observó una disminución de la exposición autoreportada al humo ambiental del tabaco y en las concentraciones de cotinina medidas en saliva en los adultos no fumadores después de la implementación de las medidas de control del tabaquismo. Esta disminución se observó en todos los ambientes estudiados. La prevalencia de consumo de tabaco autoreportado disminuyó entre el período 2004-2005 y 2011-2012 (del 26,6% al 24,1% entre los fumadores diarios). Se observa una reducción importante de la prevalencia de fumadores de cigarrillos manufacturados y un aumento de la prevalencia de fumadores de cigarrillos de liar en los años 2011-2012 en comparación a la información recogida en 2004-2005. De acuerdo a los datos obtenidos en la encuesta realizada en los años 2011-2012, podríamos describir las características de los fumadores de cigarrillos de liar como: hombres, con edades entre los 16 y 44 años y con nivel educativo más alto. Los fumadores de cigarrillos de liar reportaron baja dependencia a la nicotina y fumar pocos cigarrillos, sin intención de dejar de fumar e inhalar más profundamente que los fumadores de cigarrillos manufacturados.

Los estudios que se incluyeron en la revisión sistemática mostraron que las concentraciones de $PM_{2.5}$ en los espacios al aire libre donde hay presencia de fumadores variaban desde 8,32 a 124 $\mu g/m^3$ en la hostelería y entre 4,60 y 17,80 $\mu g/m^3$ en otras localizaciones. La mayoría de los estudios incluidos mostraron una asociación positiva entre las mediciones de humo ambiental del tabaco y la densidad de fumadores, las características estructurales del espacio exterior, las condiciones del viento y la proximidad a los fumadores.

Los datos recogidos en el 2011-2012 mostraron que los no fumadores reportaban estar expuestos en la mayoría de los espacios exteriores donde los fumadores reportaron fumar. Los datos indicaron un gran apoyo a la prohibición de fumar en la mayoría de los espacios exteriores estudiados y que fue mayor entre los no fumadores. Más del 70% de los participantes apoyaron los espacios libres de humo en parques infantiles, exteriores de colegios y recintos hospitalarios.

Conclusiones

Los resultados obtenidos muestran el impacto positivo de la implementación de las leyes para el control del tabaco en España (Ley 28/2005 y Ley 42/2010), con el resultado de una disminución de la exposición al humo ambiental del tabaco evidenciada tanto en la exposición autoreportada como en las concentraciones de cotinina cuantificadas en saliva, de la población adulta no fumadora en Barcelona, España. El aumento de la prevalencia de fumadores de tabaco de liar, especialmente entre la gente joven debería considerarse en la agenda política para desarrollar futuras intervenciones eficientes para el control del tabaquismo y recomendaciones para la población general. El gran apoyo observado para determinadas localizaciones exteriores libres de humo sugiere la factibilidad de extender la prohibición de fumar a estos espacios para proteger a los no fumadores de la exposición al humo ambiental del tabaco y establecer un modelo positivo para los jóvenes.

ABSTRACT

Background

Tobacco kills nearly 6 million people each year. From them, more than 5 million are or have been smokers. In Spain, we attribute to second-hand smoke exposure between 1,200 and 3,200 deaths per year in the non-smoking population. Steped smoke-free legislation have been implemented in Spain since the ratification of the World Health Organization Framework Convention for Tobacco Control. Law 28/2005 came into force on January 1st, 2006, and banned smoking in all enclosed public places with some exceptions in hospitality venues. On the 2nd of January, 2011, Law 42/2010 extended the ban to all enclosed public places, including hospitality venues, and some outdoor areas, such as playgrounds, educational and hospital campuses.

Hypotheses

1. - The implementation of tobacco smoke-free policies reduces second-hand smoke exposure (self-reported and assessed by means of salivary cotinine) among non-smoking adults.
2. - Tobacco consumption will be slightly reduced after the implementation of tobacco policies.
3. - Second-hand smoke levels in outdoor smoking areas and their adjacent indoor areas will raise the annual recommended levels by the air quality guidelines of the World Health Organization (10 µg/m^3 for $PM_{2.5}$).
4. – Non-smokers reported SHS exposure in outdoor settings in which smokers reported smoking. The general population supports the implementation of smoke-free outdoor areas in certain locations.

Objectives

1. - To assess the impact of smoke-free legislation implemented in Spain (Law 28/2005 and Law 42/2010) in the non-smoking adult population by measuring second-hand smoke exposure (self-reported and by means of salivary cotinine concentrations) before and after its implementation.
2. - To evaluate the changes in the prevalence of smoking in the population and the smoking pattern among the smokers before and after the implementation of Law 28/2005 and Law 42/2010.
3. - To review the scientific literature that objectively measures second-hand smoke exposure in open and semi-open settings using tobacco biomarkers and environmental markers.

4. - To describe tobacco consumption and second-hand smoke exposure in outdoor areas and to evaluate the opinions and beliefs of the adult population towards tobacco control policies in these areas.

Methods

We performed a before-after study using two cross-sectional surveys of representative samples of the adult population (≥16 years) in Barcelona. The first survey was conducted in 2004-05 and the second in 2011-12, with the same methodology. We evaluate self-reported second-hand smoke exposure at home, work/educational venues, during leisure time, and in public and private transportation vehicles (face-to-face questionnaire) and objectively measured by salivary cotinine. We evaluate changes in the prevalence of smoking and the smoking pattern among smokers. We describe attitudes towards smoke-free legislation in outdoor settings. Finally, we review the literature that measured second-hand smoke exposure using environmental and/or biomarkers of tobacco exposure.

Results

Overall, we observed a reduction in self-reported exposure to second-hand smoke and salivary cotinine concentration in adult non-smokers after the implementation of smoke-free legislations. This reduction was observed in all settings studied. We observed that smoking prevalence decreased over the period 2004-2005 and the period 2011-2012 (from 26.6% to 24.1% in self-reported daily smokers). Our results indicated an important reduction in the prevalence of smokers of manufactured cigarettes and an increase in the prevalence smokers of roll-your own cigarettes in 2011-2012, comparing with the data collected in 2004-2005. According to the data obtained in 2011-2012 we may define the pattern of roll-your own cigarettes users as: being men, aged 16-44 years old, and with higher educational level. Roll-your own cigarettes smokers also reported low dependence to nicotine, had no intention to quit, reported to smoke few cigarettes a day and to inhale more deeply than manufactured cigarettes smokers.

Studies included in the systematic review showed that mean $PM_{2.5}$ concentrations reported for outdoor smoking areas when smokers were present ranged from 8.32 to 124 $\mu g/m^3$ in hospitality venues, and from 4.60 to 17.80 $\mu g/m^3$ in other locations. Most studies reported a positive association between second-hand smoke measures and smokers' density, enclosurement of outdoor locations, wind conditions, and proximity to smokers.

Data collected in 2011-2012 showed that non-smokers perceived second-hand smoke exposure in most of outdoor settings in which smokers reported smoking. There was great support for banning smoking in the majority of outdoor areas, which was stronger among non-smokers than smokers. Over 70% of participants supported smoke-free playgrounds, school and high school courtyards, and the outdoor campuses of healthcare centers.

Conclusions

This study showed the positive impact of a stepped smoke-free legislation (laws 28/2005 and 42/2010) that was accompanied by a large reduction in second-hand smoke, both self-reported and assessed by means of salivary cotinine levels, in the adult non-smoking population in Barcelona, Spain. The increase in the prevalence of roll-your own cigarettes users, especially among young people should be consider by policymakers to develop efficient tobacco control interventions and recommendations for the population. The strong support for some smoke-free areas also suggests the feasibility to extend smoking bans to selected outdoor settings to protect non-smokers from second-hand smoke exposure and to establish a positive model for youth.

1. INTRODUCCIÓN

1.1. El consumo de tabaco

1.1.1. Efectos sobre la salud y muerte atribuible al consumo de tabaco

El consumo de tabaco es la principal causa de pérdida de salud y de muerte prematura en los países desarrollados. Es un factor de riesgo para seis de las ocho causas principales de muerte en el mundo: cardiopatía isquémica, enfermedades cerebrovasculares, infecciones del tracto respiratorio inferior, enfermedad pulmonar obstructiva crónica, tuberculosis y cáncer de pulmón(1). El tabaco mata a casi 6 millones de personas cada año, y de ellas, más de 5 millones son o han sido consumidores del producto. A menos que se tomen medidas urgentes, la cifra anual de muertes podría ascender a más de 8 millones en 2030(1).

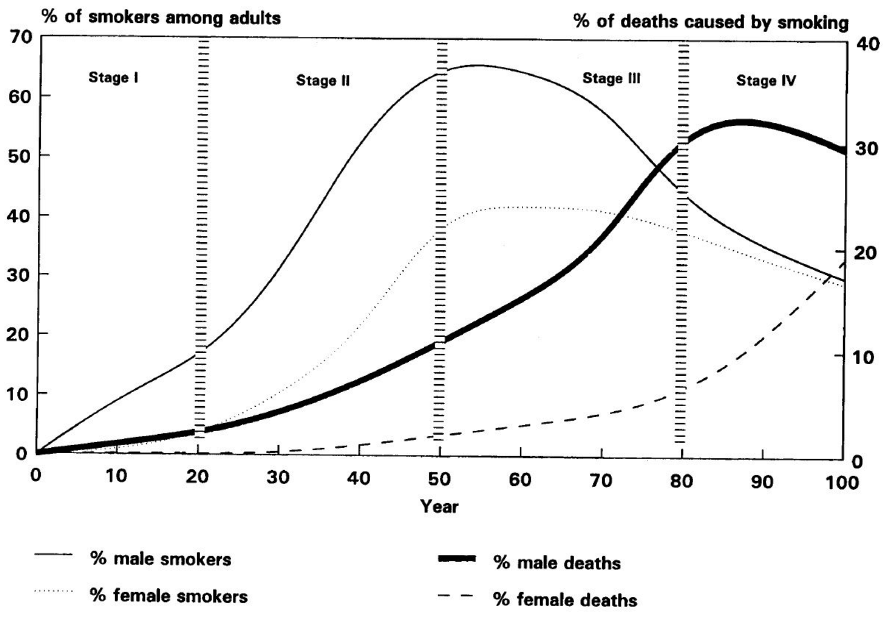
En España, en el año 2006 se produjeron 53.155 muertes atribuibles al tabaquismo en individuos ≥ 35 años, lo que supone el 14,7% (25,1% en varones y 3,4% en mujeres) de todas las muertes ocurridas en los mismos. Por causas, destacaban las muertes atribuibles por: tumores malignos (24.058), especialmente cáncer de pulmón (16.482); enfermedades cardiovasculares (17.560), especialmente cardiopatía isquémica (6.263) e ictus (4.283); y enfermedades respiratorias (11.537), especialmente enfermedad pulmonar obstructiva crónica (9.886) (2). Estas pérdidas junto a las múltiples patologías asociadas al tabaquismo generan un elevado coste económico y social.

1.1.2. Epidemia del tabaquismo

En los último años, como consecuencia de la creciente concienciación de la población sobre los efectos nocivos del consumo de tabaco y las políticas de control del tabaco promovidas por el Convenio Marco de la Organización Mundial de la Salud (OMS) para el Control del Tabaco (CMCT) (3), se observa una disminución de la prevalencia de consumo de tabaco en muchos países desarrollados, incluyendo España.

La epidemia del tabaquismo y su evolución en el tiempo puede explicarse a partir del modelo de difusión propuesto por López y cols.(4). Este modelo describe cuatro fases que vendrían determinadas por tres factores: la prevalencia de fumadores diarios en la población adulta, la cantidad fumada por adulto en un periodo determinado, y la mortalidad atribuible al consumo de tabaco (Fig. 1). La Fase I dura una o dos décadas y se caracteriza porque la prevalencia de consumo es inferior al 15% en los hombre y en las mujeres no supera el 10%. El consumo anual per cápita es inferior a 500 cigarrillos por adulto y la enfermedad y muertes asociadas al tabaquismo aún no son evidentes. La fase II suele durar entre 2 y 3 décadas. La prevalencia de consumo de tabaco en hombres alcanza valores de entre 50 y 80% y el consumo de tabaco en mujeres se inicia prácticamente en esta fase y va aumentando rápidamente. El consumo medio se estima entre 1.000 y 3.000 cigarrillos anuales, siendo mayoritario en hombres (2.000-4.000 cigarrillos anuales). Al final de esta fase aproximadamente un 10% de las muertes en los hombres se relaciona con el consumo de tabaco. La fase III dura unas 3 décadas y se caracteriza por un descenso de la prevalencia del consumo de tabaco en los hombres hasta llegar aproximadamente al 40% al final de la etapa. La prevalencia de consumo de tabaco entre las mujeres se estabiliza entre un 35 y 45%. El consumo de tabaco en hombres podría variar entre 3.000 y 4.000 cigarrillos por año, mientras que en las mujeres variaría entre 1.000 y 2.000 cigarrillos por año. La mortalidad asociada al consumo de tabaco aumenta hasta el 25-30% en hombres, mientras que en las mujeres es comparativamente más baja (aproximadamente el 5% de todas las muertes). En la fase IV la prevalencia de consumo de tabaco disminuye en ambos sexos, llegando a valores similares (alrededor del 30% en mujeres y 35% en hombres). La mortalidad atribuible al consumo de tabaco alcanzaría el 30-35% de todas las muertes en hombres y el 20-25% en mujeres.

Figura 1. Modelo de la epidemia del tabaquismo propuesto por Lopez y cols.

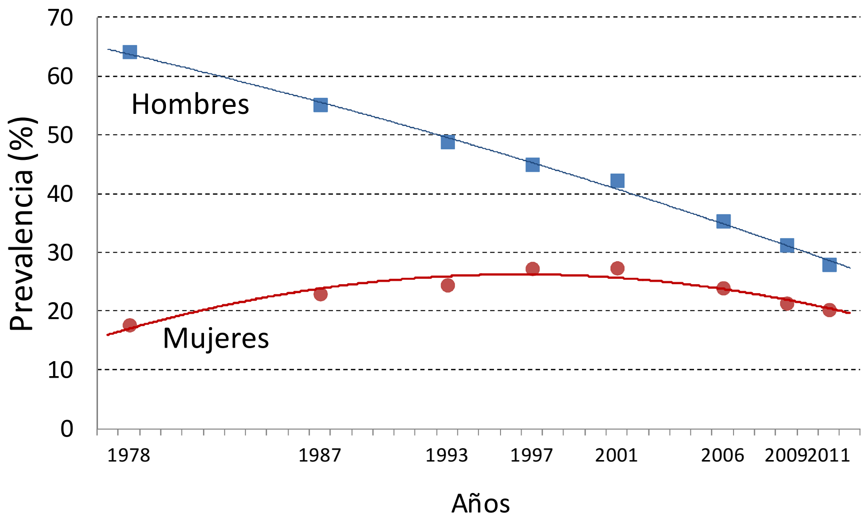


Fuente: López y cols., 1994(4)

1.1.3. Epidemia del tabaquismo en España

La epidemia del tabaquismo en España en la actualidad se sitúa al principio de la fase IV del modelo de difusión propuesto por López et al., que se caracteriza por la disminución en la prevalencia de consumo de tabaco entre los hombres, un mantenimiento sostenido entre las mujeres, y una morbimortalidad atribuible al tabaco que disminuye entre los hombres y aumenta entre las mujeres(5). Según datos de la Encuesta Nacional de Salud (ENS) durante el período de 1987 a 2006 se observa en los hombres un descenso relativo promedio anual del 2,2% en la prevalencia de fumadores actuales (diarios y ocasionales); en las mujeres se detectan dos tramos temporales: un primer período, de 1987 a 2001, en el cual se observa un incremento del 1,2%, y un segundo período de 2001 a 2006 en el cual desciende anualmente un 2,9% (Fig. 2). Este patrón se repite, pero en orden inverso, en la prevalencia del abandono: en los hombres aumenta un 3% anual durante todo el período, mientras que en las mujeres no se observan cambios de 1987 a 1997; sin embargo, a partir de ese año se produce un fuerte incremento del 5,9% anual. La prevalencia de consumo en la población adulta en el año 2011, según la ENS, es de 27,1%, con un 27,9% de los hombres y el 20,2% de las mujeres fumadores(6).

Figura 2. Prevalencia (%) de fumadores diarios, población ≥16 años, España, 1978-2011.



Fuente: Elaboración propia a partir de la Encuesta Nacional de Tabaco de 1978, las Encuestas Nacionales de Sanidad (1987, 1993, 1997, 2001, 2006 y 2011) y la Encuesta de Salud Europea para España de 2009.

Un análisis de la tendencia de las ventas de cigarrillos en España durante el período comprendido entre 1989 a 2008(7) refleja que en un comienzo las ventas experimentaron un descenso anual del 1,6%; luego se produjo un incremento anual del 4,9% entre los años 1996 y 2000, y a partir de entonces se recupera el descenso anual del 1,6%. Otro estudio describe la tendencia de consumo de cigarrillos manufacturados y de los cigarrillos de liar entre 1991 y 2012 y las proyecciones para el 2020(8). Los resultados muestran que el consumo diario *per capita* de cigarrillos manufacturados disminuye en promedio un 3,03% por año, de 7,6 unidades en 1991 a 3,8 unidades en el 2012. Sin embargo, el consumo diario *per capita* de cigarrillos de liar aumenta en promedio un 14,08% anual, desde 0,07 hasta 0,92 unidades de 0,5 gramos (que representan el 0,9% y el 19,6% de todos los cigarrillos *per capita*, respectivamente). La proyecciones del consumo diario *per capita* hasta el 2020, según este estudio, indican una disminución de los cigarrillos manufacturados (1.75 unidades *per capita*), pero un aumento de los cigarrillos de liar (1,25 unidades *per capita*, que representan el 41,6% de los cigarrillos *per capita* independientemente del tipo de cigarrillo).

1.2. Humo Ambiental del Tabaco (HAT)

1.2.1. Definición y composición

El humo ambiental del tabaco (HAT) es una mezcla de miles de partículas y gases emitidos por el humo exhalado por los fumadores activos (corriente principal o primaria) y por el humo que proviene del extremo del cigarrillo (corriente lateral o secundaria). El HAT contiene aproximadamente unos 4.500 componentes entre los cuales más de 50 de ellos han sido reconocidos como carcinógenos humanos por la IARC, además de otros muchos agentes tóxicos e irritantes(9;10).

1.2.2. Efectos de la exposición al HAT sobre la salud

No existen dudas en la actualidad que el "tabaquismo pasivo" (o exposición al humo ambiental del tabaco o tabaquismo involuntario o "second-hand smoke" en inglés), es decir, la inhalación de humo del tabaco por los no fumadores, es también causa de enfermedad(1;10;11): bajo peso al nacer y aumento del riesgo de enfermedades respiratorias en niños y niñas, cáncer de pulmón y enfermedades coronarias. Además, las revisiones ponen en evidencia que no existe un nivel de exposición al HAT que esté libre de riesgo(12). Actualmente se ha estimado la carga de enfermedad mundial de la exposición al HAT en 603.000 defunciones anuales(13). Se estima que mundialmente, en el 2004, la exposición al HAT fue responsable de 379.000 muertes por cardiopatía isquémica, 21.400 muertes por cáncer de pulmón, 165.000 por enfermedades del tracto respiratorio inferior, y 36.900 por asma(13). En la Unión Europea y atendiendo a las cuatro principales enfermedades relacionadas con el tabaquismo pasivo, se estima que fallecen 79.000 no fumadores al año(14). En España, se atribuyen entre 1.228 y 3.237 muertes por cáncer de pulmón y cardiopatía isquémica a la exposición al HAT en el año 2002(15).

La mayor parte de la evidencia publicada sobre los efectos para la salud de la exposición al HAT se basa en investigaciones sobre exposiciones a largo plazo(10). Sin embargo, algunos estudios recientes también han reportado evidencia de efectos a corto plazo en población no fumadora después de haber estado expuesta al HAT, tales como irritación de los ojos y de las vías respiratorias (16). Incluso existe evidencia que demuestra que exposiciones al HAT breves y a corto plazo pueden provocar efectos adversos significativos sobre el sistema respiratorio (17) o incluso podrían contribuir al aumento del riesgo de mortalidad cardiovascular(18).

1.2.3. Medida de la exposición al HAT

La exposición al HAT puede ocurrir tanto en los lugares de residencia (en los propios domicilios de los no fumadores) como en los lugares de trabajo, además de en otros lugares públicos o privados (p.ej zonas recreativas y de ocio, como bares y restaurantes). La prevalencia de exposición al HAT en personas no fumadoras varía considerablemente en función del país y el tipo de regulación existente y el lugar de la exposición.

Los estudios poblacionales sobre exposición al HAT incluyen tanto medidas subjetivas (cuestionarios de percepción) como marcadores objetivos, que son sustancias que se encuentran en el HAT.

Los cuestionarios son útiles para hacer una valoración cualitativa de la exposición y han sido muy utilizados para evaluar la exposición al HAT especialmente en estudios prospectivos y retrospectivos sobre sus efectos agudos y crónicos y para evaluar la prevalencia de exposición y/o el consumo y características de consumo del tabaco. Entre las ventajas del uso de cuestionarios destacan su sencillez y rapidez en su aplicación y que se trata de un método económico para estudios en poblaciones grandes. Sin embargo, se trata de un método subjetivo sometido a un sesgo de información y/o recuerdo.

El uso de marcadores nos permite cuantificar la concentración de HAT de una manera precisa y objetiva. Un buen marcador del HAT tiene que cumplir ciertas características: tiene que ser específico del HAT y, en caso de no ser específico lo más selectivo posible; que sea fácilmente detectable y de muestreo sencillo; la concentración del marcador debe de aumentar de manera proporcional al aumento del HAT; el método de análisis tiene que ser suficientemente sensible y económicamente asequible; su concentración debe poder relacionarse con la de otros compuestos del HAT; y debe tener una conducta consistente bajo un rango de condiciones ambientales. Entre los marcadores del HAT debemos distinguir los marcadores biológicos de exposición individual y los marcadores aéreos, más fáciles de obtener que los primeros(9;19).

Los **marcadores biológicos** se miden a través de los fluidos corporales como sangre, orina o saliva, o bien en el cabello o dientes. Entre ellos encontramos, por ejemplo, el monóxido de carbono, la nicotina o la cotinina (principal metabolito de la nicotina), que miden de manera muy sensible y específica la exposición involuntaria al tabaco.

La nicotina en fluidos corporales tiene una vida media de 2-3 horas antes de metabolizarse a cotinina. Es altamente específica del tabaco y, aunque existen otras posibles fuentes de nicotina, como algunas plantas de la familia de las solanáceas (hortalizas y féculas) de amplio consumo como el tomate, patata o te, en estos casos la concentración de nicotina es insignificante en comparación con la nicotina que proviene del consumo de tabaco(20).

La cotinina es el metabolito más importante de la nicotina y puede ser medido en diferentes fluidos corporales como marcador de la exposición a la nicotina inhalada, pues es específico del tabaco, es fácilmente detectable y mantiene una razón constante con otros productos del tabaco. Además, su vida media (15-17 horas) es más larga que la de la nicotina que se metaboliza rápidamente (2-3 horas) y nos informa de la exposición al tabaco en los últimos 5-7 días. El mejor indicador de la dosis absorbida de nicotina es la concentración de cotinina en sangre, pero los niveles sanguíneos pueden ser estimados razonablemente bien mediante los niveles de cotinina en saliva u orina(20).

El monóxido de carbono (CO) está presente tanto en la corriente principal como en la corriente secundaria y puede medirse su concentración en el aire espirado después de retener la respiración o en forma de carboxihemoglobina en sangre. Aunque el CO y la carboxihemoglobina se han utilizado para distinguir a los fumadores de los no fumadores, por lo general no son buenos marcadores de la exposición al HAT porque no son ni muy específicos ni selectivos. Además de originarse durante la combustión del tabaco, se encuentran en otros procesos de combustión y tienen una vida media relativamente corta (2-4h) por lo que sólo sería útil como marcador de exposiciones recientes(9;11).

Los **marcadores aéreos** permiten obtener niveles de HAT en diferentes microambientes y son más fáciles de obtener que las muestras biológicas. Dentro de éstos encontramos la nicotina aérea, las partículas respirables en suspensión o el CO. Para medir estos marcadores aéreos pueden utilizarse métodos directos o indirectos. Los directos se basan en monitores de uso individual. Los indirectos pretenden medir las concentraciones de diferentes componentes del HAT haciendo medidas en localizaciones fijas. Esto permite tener una estimación de la contribución del HAT en los niveles de contaminantes aéreos en lugares cerrados, pero no es una medida directa de la exposición individual total al HAT(9).

La nicotina aérea es un componente semivolátil orgánico exclusivo del humo del tabaco y es el más usado como marcador ambiental del HAT por su especificidad. Además presenta una buena correlación con los niveles de material particulado (PM) y cotinina en orina y saliva y se emite en grandes cantidades desde la corriente secundaria(11). La nicotina aérea puede medirse con diferentes métodos(9) ya sea de manera directa a través de monitores de uso individual(21-23) o a través de medidas indirectas con monitores fijos, que es un método más simple y económico(24). Este marcador ha sido utilizado para monitorizar los niveles de HAT ya sea en lugares públicos o privados y para medir la exposición individual de los fumadores pasivos(19).

Las partículas respirables en suspensión (RSP) se definen como partículas de naturaleza sólida y/o líquida y con unas dimensiones y morfología que les permite permanecer suspendidas en la atmósfera durante un tiempo determinado dependiendo de su tamaño, la forma, el peso específico y la turbulencia del aire. Su tamaño se expresa en términos de diámetro aerodinámico de la materia particulada (PM) y, en el caso de las RSP, éste es inferior o igual a 10µm (PM_{10}). Las más pequeñas pueden permanecer suspendidas durante horas e incluso días y pueden ser transportadas lejos de su lugar de origen por el viento o turbulencias. Se ha visto que estas partículas tienen efectos adversos para la salud ya que debido a su pequeño tamaño pueden penetrar en el sistema respiratorio(9). Además se ha visto que este riesgo aumenta con la exposición, y que no existe un umbral por debajo del cual no se produzcan efectos adversos para la salud(25). Al contrario que la nicotina, las PM no son específicas del HAT. Existen otras fuentes de emisión de las PM como cualquier combustión, emisiones de la cocina, partículas de humo adheridas a la ropa pero se ha visto que es el tabaco su fuente principal de emisión en ausencia de otras fuentes de combustión. De hecho, se han comparado medidas tomadas en ambientes donde se fuma con las tomadas en lugares donde no se fuma y se ha visto que los niveles de PM son mucho mayores en lugares cerrados donde se fuma respecto a lugares en los que no(9).

Las RSP se pueden medir con diferentes métodos: gravimétricos y ópticos para detectar la concentración o número de partículas o por métodos de fluorescencia (FPM) o adsorción ultravioleta (UVPM) para medir los límites de partículas de hidrocarburos(9). Aunque las PM o RSP no son exclusivas del HAT, es importante medir los niveles de las fracciones de partículas finas de RSP, las denominadas $PM_{2.5}$ que son las partículas de diámetros aerodinámicos de tamaño igual o inferior a 2.5 µm. Estas partículas son uno de los componentes mayoritarios emitidos durante la combustión del tabaco. Gracias a su reducidísimo tamaño pueden penetrar hasta niveles profundos del pulmón, a nivel alveolar, y tienen tiempos de semivida más lentos. Debido a esto se han asociado con enfermedades pulmonares y cardiovasculares y con una mayor mortalidad(26). Se ha demostrado que concentraciones de $PM_{2.5}$ de 3-5µg/m^3 ya son susceptibles de ocasionar efectos adversos para la salud(25).

Numerosos estudios(26-35) han utilizado las $PM_{2.5}$ como marcador del HAT ya que se generan en cantidades suficientes para ser medidas, tienden a ocupar todo el espacio y pueden permanecer suspendidas en el aire durante largo tiempo. Además pueden medirse con métodos sensibles, relativamente económicos y que permiten obtener datos en tiempo real. Los niveles de $PM_{2.5}$ están controlados por estándares de calidad del aire en zonas exteriores, usando el Air Quality Index (AQI)(25). La Organización Mundial de la Salud (OMS) ha elegido como valor guía para las $PM_{2.5}$ en exposiciones prolongadas una concentración anual media de 10 $\mu g/m^3$ para el aire exterior. Este valor representa el extremo inferior de la gama en la que se observaron efectos significativos en la supervivencia en el estudio de la Sociedad Americana del Cáncer. Vale la pena remarcar que no se han definido valores guía para ambientes interiores y que el estándar para exteriores se suele tomar como referencia también para los ambientes interiores.

La concentración de monóxido de carbono (CO) se puede medir fácilmente en el aire y existe una elevada correlación entre su concentración y el número de cigarrillos fumados(9). Las mediciones de CO en el aire se han utilizado con frecuencia junto a otros marcadores aéreos para evaluar la exposición al HAT en el hogar, los lugares de trabajo o en lugares públicos. La medición de los niveles de CO mediante análisis electroquímicos es asequible y fiable pero el CO presenta el inconveniente de ser altamente difusible y poco específico. Esto es debido a que el CO se origina durante otros procesos de combustión por lo que su uso para medir la exposición al HAT debería realizarse siempre junto a otros marcadores.

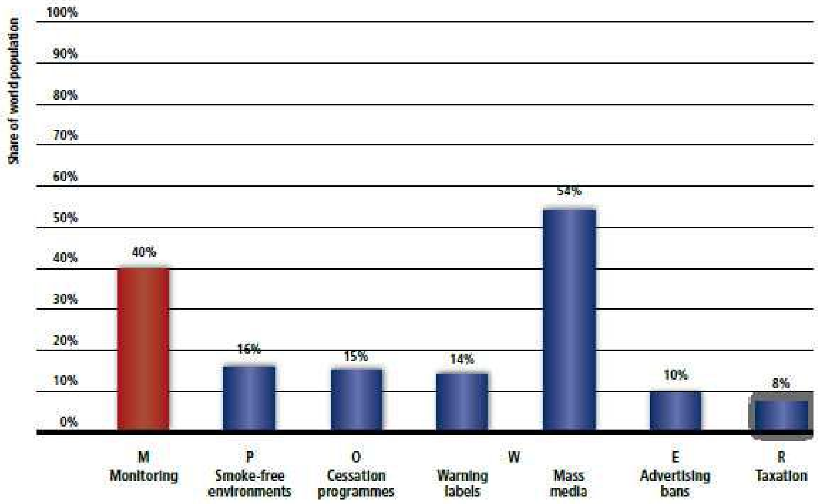
1.3. Políticas de control del tabaquismo: el Convenio Marco y la estrategia MPOWER

Debido a todos los riesgos asociados al tabaquismo activo y pasivo y a la elevada mortalidad que se les atribuye, la OMS impulsó políticas preventivas para el control del tabaquismo mediante el CMCT (36). Este convenio entró en vigor en febrero de 2005 y desde entonces se ha convertido en uno de los tratados más ampliamente adoptados en la historia de las Naciones Unidas, suscrito por más de 176 Partes que representan el 88% de la población mundial. Este tratado se basa en la evidencia que reafirma el derecho de la gente al nivel más alto posible de salud, dota de dimensiones jurídicas a la cooperación sanitaria internacional, y establece criterios estrictos para vigilar el cumplimiento. El artículo 8º del CMCT hace referencia específicamente a la protección eficaz de las personas de la exposición al HAT. Inicialmente, las políticas de espacios sin humo se centraron en proporcionar protección universal contra el humo del tabaco en los lugares públicos cerrados, en el interior de los lugares de trabajo y el transporte público. Este tipo de políticas de espacios libres de humo tienen efectos sobre la exposición y salud de los fumadores y no fumadores e incluso, aplicadas en el ambiente laboral, contribuyen a disminuir el consumo y la prevalencia de tabaquismo(10).

En 2008, la OMS identificó seis medidas para prevenir y hacer retroceder la epidemia del tabaco. Estas medidas se conocen como «MPOWER» y corresponden a una o más de las medidas de reducción de la demanda contenidas en el CMCT: monitorizar el consumo de tabaco y las políticas de prevención (*Monitor*); proteger a la población del humo ambiental del tabaco (*Protect*); ofrecer ayuda para dejar el tabaco (*Offer*); advertir de los peligros del tabaco (*Warn*); hacer cumplir las prohibiciones sobre publicidad, promoción y patrocinio del tabaco (*Enforce*); y aumentar los impuestos al tabaco (*Raise*). Estas medidas ofrecen a los países asistencia práctica para reducir la demanda de tabaco en consonancia con lo dispuesto en el CMCT, y reducir así también la morbilidad, la discapacidad y la mortalidad asociadas(1).

Desde la adopción del CMCT y desde que se introdujo la estrategia MPOWER son muchos los países que han implementado satisfactoriamente una o más de sus medidas para el control de la epidemia del tabaco. El último informe de la OMS sobre la epidemia mundial de tabaquismo publicado en 2013 muestra que cualquier país puede establecer un programa eficaz de control del tabaco para reducir su consumo, independientemente de su estructura política o nivel de ingresos(37). Este informe indica que, en el 2013, más de 2.300 millones de personas -un tercio de la población mundial- estaban protegidas por al menos una de las medidas MPOWER aplicada en su más alto grado (Fig. 3).

Figura 3. Proporción de la población mundial cubierta por alguna de las medidas "MPOWER"



Fuente: Informe de la OMS 2013(37)

La creación de lugares públicos y lugares de trabajo sin humo sigue siendo la medida que más y en mayor grado se ha implantado. El primer país que implementó este tipo de medidas fue la República de Irlanda en 2004. Tras Irlanda, otros países han tomado medidas más o menos restrictivas de prevención y control del tabaquismo. Entre 2007 y 2012 un total de 32 países aprobaron políticas de espacios libres de humo en todos los lugares de trabajo, lugares públicos y medios de transporte público. En la actualidad un 16% de la población mundial está protegida de los efectos nocivos del HAT(37) y en Europa, todos los países ya han adoptado algún tipo de política de espacios libres de humo. Estas políticas difieren considerablemente en función del país en cuanto a magnitud y alcance se refiere. Las medidas más restrictivas han sido las implementadas en Irlanda, Reino Unido, Grecia, Hungría, Bulgaria, Malta, Turquía y España.

1.4. Evaluación de las políticas de control del tabaquismo

Las políticas para el control del tabaquismo han sido implementadas para proteger a las personas no fumadoras de los efectos nocivos del HAT. Además se ha visto que tienen la capacidad de cambiar las normas sociales y de modificar la conducta tabáquica en los fumadores. Algunos resultados tras la implementación de políticas de espacios libres de humo de tabaco incluyen una reducción de la exposición al HAT de un 80-90% en entornos de alta exposición(38), una disminución de los síntomas respiratorios(39), una disminución inmediata de la incidencia de infartos de miocardio(40;41), un aumento del número de fumadores que quieren dejar de fumar(42), fomenta los hogares libres de humo(43), e incluso se ha visto que tienen un efecto neutral o positivo en los negocios del sector de la hostelería y otros negocios(44;45). Además, algunos estudios sugieren que el apoyo a las políticas de espacios libres de humo aumenta después de su adopción y con el tiempo tras su implementación(46;47).

Una revisión sistemática incluyó 50 estudios donde se evaluaba la capacidad de las políticas de control del tabaquismo para reducir la exposición al HAT, la capacidad para ayudar a las personas fumadoras a reducir su consumo y para reducir la prevalencia de consumo de tabaco y el impacto en la salud de la población afectada(38). Los 31 estudios que reportaron la exposición al HAT (19 de los cuales utilizaron biomarcadores para medir esta exposición) evidenciaron de manera consistente que las políticas de control del tabaquismo reducen la exposición al HAT en los lugares de trabajo, restaurantes, pubs y lugares públicos. Se observó una mayor reducción de la exposición al HAT en los trabajadores del sector de la hostelería en comparación con la población general. No se observaron cambios ni en la prevalencia ni en la duración de la exposición al HAT en el hogar después de la implementación de estas políticas. 23 de los estudios incluidos en la revisión reportaron medidas de tabaquismo activo, sin evidenciar de manera consistente una disminución del consumo de tabaco debido a la legislación. Los estudios incluidos en la revisión sistemática que reportaron resultados sobre los indicadores de salud observaron un impacto positivo en alguno de estos indicadores después de la implementación de políticas para el control del tabaquismo y una reducción de los ingresos hospitalarios por eventos cardíacos.

1.5. Espacios exteriores libres de humo

Si bien las políticas de espacios libres de humo han sido típicamente implementadas en ambientes interiores, algunos estudios sugieren que desde su introducción ha habido una relocalización de fumadores a espacios exteriores de conveniencia como entradas a edificios públicos, o zonas exteriores de los lugares amparados por estas políticas(34;48). En el 2007, una revisión del artículo 8 del CMCT recomendó extender las políticas de espacios libres de humo a determinados lugares públicos al aire libre en determinadas circunstancias e invitó a los países a adoptar las medidas necesarias y más efectivas para proteger a la población de la exposición al HAT en cualquier lugar donde la evidencia muestre que existe peligro(49).

En los últimos años, varios países han extendido sus políticas de espacios libres de humo a determinados espacios exteriores, incluyendo centros sanitarios, parques infantiles, playas, instalaciones deportivas, entradas a los edificios públicos, paradas de transporte público, calles parcialmente cerradas, y campus universitarios(48;50;51). Este tipo de políticas se están popularizando y son socialmente aceptadas en países con larga tradición en control del tabaquismo, con el apoyo de la población que parece ir aumentando después de su implementación y con el tiempo(47). Sin embargo, no están exentas de crítica y existen divergencias acerca de si se debe permitir o no fumar en ciertos lugares al aire libre(52-54). Quienes se oponen a tal prohibición argumentan que es éticamente insostenible porque no respeta el principio de libertad y autonomía del individuo y no hay pruebas suficientes de que el humo ambiental del tabaco en estos lugares tenga un verdadero impacto sobre la salud que justifique tal regulación(52;53). Sin embargo, la evidencia científica demuestra que no existe un nivel seguro de exposición al HAT(49). Por otra parte, las personas que están de acuerdo con la regulación argumentan que las políticas de espacios exteriores libres de humo reducen la visibilidad del consumo de tabaco, están asociados al proceso de desnormalización del tabaco, establecen un modelo social libre de humo positivo para los jóvenes, reducen las oportunidades de fumar y además protegen de la exposición al HAT, aunque esta sea más baja que en lugares cerrados. Además, estas políticas pueden ir acompañadas de beneficios para el medio ambiente, como la reducción de riesgo de incendios y evitan la contaminación por colillas(47;49;53-57).

La exposición al HAT ha sido comúnmente estudiada y bien caracterizada en espacios cerrados, especialmente en lugares de trabajo como son los centros sanitarios o en el sector de la hostelería(44;49); en cambio, en los espacios abiertos y semiabiertos la exposición al HAT ha sido poco evaluada y existen pocos datos objetivos sobre los niveles de exposición al humo ambiental del tabaco al aire libre en ese tipo de espacios. Algunos artículos recientes muestran que los niveles de HAT al aire libre son detectables y pueden ser comparables o incluso superiores a los niveles encontrados en ciertos espacios cerrados(32;56;58-60). Por otra parte, debe considerarse que los niveles de HAT en ambientes exteriores son más susceptibles a variaciones ya que no tienden a acumularse y, debido a sus características fisicoquímicas, puede dispersarse influido por la temperatura, humedad o ventilación. Esto implica que el humo del tabaco en estos espacios exteriores pueda disiparse a las zonas interiores contiguas, detectándose en éstas últimas niveles de HAT considerables, aún cuando está prohibido fumar. Es necesario revisar la literatura científica que mide objetivamente los niveles de HAT en espacios exteriores para poder caracterizar la exposición en estos lugares y en los espacios interiores adyacentes. Desconocemos también qué factores pueden influir en los niveles de HAT en estas localizaciones y si los niveles de HAT cumplen con los estándares de calidad del aire establecidos por la OMS. Toda esta información nos permitiría poder establecer medidas adecuadas de control del tabaquismo en este tipo de localizaciones.

1.6. Ley 28/2005 de medidas sanitarias contra el tabaquismo

En España, el movimiento de prevención y control del tabaquismo fue lento y progresivo. Mientras que otros países ya habían conseguido implementar políticas preventivas, no fue hasta 1996 que la creación del Comité Nacional para la Prevención del Tabaquismo (CNPT) ayudó a cambiar la situación. Con su interacción con el Ministerio de Sanidad, el CNPT ha influido en la adopción de normativas en España como la aprobación del Plan Nacional de Prevención del Tabaquismo de 2004 y posteriormente la legislación de medidas sanitarias frente al tabaquismo(61).

El 1 enero de 2006 entró en vigor en España la Ley 28/2005 de medidas sanitarias frente al tabaquismo(62). España fue el séptimo país Europeo después de Finlandia, Irlanda, Noruega, Malta, Italia y Suiza en implementar regulaciones para prevenir y controlar el tabaco(63). La nueva ley sustituía la normativa previa en España, una de las más permisivas de la Unión Europea en temas como venta de tabaco, limitación de la publicidad y restricciones de lugares de consumo. Esta ley, con el objetivo de proteger a los no fumadores del HAT y de sus efectos nocivos para la salud, prohibió el consumo de tabaco en todos los lugares públicos y centros de trabajo (salvo los que estaban al aire libre). Sin embargo, presentaba excepciones en la restauración y la hostelería(64) que podían habilitar áreas para fumadores en los locales de de igual o más de 100 m^2 y, si eran de menos de 100 m^2, el propietario podía decidir si permitir fumar o no. Esta nueva ley tuvo el apoyo de la industria del tabaco y fue promovida en otros países como el “modelo español”(65), que se caracteriza precisamente por permitir zonas de fumadores o locales de fumadores sin prohibición en el sector de la hostelería, sin tener en cuenta que un colectivo importante de trabajadores quedaba desamparado de los beneficios de la ley.

1.6.1. Cambios en la prevalencia de exposición al HAT

Dos estudios(66;67) evaluaron el impacto de la ley en cuanto a prevalencia de exposición al HAT después de la implementación de la ley 28/2005 Uno de ellos determinó la prevalencia de exposición al HAT en la región de Madrid en diversos ámbitos (hogar, trabajo, bares y restaurantes) antes y después de la ley, y halló una considerable reducción de la exposición en los lugares de trabajo (del 40,5% al 9,0%) nueve meses después de su puesta en marcha(66). En el hogar, sin embargo, tal como indican estudios previos realizados en otros países(42), no se observaron diferencias significativas. Asimismo, otro estudio con datos nacionales mostró una reducción del 58% en la prevalencia de exposición al HAT en el trabajo un año después de la implantación de la ley, mientras en casa y en el tiempo libre no encontró cambios importantes(67). No obstante, cabe destacar que, pese a las disminuciones observadas en la prevalencia de exposición, la proporción de expuestos seguía siendo muy elevada, tal como puso de manifiesto otro estudio(68) en el cual se estimaba que más de la mitad de la población no fumadora seguía estando expuesta al HAT.

Otros estudios evaluaron el impacto de ley 28/2005 sobre los niveles de HAT mediante marcadores objetivos del tabaco. En uno de ellos(69) se midió la nicotina en fase vapor en el ambiente de lugares de trabajo y hostelería en ocho Comunidades Autónomas. Todos los lugares de trabajo estudiados experimentaron una disminución significativa y muy importante (del 90%) de los niveles de HAT un año después de la implantación de la ley, con niveles muy bajos de exposición. Sin embargo, en el caso de la hostelería los cambios en la exposición estuvieron claramente asociados al tipo de política que los dueños del local decidieron adoptar. En aquellos locales que prohibieron fumar, la disminución de la exposición fue drástica, mientras que en los que seguían permitiendo fumar no se observaron cambios significativos. Por otro lado, en aquellos locales con áreas separadas para fumadores y no fumadores, las áreas de fumadores seguían teniendo niveles de exposición muy elevados, mientras que en las de no fumadores hubo una disminución significativa, pero no tan importante como en los locales con prohibición total. Otro estudio incluyó trabajadores de la hostelería de 5 Comunidades Autónomas y mostró, al año de implementación de la ley, una reducción de la exposición al HAT medida mediante cotinina en saliva en estos trabajadores del 56% y de la presencia de síntomas respiratorios del 72% sólo en los trabajadores en locales que se declararon completamente libres de humo, mientras que en aquellos trabajadores en locales con zonas habilitadas para fumar o que continuaron en locales sin restricción alguna no se apreciaron diferencias significativas(70).

1.6.2. Impacto de la ley en el consumo de tabaco

Aunque la Ley 28/2005 es conocida principalmente por la protección frente a la exposición al HAT en los espacios públicos y de trabajo, las principales líneas articuladas están relacionadas también con un control de la prevalencia del consumo, constituyendo éste un objetivo de la regulación.

Se estima que estas políticas están relacionadas con una disminución del tabaquismo del 3% al 4%, así como con una reducción del número de cigarrillos en las personas que continúan fumando(71). Además este tipo de políticas favorecen el proceso de desnormalización del tabaco, y pueden ser efectivas para prevenir el consumo de tabaco entre la gente más joven(72). Sin embargo, en Europa, las políticas para el control del tabaquismo implementadas en los últimos años no han mostrado un efecto directo sobre el consumo de tabaco. Un estudio publicado en el 2011 que consideraba 21 jurisdicciones teniendo en cuenta las tendencias seculares de la epidemia del tabaco encontró que las políticas libres de humo se acompañaron de una disminución de la prevalencia de consumo en 8 de las jurisdicciones mientras que en las otras 13 las tendencias esperadas no se alteraron(73). En España, los resultados de la evaluación del impacto de la Ley 28/2005 no evidenciaron ningún impacto sobre los indicadores de consumo de tabaco(7). El descenso observado en la prevalencia de fumadores y el número de cigarrillos consumidos, y el aumento del número de ex fumadores reflejaban la evolución esperada de la epidemia del tabaquismo en España, con la tendencia ya observada antes de la entrada en vigor de la ley (Fig. 2)

1.6.3. Aceptabilidad y percepción de la ley por la población.

El apoyo social a las medidas de control del tabaquismo es crucial para garantizar su éxito. Se asume que, en general, la población fumadora presta un menor apoyo a la regulación del consumo de tabaco. Sin embargo, también hay indicios de que el apoyo a las políticas de espacios sin humo, en lugar de decaer, aumenta con el tiempo tras su implementación(42). La Ley 28/2005 tuvo un importante apoyo social, con un 77,2% de la población que la consideraba muy positiva en el 2005 y con un 68% de apoyo un año después de su entrada en vigor, según las encuestas del Centro de Investigaciones Sociológicas(74). Otras encuestas realizadas para valorar la aceptación y el grado de apoyo a la ley obtuvieron resultados similares con valoración positiva de la ley que fue en aumento desde el 2005 hasta el 2008 entre los no fumadores con un apoyo algo inferior entre los fumadores pero que también experimentó una tendencia creciente desde 2005 y hasta 2008(61). El grado de apoyo también variaba más o menos en función del lugar de restricción de consumo. Así, según las encuestas del Eurobarómetro encargadas por la Comisión Europea, en el año 2005, antes de la entrada en vigor de la Ley 28/2005, el 58% de los encuestados se manifestó «totalmente a favor» de la prohibición de fumar en oficinas y otros lugares de trabajo cerrados, el 48% estaba «totalmente a favor» de la prohibición en restaurantes, y el 42% en bares, pubs y clubs. El apoyo a la prohibición se mantuvo o aumentó ligeramente 2 años después de su entrada en vigor(7).

1.7. Nueva ley 42/2010 del tabaco

En vista de los resultados de la evaluaciones de la Ley 28/2005, se puso de manifiesto que, aunque la ley había tenido un impacto positivo en la protección frente a la exposición al HAT, quedaba desprotegida de la ley una parte importante del sector de la restauración y la hostelería. Como resultado de las intensas campañas a favor de fortalecer la ley y las demandas de los ciudadanos entró en vigor el 2 de enero de 2011 la Ley 42/2010 de medidas sanitarias frente al tabaquismo y reguladora de la venta, el consumo y la publicidad de los productos del tabaco. Esta nueva ley modifica la Ley 28/2005 en sus limitaciones y así prohíbe fumar en todos los espacios públicos cerrados, incluyendo los locales de restauración y hostelería (bares, cafés, pubs, restaurantes, discoteca y casinos), sin excepción(75). Además ha sido la primera vez que se prohíbe fumar en Europa en algunos sitios al aire libre, como parques y lugares de ocio infantil, colegios y recintos hospitalarios(76;77). La prioridad de esta norma es proteger al colectivo de menores, retrasando la edad de inicio del consumo, y proteger a los fumadores pasivos, sobre todo a los trabajadores del sector de la hostelería. Como excepción, se puede fumar en las habitaciones que los dueños de hoteles decidan habilitar para ello, con un máximo del 30% del total disponible. También se permite fumar en espacios al aire libre de universidades y centros exclusivamente dedicados a la formación de adultos. Finalmente se pueden habilitar salas cerradas y zonas exteriores en prisiones y centros psiquiátricos de media y larga estancia y en residencias de mayores o discapacitados(75).

1.8. Justificación de la investigación

Hasta ahora, las evaluaciones que se han hecho del impacto de las leyes de prevención y control del tabaquismo en España recientemente implementadas sobre la exposición pasiva se han limitado a entornos laborales definidos (hostelería, hospitales) y a colectivos específicos a priori considerados de mayor riesgo, como los trabajadores de la hostelería y la restauración. Existen pocas evaluaciones del impacto de la legislación en los niveles de exposición en otros lugares públicos y, más concretamente, a nivel poblacional. Haw y Gruer evaluaron el impacto de la ley escocesa que prohíbe fumar en todos los lugares de trabajo y lugares públicos cerrados en la población adulta, mediante dos encuestas transversales antes y después (aproximadamente al año), con información subjetiva sobre la exposición obtenida con cuestionario y con medidas objetivas a partir de la determinación de cotinina en saliva (78). De esta manera demostraron el impacto positivo de la ley escocesa, con reducciones subjetivas de la exposición en los puestos de trabajo, transportes y lugares de ocio como pubs y restaurantes; y también con una disminución global del 39% de la media geométrica de cotinina en saliva, que fue aún mayor (del 49%) cuando los no fumadores residían en hogares completamente libres de humo. Estas reducciones, además, no supusieron un desplazamiento de la exposición desde los lugares públicos mencionados a lugares privados como los hogares o coches. En los Estados Unidos la monitorización mediante encuestas con obtención de saliva para la determinación de cotinina ha permitido también objetivar el impacto positivo de la legislación que regula el consumo de tabaco: la concentración media de cotinina disminuyó un 47% tras la aplicación de ley entre los no fumadores del estado de Nueva York(79). En España, no disponemos de una evaluación del impacto de las medidas para el control del tabaquismo que incluyan resultados posteriores a la implementación de la nueva ley (Ley 42/2010). Solamente un estudio pre-post de la Ley 42/2010 indicaba una reducción de la nicotina aérea y de $PM_{2.5}$ de más del 90% en los locales de la hostelería (80), sin resultados sobre la exposición a nivel poblacional.

También es importante monitorizar los cambios de prevalencia de consumo de tabaco así como las características de consumo, no sólo después de la implementación de medidas de control del tabaquismo sino de manera continua para estudiar posibles cambios en la tendencia esperada según la epidemia del tabaco y los cambios en el patrón de consumo. Estudios realizados en otros países indican que en los últimos años se observa un aumento considerable del consumo de tabaco de liar acompañado por una disminución del consumo de los cigarrillos manufacturados. En España, un estudio que analiza la tendencia de consumo de cigarrillos manufacturados y de los cigarrillos de liar entre 1991 y 2012 muestra que ha disminuido el consumo diario *per capita* de cigarrillos manufacturados mientras que el consumo de cigarrillos de liar ha aumentado considerablemente(8). Hasta ahora, no se han evaluado en España los cambios de prevalencia de consumo y el patrón de consumo según el tipo de tabaco consumido en población general.

Como se ha comentado, la Ley 42/2010 extiende la prohibición de fumar a algunos espacios exteriores (parques infantiles, colegios y recintos hospitalarios) siguiendo las recomendaciones del artículo 8 del CMCT. Hasta ahora no se ha analizado el grado de apoyo de la población general hacia las políticas libres de humo en espacios exteriores, tanto de la población no fumadora como fumadora. Además es importante conocer qué metodología sería adecuada para poder valorar la exposición al HAT en lugares exteriores para poder conocer la situación en estos espacios y en base a ello diseñar futuras intervenciones para proteger a la población de la exposición al HAT.

En esta tesis doctoral se realiza una evaluación del impacto de las medidas de prevención y control del tabaco a nivel nacional (Ley 28/2005 y Ley 42/2010) sobre la exposición al HAT de la población general utilizando tanto información derivada de cuestionarios como las concentraciones de cotinina en saliva. Además se utiliza la información obtenida de estas dos encuestas para analizar los cambios en la prevalencia de consumo y las características de consumo de tabaco. Este tipo de estudio es el recomendado por la la Agencia Internacional de Investigación del Cáncer de la Organización Mundial de la Salud(44) para la evaluación del impacto de las legislaciones sobre restricción del consumo de tabaco y espacios libres de humo. Finalmente, se realiza una revisión sistemática de los estudios publicados que evalúan los niveles de exposición al HAT en localizaciones al aire libre mediante marcadores y se utiliza la información obtenida en las encuesta realizada en 2011 para evaluar las actitudes y creencias sobre las políticas libre de humo en estos espacios para determinar si deberían extenderse las políticas libres de humo a estos ambientes.

2. HIPÓTESIS Y OBJETIVOS

2.1. Hipótesis

1.- La implementación de medidas sanitarias frente al tabaquismo disminuye tanto la exposición percibida al humo ambiental del tabaco como la concentración de cotinina en saliva de la población adulta no fumadora.

2.- El consumo de tabaco entre la población fumadora se verá levemente reducido después de la implementación de medidas sanitarias.

3.- Se observarán niveles de exposición al humo ambiental del tabaco por encima de los mínimos anuales permitidos por las guías de calidad del aire de la Organización Mundial de la Salud (10 µg/m^3 para las $PM_{2.5}$) en las zonas de fumadores al aire libre y en las localizaciones interiores adyacentes a estas zonas.

4. – Existen zonas al aire libre dónde la población no fumadora se siente especialmente expuesta que coinciden con las zonas dónde los fumadores declaran fumar. La población apoya la implementación de espacios exteriores libres de humo en determinadas localizaciones al aire libre.

2.2. Objetivos

1.- Evaluar el impacto de las medidas sanitarias para la prevención y control del tabaquismo implementadas a nivel nacional (Ley 28/2005 y Ley 42/2010) en la población adulta no fumadora mediante la medición de la exposición al humo ambiental del tabaco en comparación con la exposición antes de la implantación de estas medidas (años 2004-2005).

1.1. Evaluar los cambios producidos en la exposición percibida al humo ambiental del tabaco en la población adulta no fumadora mediante cuestionario;

1.2. Evaluar los cambios producidos en la exposición al humo ambiental del tabaco en la población adulta no fumadora mediante la concentración de cotinina en saliva.

2.- Evaluar los cambios de prevalencia de consumo de tabaco y el patrón de consumo de tabaco entre la población fumadora antes y después de la implementación de la Ley 28/2005 y la Ley 42/2010.

3.- Revisar la literatura científica que mide objetivamente la exposición al humo ambiental del tabaco en espacios abiertos y semiabiertos mediante el uso de marcadores biológicos y ambientales del tabaco.

4.- Caracterizar el consumo de tabaco y la exposición al humo ambiental del tabaco en lugares al aire libre y analizar las opiniones y creencias de la población hacia las políticas de control del tabaquismo en estos lugares.

3. DESCRIPCIÓN DE LOS DATOS Y DISEÑO METODOLÓGICO

3.1. Diseño y sujetos del estudio

Diseño: Los resultados analizados en esta investigación se derivan de dos encuestas transversales realizadas en 2004-2005 antes de la implementación de la Ley 28/2005 (estudio dCOT) y en el 2011-2012 después de la implementación de la Ley 42/2010 (estudio dCOT2) con idéntica metodología y dónde se incluye dos muestras representativas de la población adulta no institucionalizada de la ciudad de Barcelona (≥16 años). Los datos antes de la implementación de las medidas para el control del tabaquismo fueron recogidos entre marzo de 2004 y diciembre de 2005 (estudio dCOT). Los datos después de su implementación entre junio de 2011 y marzo de 2012 (estudio dCOT2).

Tamaño de la muestra: El tamaño muestral que se determinó para el estudio fue de 1.560 personas para cada una de las encuestas (asumiendo riesgo alfa = 5%, beta <20%, pérdidas del 20% para muestras independientes). La encuesta realizada en el 2004-2005 incluyó una muestra final de 1.245 sujetos y la encuesta de 201-2012 una muestra final de 1.307 individuos. Este tamaño muestral es suficiente para detectar cambios del 10% en los niveles de exposición al HAT en el trabajo o en el hogar y detectar una disminución del 40% en la concentración de cotinina en saliva entre las dos muestras. Todos los cálculos se realizaron con el programa GRANMO 5.2 MS Windows (http://www.imim.es/media/upload/ arxius/grmw52.zip).

Muestreo: Se realizó un muestreo aleatorio simple a partir del padrón municipal de habitantes actualizado en el momento de realización de cada una de las encuestas y se comprobó que la distribución por edad y sexo no estuviera sesgada respecto a la de la población general. La solicitud de la muestra se realizó al Instituto Municipal de Estadística de Barcelona a través de la Agencia de Salud Pública de Barcelona.

Sujetos (criterios de inclusión y exclusión): Se incluyó a todas las personas seleccionadas que tras contactar con ellas mediante carta aceptaron participar y fueron entrevistadas en su domicilio. Previo consentimiento informado, se entrevistó personalmente a los sujetos seleccionados. En el caso que los sujetos tuvieran 16 ó 17 años se obtuvo el consentimiento informado de los padres. Los participantes que no pudieron ser localizados después de varios intentos a diversas horas del día y distintos días de la semana, o bien aquellos que rechazaron la participación, fueron sustituidos por otra persona escogida al azar del mismo grupo de sexo, el mismo rango de edad y distrito de residencia. Las sustituciones representaron el 50,7% y el 54,6% de las encuestas pre y post, respectivamente.

3.2. Variables e instrumentos de medida

Cuestionario sobre tabaquismo activo y pasivo: Se utilizó el mismo cuestionario en las dos encuestas (administrado en papel tradicional en la primera encuesta y asistido por ordenador en la segunda). El cuestionario fue administrado por personal entrenado. Se incluyeron algunas preguntas adicionales en la segunda encuesta que hacían referencia específicamente a la Ley 42/2010. El cuestionario recogió información sobre datos socio-demográficos, consumo de tabaco y exposición pasiva al HAT en diferentes localizaciones, y actitudes y creencias respecto las medidas de control del tabaquismo. Mediante este cuestionario se ha observado una buena asociación entre la exposición declarada al HAT y los niveles de cotinina medidos en saliva(81), así como una validez adecuada para la exposición general, con una sensibilidad del 75,8% para la exposición en algún lugar y una especificidad del 80,6% para la percepción en todos los ambientes(82).

Recogida de muestras de saliva: Tras la realización de la encuesta se recogió una muestra de saliva. En primer lugar, se pedía a los sujetos que se enjuagaran la boca con agua y se les ofrecía un caramelo de limón (Smint®), para estimular la salivación. Se recogieron 8 ml de saliva en tubos Falcon de polipropileno mediante un embudo de tallo corto desechable. Los tubos se mantenían refrigerados a 4ºC y se transportaban al ICO donde se alicuotaron en 2 tubos de 4 ml para su posterior congelación a –20ºC, tras ser etiquetados con su correspondiente número de identificación.

Medidas antropométricas: Se midió la altura de los participantes sin zapatos mediante una cinta métrica y se determinó el peso (tras vaciar los bolsillos de los sujetos) mediante una báscula electrónica portátil calibrada. Esta información se registró en la correspondiente sección del cuestionario.

3.3. Organización del trabajo de campo

Carta de invitación y contacto: Se envió una carta de presentación del estudio y de solicitud de colaboración firmada por el Investigador Principal en la que se ofrecía un número de teléfono para solicitar información o para declinar la participación, si ese era el deseo de la persona contactada (**ver Anexo 3**). Las cartas se enviaron mensualmente en sucesivas oleadas tras lo que se intentaba localizar a los participantes personalmente en sus domicilios.

Consentimiento informado: El entrevistador se identificaba adecuadamente y solicitaba la colaboración, tras explicar el motivo de la entrevista y duración de la misma. Previamente a la realización de la entrevista se solicitó el consentimiento informado por escrito mediante un documento que cada sujeto debía leer y firmar. El entrevistador, en caso de necesidad, leyó el mismo al entrevistado y le proporcionó las explicaciones complementarias necesarias tras lo que firmaba también el documento (**ver Anexo 4**). El Comité de Investigación y Ética de Bellvitge aprobó la realización de ambas encuestas (proyectos de investigación PI 020981 y PI052072 financiados por el Instituto de Salud Carlos III) y el consentimiento informado, incluyendo el consentimiento informado de los padres para los menores de edad (**ver Anexo 5**).

Circuito para el procesamiento inicial de las muestras: La saliva se congeló durante las siguiente semana a –20ºC tras su obtención. La cotinina en saliva es muy estable, e incluso pueden transcurrir 12 días hasta su congelación. Los entrevistadores al final de su jornada laboral regresaban al centro coordinador del trabajo de campo, donde se entregaban los tubos con saliva los coordinadores/as del estudio. Los tubos fueron congelados a –20ºC en los racks destinados a este estudio en un congelador dedicado en exclusividad al mismo, en las dependencias del Laboratorio de Investigación Traslacional del propio Instituto Catalán de Oncología, y fueron transportados en contenedores (con 80 muestras cada uno) en hielo seco al Instituto Municipal de Investigación Médica (IMIM) dónde se realizó su análisis mediante cromatografía líquida acoplada a espectrometría de masas. Esta prueba tiene un límite de cuantificación de 0,1 ng/ml y un límite de detección de 0,03 ng/ml (cuantificación del error <15%).

4. RESUMEN DE LOS ARTÍCULOS

El presente trabajo de tesis doctoral lo forman un compendio de cuatro artículos originales que tratan los cambios en la exposición al HAT de la población no fumadora, el patrón de consumo de tabaco de la población fumadora, los niveles de exposición al HAT en espacios exteriores y las actitudes y creencias hacia las políticas libres de humo en estos espacios después de la implementación de las medidas sanitarias de prevención y control del tabaquismo en España. Los artículos de la tesis son:

1. **Impact of the Spanish smoke-free legislation on adult, non-smoker exposure to secondhand smoke: cross-sectional surveys before (2004) and after (2012) legislation.** Sureda X, Martínez-Sánchez JM, Fu M, Pérez-Ortuño R, Martínez C, Carabasa E, López MJ, Salto E, Pascual JA, Fernández E. PLoS ONE. 27; 9(2): e89430. doi: 10.1371/journal.pone.0089430

   PLoS One está incluida en los Journal Citation Report de Web of Science® con un factor de impacto en 2013 de 3,534 (posición 8/51 en la categoría de Multidisciplinary Science)

2. **Smoking prevalence and attributes of smokers of manufactured and roll-your-own cigarettes in Spain (2004-2005 and 2011-2012): a changing pattern.** Sureda X, Fernández E, Fu M, Martínez C, Saltó E, Martínez-Sánchez JM [ENVIADO A PUBLICAR]

3. **Secondhand Tobacco Smoke Exposure in Open and Semi-Open Settings: A Systematic Review.** Sureda X, López MJ, Nebot M, Fernández E. Environ Health Perspect. 2013;121(7):766-73.doi:10.1289/ehp.1205806

   Environmental Health Perspectives está incluida en los Journal Citation Report de Web of Science® con un factor de impacto en 2013 de 7,029 (posición 5/215 en la categoría de environmental science y posición 3/160 en la categoría Public, Environmental & Occupational Health)

4. **Secondhand smoke in outdoor settings: smokers' consumption, non-smokers' perceptions, and attitudes toward smoke-free legislation in Spain.** Sureda X, Fernández E, Martínez-Sánchez JM, Fu M, López MJ, Martínez C, Saltó E. [ENVIADO A PUBLICAR]

También se adjuntan en el anexo dos artículos originales publicados dentro de la misma línea de investigación. Uno de ellos (**Anexo 1**) evalúa la implementación de recintos hospitalarios sin humo antes y después de la Ley 42/2010 y el otro (**Anexo 2**) mide de manera objetiva mediante marcadores aéreos del tabaco la exposición al HAT en la entrada de edificios públicos y sus zonas interiores adyacentes.

1. **Impact of Tobacco Control Policies in Hospitals: Evaluation of a National Smoke-Free Campus Ban in Spain.** Sureda X, Ballbè M, Martínez C, Fu M, Carabasa E, Saltó E, Martínez-Sánchez JM, Fernández E. Preventive Medicine Reports (in press).

2. **Secondhand smoke levels in public building main entrances: outdoor and indoor PM2.5 assessment.** Sureda X, Martínez-Sánchez JM, López MJ, Fu M, Agüero F, Saltó E, Nebot M, Fernández E. Tob Control. 2012; 21(6):543-48. doi: 10.1136/tobaccocontrol-2011-050040.

Artículo 1: Impact of the Spanish smoke-free legislation on adult, non-smoker exposure to secondhand smoke: cross-sectional surveys before (2004) and after (2012) legislation. Sureda X, Martínez-Sánchez JM, Fu M, Pérez-Ortuño R, Martínez C, Carabasa E, López MJ, Salto E, Pascual JA, Fernández E. PLoS ONE. 27; 9(2): e89430. doi: 10.1371/journal.pone.0089430

Background: In 2006, Spain implemented a national smoke-free legislation that prohibited smoking in enclosed public places and workplaces (except in hospitality venues). In 2011, it was extended to all hospitality venues and selected outdoor areas (hospital campuses, educational centers, and playgrounds). The objective of the study is to evaluate changes in exposure to secondhand smoke among the adult non-smoking population before the first law (2004-05) and after the second law (2011–12).

Methods: Repeated cross-sectional survey (2004–2005 and 201–2012) of a representative sample of the adult (≥16 years) non-smoking population in Barcelona, Spain. We assess self-reported exposure to secondhand smoke (at home, the workplace, during leisure time, and in public/private transportation vehicles) and salivary cotinine concentration.

Results: Overall, the self-reported exposure to secondhand smoke fell from 75.7% (95%CI: 72.6 to 78.8) in 2004-05 to 56.7% (95%CI: 53.4 to 60.0) in 2011–12. Self-reported exposure decreased from 32.5% to 27.6% (215.1%, p<0.05) in the home, from 42.9% to 37.5% (212.6%, p = 0.11) at work/education venues, from 61.3% to 38.9% (236.5%, p<0.001) during leisure time, and from 12.3% to 3.7% (269.9%, p<0.001) in public transportation vehicles. Overall, the geometric mean of the salivary cotinine concentration in adult non-smokers fell by 87.2%, from 0.93 ng/mL at baseline to 0.12 ng/mL after legislation (p<0.001).

Conclusions: Secondhand smoke exposure among non-smokers, assessed both by self reported exposure and salivary cotinine concentration, decreased after the implementation of a stepwise, comprehensive smoke-free legislation. There was a high reduction in secondhand smoke exposure during leisure time and no displacement of secondhand smoke exposure at home.

Artículo 2: Smoking prevalence and attributes of smokers of manufactured and roll-your-own cigarettes in Spain (2004-2005 and 2011-2012): a changing pattern. Sureda X, Fernández E, Fu M, Martínez C, Saltó E, Martínez-Sánchez JM [ENVIADO A PUBLICAR]

Background: Smoking is the leading cause of preventable morbidity and premature mortality worldwide. The objectives of the present study were to describe smoking prevalence and compare the smoking attributes of smokers according to the type of tobacco product consumed in the adult population.

Methods: Repeated cross-sectional survey (2004-2005 and 201-2012) of a representative sample of the adult (≥16 years) population in Barcelona, Spain. We assessed self-reported tobacco consumption, smoking attributes of self-reported smokers, and salivary cotinine concentration.

Results: We observed that smoking prevalence decreased over the period 2004-2005 and the period 2011-2012 (from 26.6% to 24.1% in self-reported daily smokers). The prevalence of smokers that reported to use manufactured cigarettes declined from 20.4% in 2004-2005 to 16.4% in 2011-2012. Roll-your-own cigarettes users increased from 0.3% to 3.5%. Roll-your-own cigarettes users were higher among men than women (18.8% vs 7.9%), young people (19.8% compared with 5.2% among people aged 45-65 and 7.1% among ≥65 years old) and among participants with secondary and university education compared with people with less than primary and primary education (14.1%; 16.1%; and 9.1%, respectively). We did not observed differences in cotinine concentrations according to the type of tobacco product smoked.

Conclusions: To systematically collect data on smoking prevalence and smokers attributes on representative samples of the population is necessary for policymakers to develop efficient tobacco control interventions and recommendations to the population. Considering the observed increase among roll-your-own cigarettes users and the unclear consequences of their use on health, policymakers should aim to implement tax policies to equalise the prices of different types of tobacco products.

Artículo 3: Secondhand Tobacco Smoke Exposure in Open and Semi-Open Settings: A Systematic Review. Sureda X, López MJ, Nebot M, Fernández E. Environ Health Perspect. 2013;121(7):766-73. doi:10.1289/ehp.1205806

Background: Some countries have recently extended smoke-free policies to particular outdoor settings; however, there is controversy regarding whether this is scientifically and ethically justifiable.

Objectives: The objective of the present study was to review research on secondhand smoke (SHS) exposure in outdoor settings.

Data sources: We conducted different searches in PubMed for the period prior to September 2012. We checked the references of the identified papers, and conducted a similar search in Google Scholar.

Study selection: Our search terms included combinations of "secondhand smoke," "environmental tobacco smoke," "passive smoking" OR "tobacco smoke pollution" AND "outdoors" AND "PM" (particulate matter), "$PM_{2.5}$" (PM with diameter $\leq$ 2.5 μm), "respirable suspended particles," "particulate matter," "nicotine," "CO" (carbon monoxide), "cotinine," "marker," "biomarker" OR "airborne marker." In total, 18 articles and reports met the inclusion criteria.

Results: Almost all studies used $PM_{2.5}$ concentration as an SHS marker. Mean $PM_{2.5}$ concentrations reported for outdoor smoking areas when smokers were present ranged from 8.32 to 124 μg/m^3 at hospitality venues, and 4.60 to 17.80 μg/m^3 at other locations. Mean $PM_{2.5}$ concentrations in smoke-free indoor settings near outdoor smoking areas ranged from 4 to 120.51 μg/m^3. SHS levels increased when smokers were present, and outdoor and indoor SHS levels were related. Most studies reported a positive association between SHS measures and smoker density, enclosure of outdoor locations, wind conditions, and proximity to smokers.

Conclusions: The available evidence indicates high SHS levels at some outdoor smoking areas and at adjacent smoke-free indoor areas. Further research and standardization of methodology is needed to determine whether smoke-free legislation should be extended to outdoor settings.

Artículo 4: Secondhand smoke in outdoor settings: smokers' consumption, non-smokers' perceptions, and attitudes toward smoke-free legislation in Spain. Sureda X, Fernández E, Martínez-Sánchez JM, Fu M, López MJ, Martínez C, Saltó E. [ENVIADO A PUBLICAR]

Objective: To describe where smokers smoke outdoors, where non-smokers are exposed outdoors to SHS, and attitudes toward smoke-free outdoor areas after the implementation of national smoke-free legislation.

Design: This cross-sectional study. The survey was conducted between June 2011 and March 2012 (n=1,307 participants).

Setting: Barcelona, Spain.

Participants: Representative, random sample of the adult (≥16 years) population.

Primary and secondary outcome: Proportion of smoking and prevalence of exposure to SHS in the various settings according to type of enclosure. Percentages of support for outdoor smoke-free policies according to smoking status.

Results: Smokers reported smoking most in bars and restaurants (54.8%) followed by outdoor places at work (46.8%). According to non-smokers, outdoor SHS exposure was highest at home (42.5%) and in bars and restaurants (33.5%). Among non-smoking adult students, 90% claimed exposure to SHS on university campuses. There was great support for banning smoking in the majority of outdoor areas, which was stronger among non-smokers than smokers. Over 70% of participants supported smoke-free playgrounds, schol and high school courtyards, and the grounds of healthcare centers.

Conclusion Extending smoking bans to selected outdoor settings should be considered in further tobacco control interventions to protect non-smokers from SHS exposure and to establish a positive model for youth. The majority of public support for some outdoor smoke-free areas suggests that it is feasible to extend smoking bans to additional outdoor settings.

5. PUBLICACIONES

Impact of the Spanish smoke-free legislation on adult, non-smoker exposure to secondhand smoke: cross-sectional surveys before (2004) and after (2012) legislation.

Sureda X, Martínez-Sánchez JM, Fu M, Pérez-Ortuño R, Martínez C, Carabasa E, López MJ, Salto E, Pascual JA, Fernández E. PLoS ONE. 27; 9(2): e89430. doi: 10.1371/journal.pone.0089430

Impact of the Spanish Smoke-Free Legislation on Adult, Non-Smoker Exposure to Secondhand Smoke: Cross-Sectional Surveys before (2004) and after (2012) Legislation

Xisca Sureda[1,2,3], Jose M. Martínez-Sánchez[1,2,4], Marcela Fu[1,2,3], Raúl Pérez-Ortuño[5], Cristina Martínez[1,2,6,7], Esther Carabasa[1,2,6], María J. López[8,9,10], Esteve Saltó[11,12], José A. Pascual[5,13], Esteve Fernández[1,2,3,6]*

1 Tobacco Control Unit, Cancer Control and Prevention Programme, Institut Català d'Oncologia-ICO, L'Hospitalet de Llobregat, Barcelona, Spain, **2** Cancer Control and Prevention Group, Institut d'Investigació Biomèdica de Bellvitge-IDIBELL, L'Hospitalet de Llobregat, Barcelona, Spain, **3** Department of Clinical Sciences, School of Medicine, Universitat de Barcelona, L'Hospitalet del Llobregat, Barcelona, Spain, **4** Biostatistic Unit, Department of Basic Science, School of Medicine and Health Sciences, Universitat Internacional de Catalunya, Satn Cugat del Valles, Spain, **5** Bioanalysis Research Group, Neuropsychopharmacology Programme, IMIM-Hospital del Mar Research Institute, Parc de Recerca Biomèdica de Barcelona, Barcelona, Spain, **6** Catalan Network of Smoke-free Hospitals, Insitut Català d'Oncologia, L'Hospitalet de Llobregat, Barcelona, Spain, **7** Department of Nursing, School of Medicine and Health Sciences, Universitat Internacional de Catalunya, Sant Cugat del Valles, Spain, **8** Evaluation and Interventions Methods Service, Agència de Salut Pública de Barcelona, Barcelona, Spain, **9** Biomedical Research Centre Network for Epidemiology and Public Health (CIBERESP), Agència de Salut Pública de Barcelona, Barcelona, Spain, **10** Institut d'Investigació Biomèdica-IBB Sant Pau, Barcelona, Spain, **11** Public Health Agency, Ministry of Health, Generalitat de Catalunya, Barcelona, Spain, **12** Department of Public Health, School of Medicine, Universitat de Barcelona, Barcelona, Spain, **13** Department of Experimental and Health Sciences, Universitat Pompeu Fabra, Parc de Recerca Biomèdica de Barcelona, Barcelona, Spain

Abstract

Background: In 2006, Spain implemented a national smoke-free legislation that prohibited smoking in enclosed public places and workplaces (except in hospitality venues). In 2011, it was extended to all hospitality venues and selected outdoor areas (hospital campuses, educational centers, and playgrounds). The objective of the study is to evaluate changes in exposure to secondhand smoke among the adult non-smoking population before the first law (2004-05) and after the second law (2011–12).

Methods: Repeated cross-sectional survey (2004–2005 and 2011–2012) of a representative sample of the adult (≥16 years) non-smoking population in Barcelona, Spain. We assess self-reported exposure to secondhand smoke (at home, the workplace, during leisure time, and in public/private transportation vehicles) and salivary cotinine concentration.

Results: Overall, the self-reported exposure to secondhand smoke fell from 75.7% (95%CI: 72.6 to 78.8) in 2004-05 to 56.7% (95%CI: 53.4 to 60.0) in 2011–12. Self-reported exposure decreased from 32.5% to 27.6% (−15.1%, $p<0.05$) in the home, from 42.9% to 37.5% (−12.6%, $p=0.11$) at work/education venues, from 61.3% to 38.9% (−36.5%, $p<0.001$) during leisure time, and from 12.3% to 3.7% (−69.9%, $p<0.001$) in public transportation vehicles. Overall, the geometric mean of the salivary cotinine concentration in adult non-smokers fell by 87.2%, from 0.93 ng/mL at baseline to 0.12 ng/mL after legislation ($p<0.001$).

Conclusions: Secondhand smoke exposure among non-smokers, assessed both by self-reported exposure and salivary cotinine concentration, decreased after the implementation of a stepwise, comprehensive smoke-free legislation. There was a high reduction in secondhand smoke exposure during leisure time and no displacement of secondhand smoke exposure at home.

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* E-mail: efernandez@iconcologia.net

Introduction

Exposure to secondhand smoke (SHS) has been causally associated with many adverse health effects[1]. Worldwide, it has been estimated that, in 2004, exposure to SHS was responsible for 379,000 deaths due to ischemic heart disease, 21,400 deaths due to lung cancer, 165,000 due to lower respiratory infections, and 36,900 due to asthma[2]. In Spain, between 1228 and 3237 deaths due to lung cancer and ischemic heart diseases have been attributed to SHS exposure[3].

Exposure to SHS can occur in different settings, including in the home, at the workplace, in other private and public places (bars, restaurants, cafes, etc.), and inside public and private transport vehicles. Questionnaires, biomarkers, and airborne markers have been used to evaluate SHS among non-smokers. The prevalence of SHS exposure in adult non-smokers varies considerably, depending on the country, the development of the tobacco epidemic[4], the comprehensiveness of smoke-free legislation, and the location of exposure to SHS. Worldwide, 33% of male non-smokers and 35% of female non-smokers were exposed to SHS in 2004[2]. In Spain, 75% of the adult non-smoking population was exposed to SHS in 2006; of those, 26.4% was exposed at home and 39.8% at work or an educational venue[5]. In Barcelona, in the period of 2004–2005, the prevalence of self-reported exposure to SHS among non-smokers in all settings was similar to that of the whole country[6].

On the 1st of January, 2006, a smoke-free legislation (Law 28/2005) was implemented in Spain to protect the health of non-smokers. The legislation banned smoking in all public and work places, with some exceptions in hospitality venues (no ban in venues of less than 100 m^2, and 'smoking areas' were allowed in venues over 100 m^2)[7]. Some previous studies evaluated the impact of that law and showed important reductions in the exposure to SHS at the workplace[8], but no significant changes occurred either at home or during leisure time[9]; furthermore, and importantly, exposure to SHS was not reduced in bars or restaurants[8,10,11]. Due to the evidence provided by those evaluations, and after intensive advocate work, the law was amended[12]. On the 2nd of January, 2011, a new legislation (Law 42/2010) was established to amend Law 28/2005. The new Spanish legislation extended the smoking ban to all hospitality venues (bars, cafes, pubs, restaurants, discos, and casinos) without exception,[13] and extended the ban to some outdoors areas, including hospital premises, educational campuses, and playgrounds. The law included economic penalties for infringements and its enforcement is a responsibility of the regional and local health authorities. After the implementation of the new law, SHS levels (measured as the quantities of airborne nicotine and PM2.5) have decreased more than 90% in hospitality venues[14,15]. However, the impact of the more restrictive smoke-free legislation has not been assessed for SHS exposure in the general population.

The objective of this study was to evaluate whether a measurable change in SHS exposure could be detected in the adult non-smoking population with the implementation of the stepped Spanish smoke-free legislation. We compared SHS exposure measurements (self-report data and levels of salivary cotinine) before the first law (2004–05) and after the second law (2011–12) legislation.

Methods

Study design and selection of study participants

This study had a repeated cross-sectional design. We included a representative, random sample of the population of Barcelona (Spain). Surveys were conducted before and after the implementation of smoke-free legislation. The pre-legislation data were obtained between March 2004 and December 2005. We used the same strategy to collect the post-legislation data between June 2011 and March 2012. Detailed information about the pre-legislation survey (sampling, face-to-face questionnaire, saliva collection, and cotinine analysis) has been provided in previous studies[6,16].

In brief, for each survey, we determined a sample size of 1,560 people with standard procedures (α error of 5%, beta error of 20%, and 20% losses for independent samples). The pre-legislation survey (years 2004–05), included a final sample of 1,245 individuals and the post-legislation survey included a final sample of 1,307 individuals. These sample sizes were sufficient to detect 10% changes in the amount of exposure to SHS at the workplaces or at home (under the least favorable conditions) and a 40% difference in salivary cotinine concentrations between the two surveys. Sample size calculations were performed with 5.2 GRANMO MS Windows (http://www.imim.es/media/upload/arxius/grmw52.zip).

We obtained data and addresses for Barcelona residents from the updated official city census (years 2001 and 2010) provided by the Municipal Institute of Statistics of Barcelona. Individuals aged 16 years and older were eligible to participate in the study. A letter was mailed to eligible individuals to inform them about the purpose of the study and that they had been selected at random. The letter also informed them that the study required a visit from an interviewer that would administer the questionnaire and collect a saliva sample. The individuals were informed that they were free to decline participation, and that they could find out more about the study with a telephone call or email; the contact information was provided in the letter. Participants that could not be located after several attempts (at different times of the day and different days of the week) and those that declined to participate in the study were replaced at random. The replacements were chosen from eligible individuals of the same sex, within a 5-year age group, and within the same district of residence. Substitutions accounted for 50.7% and 54.6% of the pre- and post-legislation surveys, respectively. Individuals that agreed to participate were interviewed at home by trained interviewers. Participants were asked to sign an informed consent form before proceeding with the face-to-face interview. In case of subjects aged 16 an 17, parental written consent was obtained. The same questionnaire was used in both surveys (on traditional paper in the pre-legislation survey and in computer-assisted form in the post-legislation survey). Additional questions were included in the second survey regarding the smoke-free legislation. The questionnaire included information on socio-demographics, tobacco consumption, self-assessed exposure to SHS in different settings (at home, work/educational venues, during leisure time, and in public and private transportation vehicles), and attitudes toward smoking restrictions. After completing the questionnaire, respondents were asked to provide a sample of saliva for the cotinine analysis, and weight and height were measured. The Research and Ethics Committee of Bellvitge University Hospital approved the study protocols and the informed consent forms, including parental written consent.

Self-reported SHS exposure of non-smokers

Non-smokers were defined as individuals that, at the time of the interview, reported that they did not smoke, and they had a salivary cotinine concentration $\leq$10 ng/mL [17]. This group included individuals that had never smoked and ex-smokers.

Exposure to SHS at home was determined with two questions: "Currently, how many individuals per day usually smoke inside your home?" and "During the past week, how many cigarettes (per day) have been smoked in your presence inside your home?" Answers were gathered for typical working and non-working days. Based on these two questions, we derived a dichotomous variable of exposure to SHS at home: (1) non-exposed individuals, which included those with no exposure according to answers to both questions, and (2) exposed individuals, which included all others. *Exposure to SHS at work or an education venue* was determined with two questions: "Does anybody smoke in close proximity to you at work?" and "How many hours per day do you think you are exposed to tobacco smoke at your education venue?" We also derived a dichotomous variable of exposure to SHS at the workplace and/or education venue: (1) non-exposed individuals, which included those with no exposure according to answers to both questions, and (2) exposed individuals, which included all others. *Exposure to SHS at leisure time* was determined with the question "How much time have you spent in any place with tobacco smoke that was not home or work?" The answers were gathered for typical working and non-working days. For analysis, we derived a dichotomous variable of exposure to SHS during leisure time: (1) non-exposed individuals, which included those with no exposure according to the answer to the question, and (2) exposed individuals, which included all others. *Exposure to SHS at public and private transportation* was determined with two questions: "During the last week, were you in a public transportation vehicle while someone was smoking?" and "During the last week, were you in a private transportation vehicle while someone was smoking?" Based on these two questions, we derived a dichotomous variable of exposure to SHS in public and private transportation vehicles: (1) non-exposed individuals, which included those with no exposure according to answers to both questions, and (2) exposed individuals, which included all others. *Exposure to SHS in any setting* was defined as exposure in at least one of the above mentioned settings.

Salivary cotinine

We asked the participants to provide a saliva sample to determine the cotinine levels. Cotinine is the main metabolite of nicotine; it is a stable, specific, sensitive biomarker of tobacco smoke in biological fluids, with a half-life of 15–17 h, and it reflects SHS exposure in the last 5–7 days[18]. We followed the same protocol in both surveys for collecting the saliva sample[6,16]. Briefly, participants were asked to rinse their mouths and then suck on a lemon candy (Smint^R) to stimulate saliva production. They were asked to provide about 9 mL of saliva by spitting into a funnel placed in a test tube. The sample was separated into 3 mL aliquots and frozen at -80°C for storage. The frozen samples were sent to the Bioanalysis Research Group of IMIM (Hospital del Mar Medical Research Institute) in Barcelona. Salivary samples from the pre-legislation survey were analyzed in 2007 with gas chromatography followed by mass spectrometry detection (GC/MS). The limit of quantification was 1 ng/mL and the limit of detection was 0.3 ng/mL. Salivary samples from the post-legislation survey were analyzed in 2012 with liquid chromatography coupled with tandem mass spectrometry (LC/MS/MS) with multiple reaction monitoring. The limit of quantification was 0.1 ng/mL and the limit of detection was 0.03 ng/mL; the quantification error was <15%. Because the latter method was more sensitive and had a lower limit of quantification than the former method, all available saliva samples from the pre-legislation survey with cotinine concentrations below 1 ng/mL (n = 245) were reanalyzed in 2012 with the LC-MS/MS method. The values from the second analysis were used in the statistical analysis. To determine the reliability of cotinine values from the pre-legislation survey, 41 saliva samples with previous values between 1 and 10 ng/mL were chosen at random, and cotinine was assessed with the LC/MS/MS. This analysis showed very low variation (less than +/− 1 ng/mL) in the concentration values obtained with both methods of analysis.

Statistical analysis

We calculated prevalence rates (%) and 95% confidence intervals (CI) for exposure to SHS among non-smokers in the different settings. Results were stratified by sex, age (16–44, 45–64, and ≥65 years), and educational level (less than primary and primary school, secondary school, and university). The data were fitted with multivariate log-binomial models to assess the prevalence ratios (PR) and 95% CI of exposure to SHS among non-smokers before and after the implementation of the legislation. The models were adjusted for sex, age, and educational level. Geometric means (GM) and geometric standard deviations (GSD) were computed to describe the cotinine concentrations among non-smokers, due to its skewed distribution[17,19]. The data were fitted with generalized linear regression models of the log-transformed salivary cotinine concentration, adjusted for potential confounders. We also estimated the percentage changes in salivary cotinine concentration by comparing the geometric mean of the concentrations before and after the legislation. Samples with values below the limit of detection were assigned a value of 0.05 ng/mL (half the limit of detection value). Statistical analyses were performed with SPSS v17.0 and Stata 10.

Results

Sample

A total of 2,552 participants were interviewed; 1,245 subjects were in the pre-legislation survey and 1,307 were in the post-legislation survey. The samples were similar in the proportions of men and women, but we found significant differences in age and educational level. 879 (70.6%) participants in the pre-legislation survey and 947 (72.5%) participants in the post-legislation survey were self-reported non-smokers. Of the non-smokers, 110 (62 in the pre-legislation and 48 in the post-legislation surveys) were not included in the analysis, because they did not provide a saliva sample; in addition, 12 (10 in the pre-legislation and 2 in the post-legislation survey) were excluded, because cotinine analysis was not possible (i.e., insufficient sample). 83 non-smokers from the pre-legislation survey and 19 from the post-legislation survey were excluded, because they had cotinine concentrations consistent with active smoking (>10 ng/mL). Therefore, the final sample for analysis included a total of 1602 non-smokers; 724 (58.2% of those interviewed) before the legislation and 878 (67.2% of those interviewed) after the legislation (Figure 1).

Changes in self-reported exposure to SHS

The prevalence of self-reported exposure to SHS in any setting fell from 75.7% in 2004–05 to 56.7% in 2011–12 (relative reduction −25.1, $p<0.001$) (Table 1); this included reduced exposures in the home, from 32.5% to 27.6% (−15.1%, $p<0.05$); at work/education venue, from 42.9 to 37.5 (−12.6%, $p = 0.11$); during leisure time, from 61.3% to 38.9% (−36.5%, $p<0.001$); and in public transportation vehicles, from 12.3% to 3.7% (−69.9%, $p<0.001$). Overall, the prevalence of SHS exposure declined more sharply among women than among men (29.2% vs. 19.4%, $p<0.001$). Non-smoking adults between 45 and 64 years old showed the greatest reduction in the prevalence of SHS exposure (−34.3%, $p<0.001$); the prevalence in adults aged 65 years or older was reduced by 25.6% ($p<0.001$), and the prevalence in adults between 16 and 44 was reduced by 24.6% ($p<0.001$) (Appendix S1). The prevalence of exposure to SHS was reduced to a similar extent for individuals with different educational levels (Appendix S1). After controlling for sex, age, and educational level, self-reported exposure to SHS in any setting after the legislation was significantly reduced (PR: 0.46; 95%CI:

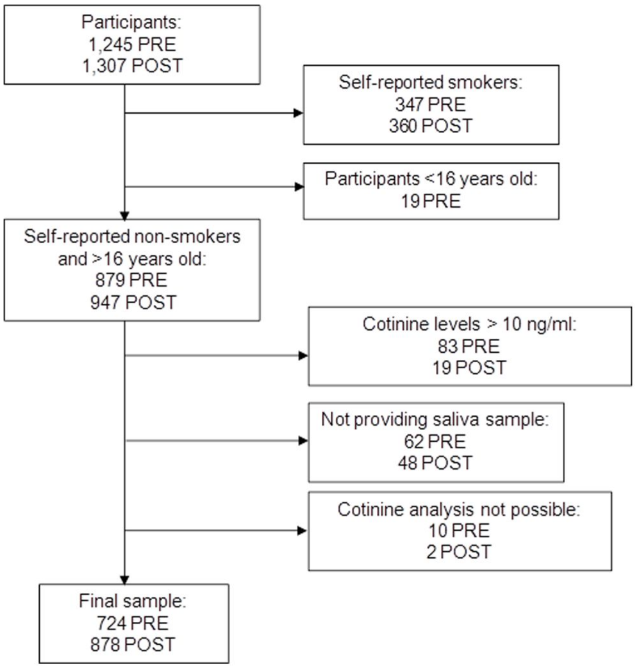

Figure 1. Flow chart with the sample selection in both surveys (PRE: 2005–06 and POST: 2011–12) and exclusions from the initial sample. Footnote to Figure 1. From the initial sample in each survey, we excluded people who declared to be smokers and people <16 years old. Among people who declared to be non-smokers, we excluded those with unreliable cotinine levels for non-smokers (this is, they had smoked at the time of the interview). We also excluded people who did not provide the saliva sample or in which the cotinine analysis was not possible because of insufficient sample or technical error.
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0.40 to 0.54), including at home, at work/educational venues, during leisure time, and in public transport vehicles (Table 1).

Changes in salivary cotinine levels

Figure 2 shows the distribution of cotinine values among the non-smokers before and after legislation. The proportion of non-smokers with cotinine concentrations below the quantification limit (0.1 ng/mL) increased from 7.3% (53 samples) before the legislation to 53.2% (467 samples) after the legislation.

Table 2 compares the geometric mean values of salivary cotinine concentrations before and after the legislation among non-smokers. The results are stratified according to socio-demographic variables. The geometric mean of the cotinine concentrations among all adult non-smokers fell from 0.93 ng/mL before the legislation to 0.12 ng/mL ($p<0.001$) after the legislation. After adjusting for sex, age, and educational level, the reduction in cotinine concentration was 87.6% ($p<0.001$). The adjusted reduction in cotinine concentration after the implementation of the law was similar for participants of all ages. However, adult non-smokers with a university education showed the greatest adjusted reduction in cotinine concentration (Table 2).

Discussion

This was the first study to evaluate using both self-reports and a personal biomarker of exposure to SHS the impact of the stepped Spanish smoke-free legislation (laws 28/2005 and 42/2010) on SHS exposure in different settings among adult non-smokers from the general population. We found that self-reported exposure to SHS and salivary cotinine levels significantly decreased after the implementation of the legislation. This reduction was observed at workplaces, during leisure time, and even in settings not regulated by the law, like in the home and public transportation.

Self-reported second-hand smoke exposure

The reduction in SHS exposure between 2004–05 and 2011–12 was greater for women than men and for individuals aged 45 to 64 compared with other age groups. Haw and Gruer[20] also evaluated changes in self-reported exposure to SHS among adult non-smokers after the implementation of smoke-free legislation in Scotland. They found that, after legislation, self-reported SHS exposure fell for all the settings assessed. Similarly, we observed a 25.1% reduction in SHS exposure among participants exposed in any setting. However, we are not able to distinguish the effects of the first (28/2015) and second (42/2010) bans on the reductions observed. Previous evaluations of the 28/2005 law showed important reductions in the exposure to SHS at the workplace[8], but that law did not affect the exposure to SHS at home or during leisure time[9,11] nor in bars or restaurants[8,10]. In the present study, the highest reductions in self-reported SHS exposure were observed in public transportation vehicles and during leisure time.

Data from another study in Spain showed that both airborne nicotine and PM2.5 decreased by more than 90% in bars and restaurants after the implementation of law 42/2010[14]. At the population level, a reduction in the self-reported exposure to SHS during leisure time after 2010 has been also oberved in Galicia[11]. Those results and the results obtained in the present study demonstrated the importance of the new legislation (Law 42/2010), which extended the prohibition of smoking to all hospitality venues without exception. These venues were places where young, adult non-smokers were mostly exposed during their leisure time. We also observed a significant relative reduction (15.1%) in the home, which confirmed no displacement of smoking to this setting but an unexpected positive side-effect of the smoke-free legislation. This finding agreed with other previous studies performed at the individual level[20–24] and at the ecological level[25]. We found a 12.6% reduction in self-reported exposure to SHS at work and educational venues. Previous studies in Spain[9,11] showed greater reductions in self-reported exposure at work between 2005 and 2006. However, our results were consistent with another study,[5] which showed that 39.8% of non-smokers were exposed to SHS at work and educational venues after the implementation of Law 28/2005 (which prohibited smoking in the workplace, but not hospitality venues).

Cotinine concentrations

The proportion of non-smokers that had undetectable cotinine concentrations increased from 7.3% before the 28/2005 law to 53.2% after the implementation of the 42/2010 law. Our results confirmed the positive impact of smoke-free laws on SHS exposure at the population level. For example, after legislation, in New York, Bauer et al.[26] found an increase in the proportion of respondents with cotinine concentrations below the detection limit (from 32.5% to 52.4%); in Scotland, Haw and Gruer[20] also observed an increase in individuals with undetectable cotinine (from 11.3% to 27.6%); and, in England, Sims et al.[27] found that the odds of having undetectable cotinine were 1.5 times higher than before the legislation.

In addition to this shift in the distribution of the non-smoking population towards lower levels of cotinine, the mean concentration declined from 0.93 ng/mL to 0.12 ng/mL (adjusted reduction of 87.6%). This reduction in cotinine concentration was greater than those obtained after the implementation of smoke-free

Table 1. Self-reported exposure to secondhand smoke in non-smokers before (2004–05) and after (2011–12) the smoke-free legislation, Barcelona, Spain; results are stratified by setting.

Self-reported exposure to secondhand smoke	n	% of non-smokers exposed (95% CI)	Prevalence ratio* (95% CI)
Any setting**			
Before the legislation	720	75.7 (72.6–78.8)	1
After the legislation	871	56.7 (53.4–60.0)	0.46 (0.40 to 0.54)
Home**			
Before the legislation	721	32.5 (29.1–35.9)	1
After the legislation	878	27.6 (24.6–30.6)	0.78 (0.65 to 0.94)
Work/education venues**			
Before the legislation	364	42.9 (37.8–48.0)	1
After the legislation	507	37.5 (33.3–41.7)	0.79 (0.63 to 0.98)
Leisure time**			
Before the legislation	723	61.3 (57.7–64.9)	1
After the legislation	872	38.9 (35.7–42.1)	0.38 (0.32 to 0.44)
Public transportation **			
Before the legislation	626	12.3 (9.7–14.9)	1
After the legislation	669	3.7 (2.3–5.1)	0.26 (0.16 to 0.41)
Private transportation**			
Before the legislation	585	9.4 (7.0–11.8)	1
After the legislation	616	10.7 (8.3–13.1)	0.97 (0.67 to 1.41)

*Based on multivariate log-binomial models, adjusted for sex, age, and educational level.
**The figures do not sum the total because of missing values.
doi:10.1371/journal.pone.0089430.t001

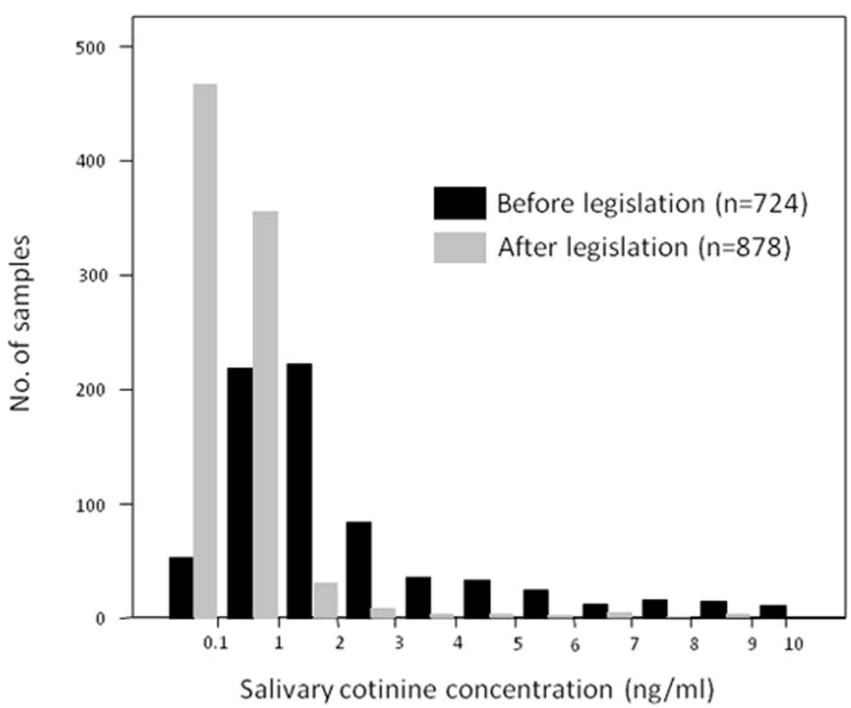

Figure 2. Distribution of salivary cotinine concentrations (ng/mL) among the non-smoker adult population, before (2004–05) and after (2011–12) the smoke-free legislation, in Barcelona, Spain.
doi:10.1371/journal.pone.0089430.g002

Table 2. Change in the geometric means of salivary cotinine concentrations (ng/mL) before (2004–05) and after (2011–12) the smoke-free legislation, Barcelona, Spain; results are stratified according to socio-demographic variables.

	Before legislation		After legislation		Percentage of change* (95% CI)
	N	GM (GSD) (ng/mL)	N	GM (GSD) (ng/mL)	
All subjects	724	0.93 (4.01)	878	0.12 (3.12)	87.6 (76.7–102.0)
Sex					
Men	296	1.11 (3.65)	380	0.12 (2.91)	89.4 (80.6–102.1)
Women	428	0.82 (4.22)	498	0.12 (3.28)	86.1 (74.4–102.7)
Age (years)**					
16–44	236	1.00 (3.66)	361	0.12 (3.09)	88.0 (78.1–102.7)
45–64	234	0.82 (4.17)	254	0.13 (3.18)	85.4 (73.9–104.1)
≥65	251	0.98 (4.19)	263	0.11 (3.10)	89.2 (80.6–102.9)
Educational level**					
Less than primary and primary	342	0.87 (4.16)	236	0.12 (3.27)	86.1 (79.4–103.5)
Secondary	132	0.97 (3.95)	341	0.14 (3.28)	85.2 (73.7–104.3)
University	249	0.98 (3.83)	300	0.10 (2.75)	90.2 (82.2–102.1)

GM: Geometric mean.
GSD: Geometric standard deviation.
*Based on the adjusted geometric mean derived from a generalized linear model that included all the variables in the table.
**The figures do not sum the total because of missing values.
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legislation in New York[26], Scotland[20], and England[27] (reductions of 47%, 39%, and 27%, respectively). The larger decrease in Spain might be explained by the fact that the salivary cotinine concentrations among non-smokers in our study (0.93 ng/mL) before the 28/2005 legislation was 2 to 9 times higher than salivary cotinine concentrations obtained in New York[26], England[27], and Scotland[20] before the smoke-free bans (0.078 ng/mL, 0.14 ng/mL, and 0.43 ng/mL, respectively); the post-legislation concentrations were similar in the four different populations. In the absence of smoke-free legislation, the higher salivary cotinine levels in Spain among non-smokers (higher SHS exposure) could be explained by the higher prevalence of smoking in the population. After the implementation of smoke-free legislation, SHS exposure would decrease, regardless of the prevalence of smoking.

Strengths and limitation of the study

One potential limitation of the study was an information bias derived from the use of a questionnaire. Self-reported, adult non-smokers represented 70.6% of the participants interviewed in the pre-legislation survey and 72.5% in the post-legislation survey. These prevalences were consistent with data from the 2006 and 2011 Spanish National Health Interview Surveys (Ministerio de Sanidad y Consumo: Encuesta Nacional de Salud 2006, 2013). This limitation was reduced by using an objective, specific biomarker of SHS exposure, and by asking the participants about their exposure in both private and public places, including the home, work/educational venues, leisure venues, and transportation vehicles. Thus, we covered the primary settings where SHS exposure can occur.

Another limitation is that we did not have data after the first law and previous to the second law, thus preventing us to elucidate the separate effects of both laws, as would have been of great interest given the stepped nature of the Spanish smoke-free legislation. However, the interpretation of our results together with the previous studies focused on the first law allows to globally evaluating the effects of the Spanish smoke-free laws.

This was a repeated cross-sectional study, which was potentially more likely to be biased than a longitudinal study. However, longitudinal studies can be subject to some bias, due to the loss of participants in the follow-up, which reduces its advantages. Nevertheless, repeated cross-sectional surveys that include a biological marker have been shown to be a valid method for evaluating smoke-free legislation[18,28,29].

This study included representative, random samples of the population of Barcelona (Spain) and it evaluated the impact of smoke free legislation on exposure to SHS with a combination of self-reported exposure and cotinine as an objective biomarker of SHS exposure. To minimize differences between the two collection periods, we used the same strategy in collecting the pre and post legislation data. Additionally, the fieldwork was performed during different days of the week, including weekends, and in different months to avoid systematic biases due to potential seasonal and timing aspects of data collection. The method for analyzing cotinine in the post legislation survey was more sensitive and had a lower limit of quantification than that used in the pre legislation survey. However, we reanalyzed the samples in the pre-legislation survey with the new method, and found satisfactory agreement in the results. Individuals that declined to participate were replaced at random with individuals with the same characteristics to prevent problems with sample size and selection biases. Although we had a high percentage of substitutions in both surveys, we obtained a high percentage of non-smokers that provided saliva samples in the pre- and post- legislation surveys (92.9% and 94.9%, respectively); this proportion was higher than those observed in similar assessments in Scotland (64.8% and 63.1%, respectively) [20] and in New York (33%, overall)[26].

Conclusions

This study showed that the implementation of a stepped smoke-free legislation (laws 28/2005 and 42/2010) was accompanied by a large reduction in SHS, both self-reported and assessed by means of salivary cotinine levels, in the adult non-smoking population in

Barcelona, Spain. The strategy of strengthening Law 28/2005 to hospitality venues without exceptions was clearly effective. We observed a high reduction in SHS exposure during leisure time, and a reduction in SHS exposure at home contrary to the speculative tobacco industry hypothesis of displacement of smoking from public to private places. Based on the results of this study, comprehensive tobacco control policies were effective in reducing SHS exposure. Thus, over time, the law will result in a reduction in morbidity and mortality among nonsmoking adults.

Supporting Information

Appendix S1 Prevalence of self-reported exposure to secondhand smoke in non-smokers measured before (2004-05) and after (2011–12) the smoke-free legislation, Barcelona, Spain; results are stratified by sex, age, educational level, and settings.
(DOCX)

Checklist S1 STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies.
(DOCX)

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Author Contributions

Conceived and designed the experiments: EF. Performed the experiments: XS MF CM EC ES EF. Analyzed the data: XS JMMS MF MJL. Contributed reagents/materials/analysis tools: RPO JAP. Wrote the paper: XS EF. Critically revised the manuscript and contributed to the final version: XS JMMS MF RPO CM EC MJL ES JAP EF.

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Smoking prevalence and attributes of smokers of manfactured and roll-your-own cigarettes in Spain (2004-2005 and 2011-2012): a chnging pattern.

Xisca Sureda, Esteve Fernández, Marcela Fu, Cristia Martínez, Esteve Saltó. Jose M Martínez-Sánchez. [ENVIADO A PUBLICAR]

Smoking prevalence and attributes of smokers of manufactured and roll-your-own cigarettes in Spain (2004-2005 and 2011-2012): a changing pattern.

Xisca Sureda[a,b,c], Esteve Fernández[a,b,c,d], Marcela Fu[a,b,c] , Cristina Martínez[a,b,d,e], Esteve Saltó[f,g]. Jose M Martínez-Sánchez[a,b,h]. [ENVIADO A PUBLICAR]

[a]*Tobacco Control Unit, Cancer Control and Prevention Programme, Institut Català d'Oncologia-ICO. Gran Via de L'Hospitalet 199-201, 08908 L'Hospitalet de Llobregat (Barcelona), Spain*

[b]*Cancer Control and Prevention Group, Institut d'Investigació Biomèdica de Bellvitge-IDIBELL, Gran Via de L'Hospitalet 199-201, 08908 L'Hospitalet de Llobregat (Barcelona), Spain*

[c]*Department of Clinical Sciences, School of Medicine, Universitat de Barcelona, Carretera de la Feixa llarga s/n. 08908 L'Hospitalet del Llobregat (Barcelona), Spain*

[d]*Catalan Network of Smoke-free Hospitals, Insitut Català d'Oncologia. Gran Via de L'Hospitalet 199-201, 08908 L'Hospitalet de Llobregat, Barcelona, Spain*

[e]*Department of Nursing, School of Medicine and Health Sciences, Universitat Internacional de Catalunya, Carrer Josep Trueta s/n. 08915 Sant Cugat del Valles, Spain*

[f]*Direcció General de Planificació i Recerca en Salut, Generalitat de Catalunya, Travessera de les Corts, 131-159, 08028 Barcelona, Spain*

[g]*Department of Public Health, School of Medicine, Universitat de Barcelona, Carrer Casanova 143, 08036 Barcelona, Spain.*

[h]*Biostatistic Unit, Department of Basic Science, School of Medicine and Health Sciences, Universitat Internacional de Catalunya, Carrer Josep Trueta s/n. 08915 Sant Cugat del Valles,*

Correspondence to:

Xisca Sureda Llull, BPharm, MPH

Tobacco Control Research Unit.

Institut Català d'Oncologia.

Av. Gran Via de l'Hospitalet, 199-203.

08908 l'Hospitalet de Llobregat (Barcelona), Spain

E-mail: fsureda@iconcologia.net

ABSTRACT

Background: Smoking is the leading cause of preventable morbidity and premature mortality worldwide. The objectives of the present study were to describe smoking prevalence and compare the smoking attributes of smokers according to the type of tobacco product consumed in the adult population.

Methods: Repeated cross-sectional survey (2004-2005 and 201-2012) of a representative sample of the adult (≥16 years) population in Barcelona, Spain. We assess self-reported tobacco consumption, smoking attributes of self-reported smokers, and salivary cotinine concentration.

Results: We observed that smoking prevalence decreased over the period 2004-2005 and the period 2011-2012 (from 26.6% to 24.1% in self-reported daily smokers). The prevalence of smokers that reported to use manufactured cigarettes declined from 20.4% in 2004-2005 to 16.4% in 2011-2012. Roll-your-own cigarettes users increased from 0.3% to 3.5%. Roll-your-own cigarettes users were higher among men than women (18.8% vs 7.9%), young people (19.8% compared with 5.2% among people aged 45-65 and 7.1% among ≥65 years old) and among participants with secondary and university education compared with people with less than primary and primary education (14.1%; 16.1%; and 9.1%, respectively). We did not observed differences in continine concentrations according to the type of tobacco product smoked.

Conclusions: To systematically collect data on smoking prevalence and smokers attributes on representative samples of the population is necessary for policymakers to develop efficient tobacco control interventions and recommendations to the population. Considering the observed increase among roll-your-own cigarettes users and the unclear consequences of their use on health, policymakers should aim to implement tax policies to equalise the prices of different types of tobacco products.

INTRODUCCTION

Smoking is the leading cause of preventable morbidity and premature mortality worldwide(1). Tobacco use kills more than 5 million people a year and, unless urgent action is taken, tobacco's annual death toll is expected to rise to more than eight million by year 2030(1). In Spain, there were 53,155 deaths attributable to smoking in 2006 among individuals ≥ 35 years, representing 14.7% (25.1% in men and 3.4% in women) of all deaths in the same population(2).

In the last years, as a result of the growing awareness by the public about the harmful effects of smoking and tobacco control policies promoted by the WHO Framework Convention on Tobacco Control (FCTC), prevalence rates of tobacco consumption have decreased in many developed countries(3;4). In Spain, by the year 201, smoking prevalence was 27.9% in men and 20.2% in women(5).

It is estimated that smoking bans in public and workplaces are related to a decreased in smoking from 3% to 4% as well as to a reduction in the number of cigarettes smoked(6). Moreover, tobacco control policies favor the denormalization of tobacco, and may be effective in preventing the tobacco consumption among young people(7). However, in Europe, regulations implemented in recent years have not shown a direct effect on tobacco consumption, but the expected trends in the tobacco epidemic were observed. A study in 21 jurisdictions that considered secular trends in the tobacco epidemic found that smoke-free laws were accompanied by a decline in smoking prevalence in 8 of the jurisdictions and that the laws did not affect the trends in 13 others(8).

In Spain, stepwise smoke-free legislation has been implemented in the last decade. Law 28/2005 implemented on the 1st of January, 2006, banned smoking in all public and work places, with some exceptions in hospitality venues(9). No apparent effect on the tobacco consumption beyond the expected secular trend accompanied Law 28/2005(10). Law 42/2010 was established on the 2nd of January, 2011, and extended the smoking ban to all hospitality venues (bars, cafes, pubs, restaurants, discos, and casinos) without exception, and also included some outdoors areas(11).

At the same period the tobacco smoke-free laws were implemented, Spain suffered from the economic crisis. This seems to have favored an increase in the consumption of other tobacco products subject to lower taxes and thus being cheaper for smokers(12). A study that describes trends in the consumption per capita of manufactured cigarettes and roll-your-own cigarettes in Spain shows that daily consumption per capita of manufactured cigarettes decreased on average 3.03% per year, from 7.6 units in 1991 to 3.8 units in 2012, while daily consumption per capita of roll-your-own cigarettes increased on average 14.08% per year, from 0.07 to 0.92 units of 0.5 grams(13).

The objective of this study was to describe smoking prevalence and compare the smoking attributes of smokers according to the type of tobacco product consumed in the adult population measured by self-reported data and levels of salivary cotinine collected in 2004-05 and 2011-12, before and after stepwise smoke-free legislation was implemented in Spain.

Methods

Study design and selection of study participants

This study had a repeated cross-sectional design. We included 2 representative, random sample of the population of Barcelona (Spain). Surveys were conducted before and after the implementation of stepwise smoke-free legislations. The pre-legislation data were obtained between March 2004 and December 2005. We used the same strategy to collect the post-legislation data between June 2011 and March 2012. Detailed information about the pre-legislation survey (sampling, face-to-face questionnaire, saliva collection, and cotinine analysis) has been provided elsewhere(14-16).

In brief, for each survey, we determined a sample size of 1,560 people with standard procedures (error of 5%, beta error of 20%, and 20% losses for independent samples). The pre-legislation survey (years 2004-05), included a final sample of 1,245 individuals and the post-legislation survey included 1,307 individuals.

We obtained data and addresses for Barcelona residents from the updated official city census (years 2001 and 2010) provided by the Municipal Institute of Statistics of Barcelona. Substitutions accounted for 50.7% and 54.6% of the pre- and post-legislation surveys, respectively. Individuals that agreed to participate were interviewed at home by trained interviewers. Participants were asked to sign an informed consent form before proceeding with the face-to-face interview. The same questionnaire was used in both surveys (on traditional paper in the pre-legislation survey and in computer-assisted form in the post-legislation survey). Additional questions were included in the second survey regarding the smoke-free legislation. The questionnaire included information on socio-demographics, tobacco consumption, self-perceived exposure to SHS in different settings, and attitudes toward smoking restrictions. After completing the questionnaire, respondents were asked to provide a sample of saliva for the cotinine analysis, and weight and height were measured. The Research and Ethics Committee of Bellvitge University Hospital approved the study protocols and the informed consent forms.

Self-reported smoking behaviour and smokers' characteristics

Self-reported smoking behaviour was determined with the question: "Which of the following statements describes the best your smoking behavior?". This question categorizes the participants as (1) Daily smokers, defined as individuals that, at the time of the interview, reported that they smoked at least one cigarette per day; (2) Occasional smokers, those reporting that they smoked occasionally; (3) Former smokers, those reporting not smoking at present but they had smoked at least one cigarette per day or occasionally in the past, and (4) Never smokers, those who declared that had never smoked. Self-reported non-smokers (never and former) that had a salivary cotinine concentration > 10 ng/mL were considered missing data since they had cotinine concentration consistent with active smoking(17).

For daily smokers, detailed information was collected on self-reported smoking characteristics: number of cigarettes smoked daily, age when they started smoking, number of cigarettes smoked during the previous 24 and 48 hours, duration of smoking, brand of cigarettes smoked most often, type of tobacco product smoked (manufactured cigarettes, roll-your-own cigarettes, cigars, cigarillos, pipe, snus), use of filter tips, depth and frequency of inhalation, attempts to quit, and use of nicotine gum or patches for smoking cessation.

We also collected information on nicotine dependence with the Fagerström Test for Nicotine Dependence (FTND)(18;19). Based on the FTND scores (range 0–10 points), we classified subjects according to their nicotine dependence (low=0–4; medium=5; high=6–10).

Finally, we registered stage of change based on the Prochaska and DiClemente algorithm(20). We considered three stages of change: (1) the precontemplators, smokers that were not seriously considering quitting within the next 6 months; (2) the contemplators, smokers that were seriously considering quitting within the next 6 months, but not within the next 30 days or smokers that had not attempted to quit for at least 24 hours in the past year, or both; (3) and the preparation stage, smokers that were planning to quit within the next 30 days and had attempted to quit for at least 24 hours in the past year(21;22). In this study, we focused on current daily smokers; therefore, we did not consider the other two stages: action (those who had quit during the past 6 months) and maintenance (those who had quit for more than 6 months).

Salivary cotinine

We asked the participants to provide a saliva sample to determine the cotinine concentrations. Cotinine is the main metabolite of nicotine; it is a stable, specific, sensitive biomarker of tobacco consumption(23). We followed the same protocol in both surveys for collecting the saliva sample and that had been explained in a previous study in detail(16). The limit of quantification was 0.1 ng/mL and the limit of detection was 0.03 ng/mL; the quantification error was <15%.

Statistical analysis

We calculated prevalence rates (%) to characterize smoking behaviour before and after stepwise smoke-free legislation among the population. For daily smokers we computed the proportion of self-reported use of tobacco products consumed before and after the legislation. Results were stratified by sex, age (16–44, 45–64, and ≥65 years), and educational level (less than primary and primary school, secondary school, and university). For continuous variables we considered mean and standard deviation (SD), except for cotinine levels that we used geometric mean (GM) and geometric standard deviation (GSD). For categorical variables we used relative frequency (%) for categorical variables to compare smoking attributes according to the type of tobacco consumed using the post legislation data (2011-2012). GM and GSD were computed to describe the cotinine concentrations among current daily smokers using manufactured cigarettes, roll-your-own cigarettes and using both types of cigarettes and stratified by other smoking characteristics. Samples with cotinine concentrations below the limit of detection were assigned a value of 0.05 ng/ml (half the limit of detection value). All statistical tests were two-sided, and p values of less than 0.05 were considered to be statistically significant. Statistical analyses were performed with SPSS v17.0 and Stata 10.

Results

Sample characteristics and smoking prevalence

A total of 2,552 participants were interviewed; 1,245 subjects in the pre-legislation survey and 1,307 in the post-legislation survey. The samples were similar in the proportions of men and women, but we found significant differences in age and educational level. 19 participants in the pre-legislation survey were excluded since they were <16 years old. Of the self-reported non-smokers (former and never smokers), 110 (62 in the pre-legislation and 48 in the post-legislation surveys) were not included in the analysis, because they did not provide a saliva sample; in addition, 12 (10 in the pre-legislation and 2 in the post-legislation survey) were excluded, because cotinine analysis was not possible (i.e., insufficient sample). 83 non-smokers from the pre-legislation survey and 19 from the post-legislation survey were excluded, because they had cotinine concentrations consistent with active smoking (>10 ng/mL). Therefore, the final sample for analysis included a total of 1,071 participants before the legislation and 1,238 participants after the legislation.

We observed that smoking prevalence decreased from 26.6% in 2004-05 to 24.1% in 2011-12 in self-reported daily smokers; and, from 5.8% to 5.0% in occasional smokers. Self-reported former smokers represented 27.7% of participants in 2004-05 and 26.8% of participants in 2011-12. As shown in **Fig. 1** none of these changes was statistically significant.

The prevalence of daily smokers fell from 32.5% to 29.4% in men (p=0.021), and from 21.7% to 19.3% in women (p=0.580). The decline in smoking prevalence among daily smokers between 2004-05 and 2011-12 was higher among people aged 16-44 (from 36.4% to 29.4%, p=0.001). No substantial changes in daily smokers prevalence were observed among people aged 45 and 64 years old and ≥65 years old (data not shown). When comparing by educational level we observed the highest decrease among participants secondary education (from 38.9% to 26.1%, p<0.001) followed by participants with university education (from 24.3% to 22.00%, p=0.041). Prevalence of daily smokers with less than primary and primary education increased from 21.3% to 23.8% (p=0.861).

Among those current daily smokers of only manufactured cigarettes (n= 206 in 2004-05, and n=165 in 2011-12) we did not observed significant differences of nicotine dependence level and stages of change. Nevertheless, we obtained significant differences in the self-reported number of cigarettes smoked per day (CPD). Heavy smokers (> 20 CPD) were 26.7% before the legislation vs 15.1% after the legislation (p= 0.034). The mean for FTND scores for all daily smokers was 4.97 (SD=2.10) in 2004-2005 and 5.10 (SD= 2.22) in 2011-2012 (p=0.585). The mean for CPD reported for daily smokers was 16.31 (SD=10.58) in 2004-2005 and 15.14 (SD=9.12) in 2011-2012 (p=0.091). The overall GM of salivary cotinine concentration before and after the implementation of the legislation was, respectively, 130.14 (SD=2.33) and 185.05 (SD=2.20) (p< 0.001).

Type of tobacco consumed among self-reported daily smokers

Fig. 2 shows the distribution of daily smokers according to the type of tobacco product smoked. The prevalence of smokers that reported to use manufactured cigarettes (only or combined with other types of tobacco product different from roll-your-own cigarettes) declined from 20.4% in 2004-2005 to 16.4% in 2011-2012. Roll-your-own cigarettes users (only or combined with other types of tobacco product different from manufactured cigarettes) significantly increased from 0.3% to 3.5% and users of both manufactured cigarettes and roll-your-own cigarettes (with or without other types of tobacco product) increased from 0.8% to 1.6% (**Fig. 2**). **Table 1** shows the percent distribution (overall and stratified by socio-demographic characteristics) of daily smokers according to the type of tobacco product consumed, before and after the stepwise legislation. We observed a significant increase of roll-your-own users both in men and women, in people aged 16-44 years old and in people with secondary and higher education level. We observed the same pattern among people aged between 45 and 65 and ≥65 years and participants with less than primary and primary education, but with no statistically significant differences.

Characteristics among daily smokers in 2011-12 according to the use of manufactured and roll-your-own cigarettes

Table 2 shows the smoking attributes (nicotine dependence levels, stages of change, time to first cigarette, cigarettes per day, and frequency and depth of inhalation) of self-reported daily smokers obtained in the 2011-12 survey according to the use of manufactured and roll-your-own cigarettes (manufactured cigarettes only, roll-your-own cigarettes only, and both manufactured and roll-your-own cigarettes only) (n=260). We excluded 58 participants for different reasons (see footnote to **Table 2**), and hence we finally included 202 participants in the analysis. Roll-your-own cigarettes use was higher among men than women (18.8% vs 7.9%), young people (19.8% compared with 5.2% among people aged 45-65 and 7.1% among ≥65 years old) and among participants with secondary and university education compared with people with less than primary and primary education (14.1%; 16.1%; and 9.1%, respectively). Roll-your-own cigarettes users had lower nicotine dependence according to FTND scores compared to only manufactured cigarettes users and users of both manufactured and roll-your-own cigarettes users (52.2%, 40.3%, and 42.9%, respectively). Manufactured cigarettes users reported the highest nicotine dependence levels (45.6% vs 39.1% among roll-your-own cigarettes users) with no significant differences (p=0.151). The majority of smokers were precontemplators, independently of the tobacco product smoked. More manufactured cigarette users were in the contemplation stage compared with roll-your-own and both manufactured and roll-your-own cigarettes users. None roll-your-own cigarettes users were in the preparation stage of change. More roll-your-own cigarettes users reported to smoke ≤10 CPD compared with manufactured cigarettes users and users of both manufactured and roll-your-own cigarettes who mostly reported to smoke between 11 and 20 CPD.

We did not observed significant differences in the mean for FTND scores, the mean for CPD nor the frequency and depth of inhalation according to the tobacco product smoked.

Table 3 shows cotinine levels stratified by socio-demographic and smoking attributes (nicotine dependence levels, stages of change, time to first cigarette, cigarettes per day, and depth and frequency of inhalation) of self-reported daily smokers obtained in the 2011-2012 according to the type of tobacco product consumed. The analysis included 202 participants after the exclusions (same than in **table 2**). Overall, GM of salivary concentration was 223.41ng/ml among users of both type of tobacco product, 186.7 ng/ml among roll-your-own users, and 185.05 ng/ml among manufactured cigarettes users, but with no significant different between them (p=0.863). We did not observed differences in continine concentrations according to the type of tobacco product smoked when we stratified by socio-demographic characteristics and different smoking attributes. Mean cotinine concentrations increased together with the increase of FTND scores and the CPD smoked.

DISCUSSION

Our results indicate a relative reduction in the smoking prevalence among daily smokers of 9.4% (-9.5% in men, and -11.1% in women) between 2004-05 and 2011-12. The highest relative reduction in the smoking prevalence was observed among people aged 16-44 years old. During this period two tobacco smoke-free policies were implemented in Spain (Law 28/2005 and Law 42/2010) introducing regulation on publicity, sales, supply, and consumption of tobacco products. However we can not attribute this reduction in smoking prevalence solely to the implementation of smoke-free policies. According to data from the National Health Interview Survey (NHIS), for the period from 1987 to 2006, we observe a relative reduction in smoking prevalence of 2.2% per year among current male smokers (daily and occasional). Among women, two time segments are described: during the first period, from 1987 to 2001, an increase of 1.2% in smoking prevalence, followed by a second period, from 2001 to 2006, in which this prevalence drops 2.9% annually(5;10). One study conducted in England to examine the impact of the legislation on smoking prevalence controlling for secular trends through the end of 2008 observed a reduction in smoking prevalence from 25% in 2003 to 21% in 2008. However, after taking these trends into account, the implementation of smoke-free legislation was not associated with a statistically significantly change in smoking prevalence(24).

In our study, we observed a reduction in the number of heavy smokers (> 20 CPD) (26.7% before the legislation vs 15.1% after the legislation). A local study conducted in north-west England 3 months after the implementation of tobacco smoke-free policy found no significant change in smoking prevalence but found also a reduction in the proportion of heavy smokers(25).However FTND scores and the stages of change among users of manufactured cigarettes did not differ before and after the legislation.

Our results indicate an important reduction in the prevalence of manufactured cigarettes users in 2011-12 comparing with the data collected in 2004-05. However, roll-your-own cigarettes users considerably increase as well as mixed manufactured and roll-your-own cigarettes users. This data makes sense with the decrease in Spain in sales of manufactured cigarettes per capita jointly with an increase on roll-your-own cigarettes sales(13). Among self-reported daily smokers, roll-your-own cigarettes users represented a 15.4% in 2011-2012. This percentage is higher than that obtained in a study evaluating smoking prevalence in Italy in 2011 and 2012 in which 4.6% of smokers reported to regularly use roll-your-own cigarettes, although they observed an increased between this 2 years (3.4% in 2011 to 5.9% in 2012)(26). In other countries the prevalence of roll-your-own cigarettes use was 28.4% of UK smokers, 24.3% of Australian smokers, 17.1% of Canadian smokers, and only 6.7% of US, according to data obtained in 2002(27).

Our data show that the increase in roll-your-own tobacco users for the period studied is remarkable for both men and women, in ages between 16-44 years old and among people with secondary and university studies. For mixed manufactured and roll-your-own cigarettes users, the increase between 2004-05 and 2011-12 is not very pronounced for men but it is for women, and among younger people. According to the data obtained in 2011-12 we could define the pattern of roll-your-own cigarettes users as: men, people aged 16-44 years old and people with higher education level. This pattern is the same than that obtained in other studies focusing on the attributes of roll-your-own cigarettes smokers(26;27).

Previous studies including data obtained from the ITC study in Australia, Canada, the UK, and US, found that roll-your-own cigarettes users had higher level of nicotine addiction than manufactured cigarettes users(27). Our results indicate no significant differences in nicotine dependence levels according to the type of tobacco product smoked although the percentage of daily smokers with low nicotine dependence level was higher among roll-your-own cigarettes users compared with other types of tobacco products smoked. In the same study they did not found differences between the proportion of manufactured cigarettes smokers and mixed manufactured and roll-your-own cigarettes smokers who made quit attempts, but found that roll-your-own cigarettes users were less likely to have made quit attempts(27). Accordingly, we found that roll-your-own cigarettes users were more likely to be in the precontemplation stage of change. Finally, almost all roll-your-own cigarettes users reported to smoke ≤ 20 CPD with only a 7.4% of heavy smokers (>20 CPD). As also reported in another study(27), we found that depth of inhalation among both roll-your-own and mixed manufactured and roll-your-own cigarettes smokers was deeper than among manufactured smokers. According to the smoking attributes we could defined the roll-your-own cigarettes users as smokers with little dependence to nicotine, that have no intention to quit, they claim to smoke few cigarettes a day and to inhale more deeply than manufactured smokers. These smoking characteristics together with the younger ages among roll-your-own cigarettes users would make sense with the belief that roll-your-own tobacco is less harmful compared to other forms of tobacco, and that the amount of smoke is reduced together with a more positive perception of tobacco use, and the satisfaction feeling they produced(27;28).

Contrary to the general belief that the amount of smoke is reduced with roll-your-own cigarettes we found that roll-your-own cigarettes users had similar cotinine levels than manufactured cigarettes users. Furthermore, these cotinine levels where similar for smokers with the same smoking characteristics (FTND scores, stages of change and depth and frequency of inhalation) independently of the type of tobacco product smoked. These findings could be related with the theory that people regulate their intake of nicotine to reach the desire doses(29), and this condition would be the same for manufactured, roll-your-own or mixed manufactured and roll-your-own cigarettes users, and also agrees with the observation that the content of nicotine of roll-your-own cigarettes are even higher than manufactured(30;31).

Public Heath Implication

It has been report that manufactured cigarette prices results in a decrease in smoking prevalence and intensity(32-34). In Spain, the government has strengthened tobacco policies, including regulations on tobacco taxes. However, these changes have mainly affected manufactured cigarettes while other tobacco products have become a cheaper alternative for smokers(12). In fact, prices of manufactured cigarettes were about 50% higher than the rolling tobacco in 2009, when a small tax was introduced. The tobacco industry has used the asymmetric structure of taxation of different tobacco products in marketing fine-cut tobacco at cheap prices. Thus, it is not rare to observe such increase in the proportion of self-reported roll-your-own cigarettes users or even in the proportion of both manufactured and roll-your-own cigarettes users, especially among young people, and considering the collateral effects of the current economic crisis in Spain. In fact, the cheaper prices of roll-your-own cigarettes have been reports as the main reason why smokers switch from manufactured cigarettes to roll-your-own cigarettes(28).

Economics is not the only reason to switch from manufactured cigarettes to roll-your-own cigarettes. Some smokers enjoy the ritual of rolling a cigarette; others think roll-your-own cigarettes are more satisfying and taste better; and some smokers have the sensation they reduce the amount smoke and contain less additives(28). Finally, roll-your-own cigarettes users believe these cigarettes are safer(27;28). However, rolling tobacco yields higher nicotine, tar and carbon monoxide levels than manufactured cigarettes(27;30;31;35). These reasons mimic the arguments rose several decades ago to favour the use of "less harmful cigarettes" under the mask of low tar and light brands(36). Although it is still unclear the consequences of roll-your-own cigarettes use for health, there are some studies that reported higher risk to develop cancer lung cancer, and other diseases related to smoking(28).

Limitations and strengths of this study

One potential limitation of the study was an information bias derived from the use of a questionnaire. However, we could validate our results on smoking status with salivary cotinine measurements; and we also used trained personnel to conduct interviews and a protocol of interview and collection of saliva sample was used. Another potential limitation would be that we use the limit of 35 ng/ml of cotinine per one cigarettes smoked, as a boundary above which a level would be considered not biologically plausible in relation to the self-reported consumption, for roll-your-own and mixed roll-your-own and manufactured cigarettes users. This level of cotinine represents the maximum level of absorption per one cigarette smoked, assuming that the typical cotinine concentration of 12 ng/ml per cigarette is equivalent to the usual absorption of 1 mg of nicotine per cigarette, and that a cigarette smoker can absorb up to 3 mg of nicotine per cigarette with very intense smoking (37). However, this limit was obtained in experimental studies with manufactured cigarettes. This limit could have been different for roll-your-own cigarettes smokers but to our knowledge there are no data published for roll-your-own cigarettes.

This study included representative, random samples of the population of Barcelona (Spain). This is the first study that systematically evaluates smoking prevalence and smokers attributes focusing in manufactured and roll-your.own cigarettes users in Spain, before and after the implementation of a stepwise smoke-free legislation. Moreover, to our knowledge, this is the first study that considers cotinine levels among smokers according to the type of tobacco product smoked.

Conclusions

To systematically collect data on smoking prevalence and smokers attributes, including types of tobacco product consumed, on representative samples of population is necessary for policymakers to develop efficient tobacco control interventions and recommendations for the population. Considering such increase among roll-your-own cigarettes users and the unclear consequences on health of their use, policymakers should aim to implement tax policies to equalise the prices of different types of tobacco products. Moreover, further research is needed to determine exposure to tobacco biomarkers and the health effects of roll-your-own cigarettes use. Specific tobacco control strategies should be developed to tackle roll-your-own cigarette smoking, this emerging type of tobacco consumption targeting young people.

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Competing interests: None

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Figure 1. Smoking prevalence among adult population of Barcelona, Spain (2004-05 and 2011-12).

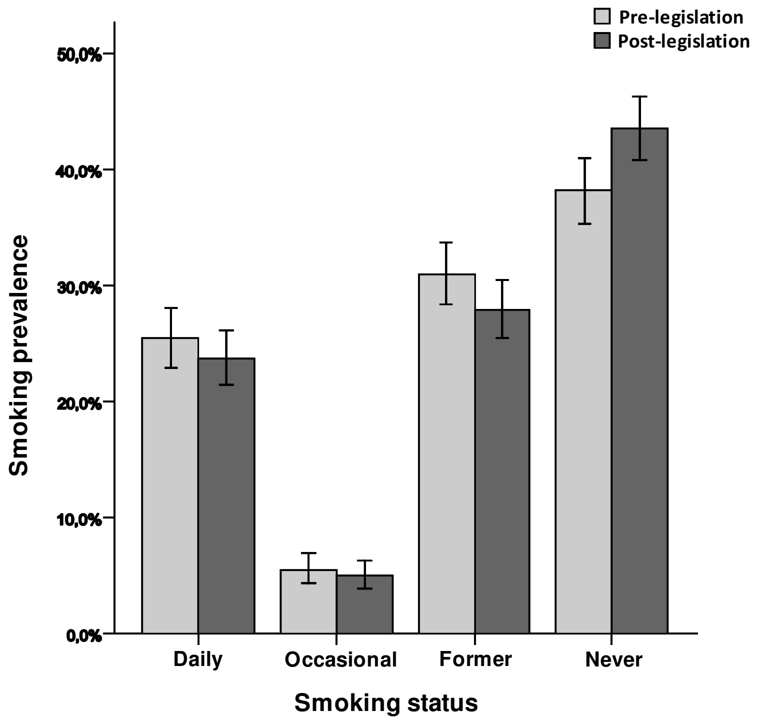

Figure 2. Smoking prevalence among adult population of Barcelona, Spain (2004-05 and 2011-12), according to the type of tobacco consumed.

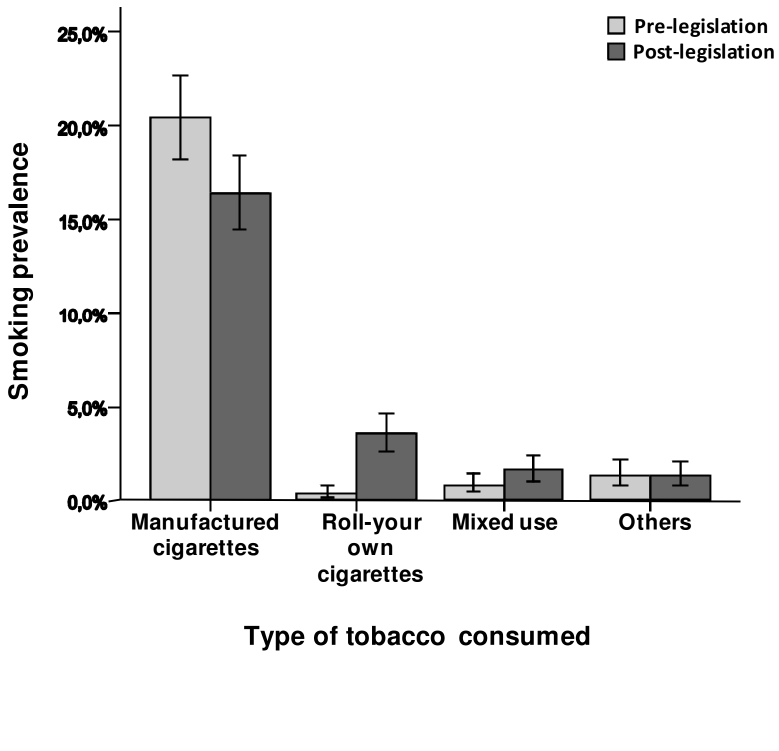

Table 1. Self-reported tobacco products consumed among daily smokers in Barcelona, Spain (2004-05 and 2011-12)

	N		Manufactured cigarettes (%)		Roll-your-own cigarettes (%)		Manufactured and roll-your-own cigarettes (%)		Other types (%)		
	Before	After	% before	% after	% before	% after	% before	% after	% before	% after	p_value
Overall	285	298	89.1	71.8	1.4	15.4	3.5	7.0	6.0	5.7	<0.001
Sex											
Men	158	172	82.9	64.0	1.9	19.8	5.1	6.4	10.1	9.9	<0.001
Women	127	126	96.9	82.5	0.8	9.5	1.6	7.9	0.8	0.0	0.001
Age (years)											
16-44	156	170	91.0	62.9	1.3	22.9	5.1	11.8	2.6	2.4	<0.001
45-64	102	103	90.2	85.4	2.0	5.8	2.0	1.0	5.9	7.8	0.440
≥65	27	25	74.1	76.0	0.0	4.0	-	-	25.9	20.0	0.526
Educational level											
Less than primary and primary	96	76	89.6	82.9	2.1	7.9	2.1	5.3	6.3	3.9	0.175
Secondary	98	130	89.8	66.2	1.0	17.7	6.1	11.5	3.1	4.6	<0.001
University	89	92	87.6	70.7	1.1	18.5	2.2	2.2	9.0	8.7	0.002

Table 2. Characteristics of adult daily smokers (manufactured vs roll-your-own). Barcelona, Spain (2011-12)

	Only manufactured	Only roll-your-own	Manufactured and roll-your-own	p_value
Overall (N)	165	27	10	
Nicotine dependence level (%)				0.151
Low (0-4 points)	40.3	52.2	42.9	
Medium (5 points)	14.1	8.7	42.9	
High (6-10 points)	45.6	39.1	14.3	
Stages of change (%)				0.023
Precontemplation	74.5	87.5	70.0	
Contemplation	22.8	12.5	10.0	
Preparation	2.8	-	20.0	
Time to first cigarette (%)				0.501
>60 min	28.5	23.1	40.0	
31-60 min	14.5	26.9	20.0	
6-30 min	35.2	30.8	40.0	
≤5min	21.8	19.2	-	
Cigarettes per day (%)				0.046
≤10	32.7	51.9	-	
11-20	52.1	40.7	70.0	
21-30	10.3	7.4	30.0	
>30	4.8	-	-	
Frequency of inhalation (%)				0.549
All the time	22.6	18.5	10.0	
Half the time	66.5	74.1	90.0	
Seldom	11.0	7.4	-	
Depth of inhalation (%)				0.515
Light	8.0	3.7	10.0	
Moderate	39.3	29.6	20.0	
Deep	52.8	66.7	70.0	
Overall FTND score, mean (SD)	5.10 (2.22)	4.70 (1.96)	4.57 (1.40)	0.659
Overall CPD, mean(SD)	15.40 (8.88)	12.28 (6.60)	18.21 (5.35)	0.064

Footnote: We excluded 6 participants using nicotine gum or nicotine patch for cessation, and 18 participants that did not provide a saliva specimen or that cotinine determination was not possible. Additionally, 34 people were excluded because their cotinine concentrations were too high in relation to the self-reported consumption, that is, over 35 ng/ml per one cigarette smoked.

Table 3. Cotinine concentrations in daily smokers according to type of tobacco smoked (manufactured vs roll-your-own). Barcelona, Spain (2011-12)

	Only manufactured		Only roll-your-own		Manufactured and roll-your-own		p_value*
	n	GM (GSD)	N	GM (GSD)	n	GM (GSD)	
Overall	165	185.05 (2.20)	27	186.77 (2.35)	10	223.41 (1.67)	0.863
Sex							
Men	78	207.06 (2.19)	19	178.07 (2.33)	4	258.46 (1.47)	0.697
Women	87	167.34 (2.18)	8	209.22 (2.53)	6	202.72 (1.82)	0.607
Age (years)							
16-44	80	168.00 (2.24)	22	172.66 (2.50)	9	207.35 (1.62)	0.783
45-64	72	213.99 (2.04)	4	235.34 (1.48)	1	437.52	0.376
≥65	13	150.07 (2.66)	1	417.16	-		0.385
Educational level							
Less than primary and primary	48	198.61 (2.05)	5	200.26 (2.11)	2	164.63 (1.08)	0.640
Secondary	65	191.12 (2.33)	12	255.33 (1.77)	8	241.16 (1.74)	0.498
University	52	166.49 (2.18)	10	123.97 (2.91)			0.455
Nicotine dependence level							
Low (0-4 points)	60	115.35 (2.11)	12	118.00 (2.64)	3	175.63 (2.28)	0.616
Medium (5 points)	21	201.42 (1.97)	2	493.86 (1.27)	3	180.18(1.18)	0.043
High (6-10 points)	68	279.25 (1.81)	9	269.77 (1.73)	1	326.21	0.950
Stage of change							
Precontemplation	108	190.46 (2.35)	21	195.16 (2.49)	7	247.86 (1.50)	0.895
Contemplation	33	211.11 (1.69)	3	282.10 (1.04)	1	76.58	0.174
Preparation	4	92.75 (1.45)	0	-	2	265.34 (1.34)	0.064
Time to first cigarette							
>60 min	47	96.41 (2.15)	6	111.89 (2.38)	4	170.53 (1.96)	0.430
31-60 min	24	173.90 (1.63)	7	129.81 (2.86)	2	261.82 (1.02)	0.314
6-30 min	58	235.88 (1.93)	8	249.12 (1.88)	4	270.40 (1.51)	0.965
≤5min	36	305.56 (1.80)	5	380.28 (1.16)			0.498
Cigarettes per day							
≤10	54	90.47 (2.17)	14	105.93 (2.27)			0.339
11-20	86	245.19 (1.62)	11	346.42 (1.35)	7	252.41 (1.39)	0.043
21-30	17	292.89 (1.83)	2	331.21 (1.27)	3	168.11 (2.28)	0.518
>30	8	424.23 (1.31)	0		0		-
Frequency of inhalation (%)							
All the time	37	200.22 (2.35)	5	191.82 (2.00)	1	397.28	0.555
Half the time	109	169.51 (2.21)	20	210.81 (2.13)	9	209.56 (1.65)	0.420
Seldom	18	250.15 (1.58)	2	52.08 (5.21)			0.059
Depth of inhalation (%)							
Light	13	144.51 (2.32)	1	280.48	1	173.58	0.510
Moderate	64	181.05 (2.29)	8	93.80 (2.84)	2	290.20 (1.18)	0.098
Deep	86	193.02 (2.11)	18	247.97 (1.81)	7	214.93 (1.81)	0.430

***Non-parametric test for independent samples**

Secondhand Tobacco Smoke Exposure in Open and Semi-Open Settings: A Systematic Review.

Sureda X, López MJ, Nebot M, Fernández E. Environ Health Perspect. 2013;121(7):766-73.

Secondhand Tobacco Smoke Exposure in Open and Semi-Open Settings: A Systematic Review

Xisca Sureda,[1,2,3] Esteve Fernández,[1,2,3] María J. López,[4,5] and Manel Nebot[4,5,6,*]

[1]Tobacco Control Unit, Cancer Control and Prevention Programme, Institut Català d'Oncologia-ICO, L'Hospitalet de Llobregat, Barcelona, Spain; [2]Cancer Control and Prevention Group, Institut d'Investigació Biomèdica de Bellvitge-IDIBELL, L'Hospitalet de Llobregat, Barcelona, Spain; [3]Department of Clinical Sciences, School of Medicine, Universitat de Barcelona, L'Hospitalet del Llobregat, Barcelona, Spain; [4]Agència de Salut Pública de Barcelona, Barcelona, Spain; [5]Institut d'Investigació Biomèdica-IBB Sant Pau, Barcelona, Spain; [6]Department of Experimental and Life Sciences, Universitat Pompeu Fabra, Barcelona, Spain

Background: Some countries have recently extended smoke-free policies to particular outdoor settings; however, there is controversy regarding whether this is scientifically and ethically justifiable.

Objectives: The objective of the present study was to review research on secondhand smoke (SHS) exposure in outdoor settings.

Data sources: We conducted different searches in PubMed for the period prior to September 2012. We checked the references of the identified papers, and conducted a similar search in Google Scholar.

Study selection: Our search terms included combinations of "secondhand smoke," "environmental tobacco smoke," "passive smoking" OR "tobacco smoke pollution" AND "outdoors" AND "PM" (particulate matter), "$PM_{2.5}$" (PM with diameter ≤ 2.5 μm), "respirable suspended particles," "particulate matter," "nicotine," "CO" (carbon monoxide), "cotinine," "marker," "biomarker" OR "airborne marker." In total, 18 articles and reports met the inclusion criteria.

Results: Almost all studies used $PM_{2.5}$ concentration as an SHS marker. Mean $PM_{2.5}$ concentrations reported for outdoor smoking areas when smokers were present ranged from 8.32 to 124 μg/m^3 at hospitality venues, and 4.60 to 17.80 μg/m^3 at other locations. Mean $PM_{2.5}$ concentrations in smoke-free indoor settings near outdoor smoking areas ranged from 4 to 120.51 μg/m^3. SHS levels increased when smokers were present, and outdoor and indoor SHS levels were related. Most studies reported a positive association between SHS measures and smoker density, enclosure of outdoor locations, wind conditions, and proximity to smokers.

Conclusions: The available evidence indicates high SHS levels at some outdoor smoking areas and at adjacent smoke-free indoor areas. Further research and standardization of methodology is needed to determine whether smoke-free legislation should be extended to outdoor settings.

Key words: exposure markers, outdoor tobacco smoke, particulate matter, passive smoking, secondhand smoke, smoking ban, tobacco smoke pollution.

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Secondhand smoke (SHS) is a complex mixture of thousands of compounds including particulate matter emitted by the combustion of tobacco products and from smoke exhaled by smokers [International Agency for Research on Cancer (IARC) 2004]. It contains > 50 chemicals recognized as known and probable human carcinogens, other animal carcinogens, and many toxic and irritant agents (U.S. Department of Health and Human Services 2006). Over the past two decades, scientific evidence has accumulated linking SHS exposure to adverse health outcomes, including respiratory outcomes in children and adults, acute cardiovascular effects, and lung cancer (IARC 2004; Ott et al. 2006; U.S. Department of Health and Human Services 2006). Most of this evidence is based on long-term SHS exposure research (IARC 2004). Some recent studies have also reported evidence of effects following short-term exposure to tobacco smoke, such as eye irritation and respiratory irritation among nonsmokers (Junker et al. 2001). Even brief and short-term exposures to SHS may generate significant adverse effects on the human respiratory system, as discussed in a recent review (Flouris and Koutedakis 2011). Finally, Pope et al. (2001) suggested that effects of acute exposure to tobacco smoke on cardiac autonomic function may contribute to pathophysiological mechanisms linking exposure to SHS to increased risk of cardiovascular mortality.

Smoke-free policies have been expanding worldwide since the World Health Organization (WHO) encouraged countries to follow Article 8 of the Framework Convention on Tobacco Control (FCTC) (WHO 2003) to protect people from SHS (Globalsmokefree Partnership 2009). Legislation has been widely implemented in indoor public places, workplaces, and public transportation (WHO 2009). Since the implementation of indoor smoke-free environments, several studies have demonstrated important reductions of SHS exposure, including an 80–90% decrease in previously high-exposure settings, such as workplaces and hospitality venues such as bars and restaurants (IARC 2008). However, indoor smoking bans may increase the likelihood that smokers will gather at convenient outdoor locations such as public areas near building entrances (Kaufman et al. 2010a). In 2007, a revision of the FCTC Article 8 guidelines further recommended that quasi-outdoor and outdoor public places should be smoke-free under some circumstances, and called upon countries to "adopt the most effective protection against exposure wherever the evidence shows that hazard exists" (WHO 2009). Recently, some countries have extended smoking bans to some outdoor locations (Globalsmokefree Partnership 2009; Repace 2008), particularly health care centers and settings where children are present (Globalsmokefree Partnership 2009). However, there remain some outdoor locations close to smoke-free areas where people may be exposed to SHS, such as terraces and patios in hospitality venues and near entrances to smoke-free buildings (Globalsmokefree Partnership 2009).

Some controversy exists regarding whether smoking should be prohibited in outdoor settings (Chapman 2008; Thomson et al. 2008). Health concerns about SHS exposure, nuisance from SHS, litter, fire hazards, concern about establishing positive smoke-free models for youth, and reducing youth opportunities to smoke (Bloch and Shopland 2000; Brennan et al. 2010; Cameron et al. 2010; Chapman 2008; Repace 2008; Thomson et al. 2008, 2009) exemplify the reasons why smoking should be banned in selected outdoor locations. Outdoor smoking bans might also support smokers who are trying to quit by limiting their overall cigarette consumption (Williams et al. 2009). Selected outdoor smoking bans should also help to denormalize smoking in outdoor areas (Thomson et al.

Address correspondence to E. Fernández, Tobacco Control Unit, Institut Català d'Oncologia, Av Gran Via 199-201, 08908 L'Hospitalet de Llobregat, Barcelona, Spain. Telephone: 34 932 607 345. E-mail: efernandez@iconcologia.net

*M. Nebot, a leader in design and evaluation of public health interventions and in tobacco control research, died 18 October 2012.

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2008). In a number of jurisdictions, the majority of the public supports restricting smoking in various outdoors settings, and this support appears to be increasing over time (Thomson et al. 2009). However, those who oppose outdoor smoking bans argue that it is ethically unsustainable because it does not respect the principle of freedom and autonomy of individuals, and that there is insufficient evidence that SHS in these environments has an impact on health (Chapman 2000, 2008).

SHS exposure has been commonly studied in different indoor locations, especially in workplaces such as hospitality venues or health care centers (IARC 2009); however, outdoor SHS has been scarcely evaluated. It has been hypothesized that the introduction of indoor smoking bans has led to a relocation of smokers to outdoor areas, with a subsequent increase of tobacco smoke levels in outdoor places (Sureda et al. 2012). The aim of the present study is to review research on objectively assessed SHS levels in outdoor settings, including information on indoor and outdoor SHS concentrations, the effect of smoking bans on indoor and outdoor SHS levels, the relation between outdoor and indoor SHS levels, factors that influence outdoor and indoor SHS concentrations, and whether measured SHS levels comply with the air quality standards established by the WHO (2005).

Methods

We conducted several different searches in PubMed (http://www.ncbi.nlm.nih.gov/pubmed) for papers published before September 2012 to identify papers on SHS assessment in outdoor settings. We combined different terms as follows:

> ((“Secondhand smoke” OR “environmental tobacco smoke” OR “passive smoking” AND “outdoor”) OR (“Tobacco Smoke Pollution”[Mesh] AND “outdoor”)) AND (PM OR RSP OR PM2.5 OR particulate matter OR nicotine OR CO OR cotinine OR marker OR markers OR biomarker OR airborne marker) AND (English[lang] OR French[lang] OR German[lang] OR Italian[lang] OR Spanish[lang] OR Catalan[lang]).

The search was more sensitive than specific; therefore, we arrived at the first selection of manuscripts by checking the results of every search and reading titles and abstracts. We then obtained the selected papers and read them carefully. Finally, we completed our search by checking the references of the papers and conducting similar searches in Google Scholar (http://www.scholar.google.com/; with search terms in English).

Our final selection included studies whose main objectives were to measure SHS or tobacco smoke exposure in outdoor settings using a tobacco biomarker or airborne marker. Outdoor areas included completely open spaces and quasi-outdoor areas with temporary or permanent structures, such as a roof or side walls, that would impede upward or lateral airflow, respectively.

We excluded articles that studied SHS exposure indoors but not outdoors and articles that studied air pollution outdoors, but not specifically SHS. We were able to consider papers in English, French, German, Italian, Spanish, and Catalan.

Results

Our initial searches identified 263 papers; after checking the titles, 67 abstracts were reviewed (Figure 1). Of these, 51 were determined not to meet eligibility criteria. We read the remaining 16 papers in full, plus 6 additional papers identified from references. We finally identified 18 articles and reports that satisfied the inclusion criteria, including 15 published in peer-review journals and 3 academic reports available on the Internet. One report was a pilot study for which we obtained data from the subsequently published study (Klepeis et al. 2007). We included only results related to SHS in outdoor areas from another report [California Air Resources Board (CARB) 2005] concerning SHS exposure in California.

The 18 papers included were published between 2005 and 2012. The studies were conducted in Australia (n = 3), Canada (n = 2), New Zealand (n = 4), the United States (n = 6), Denmark (n = 1), and Spain (n = 1), and a multicenter study was conducted in eight European countries (n = 1) (Table 1). Almost all (n = 16) used airborne markers to assess SHS exposure, including 14 studies that measured particulate matter ≤ 2.5 µm in diameter ($PM_{2.5}$). Airborne nicotine, carbon monoxide (CO), $PM_{3.5}$ (≤ 3.5 µm in diameter), and polycyclic aromatic hydrocarbons (PAHs) were used infrequently and mostly to complement $PM_{2.5}$ assessment (n = 5). Two studies used personal biological markers {salivary cotinine in both studies and NNAL [4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol] in one of the studies} to assess tobacco exposure among participants (Hall et al. 2009; St.Helen et al. 2012).

The studies included between 2 and 127 locations. Depending on the specific study objectives, different locations were tested. Nine studies were conducted in hospitality venues (Table 1) such as pubs, restaurants, bars, cafés, and outdoor dining areas. Six studies measured SHS in other locations such as entrances to buildings and the adjacent indoor area and transportation settings, including an airport, parks, streets, university campuses, and one junior college campus (Table 2). Three studies assessed SHS in both hospitality and non-hospitality venues. Most studies were observational studies, with only two experimental studies. All included papers were written in English.

SHS in outdoor smoking areas. Mean $PM_{2.5}$ concentrations reported for outdoor smoking areas at hospitality venues ranged from 8.32 µg/m^3 (Stafford et al. 2010) to 124 µg/m^3 (Wilson et al. 2007) when smokers were present (Table 2). In non-hospitality venues, mean $PM_{2.5}$ concentrations reported for outdoor settings ranged from 4.60 µg/m^3 (Boffi et al. 2006) to 17.80 µg/m^3 (Boffi et al. 2006) (Figure 2). Klepeis et al. (2007) obtained an overall $PM_{2.5}$ mean of 30 µg/m^3 for the observational data for hospitality

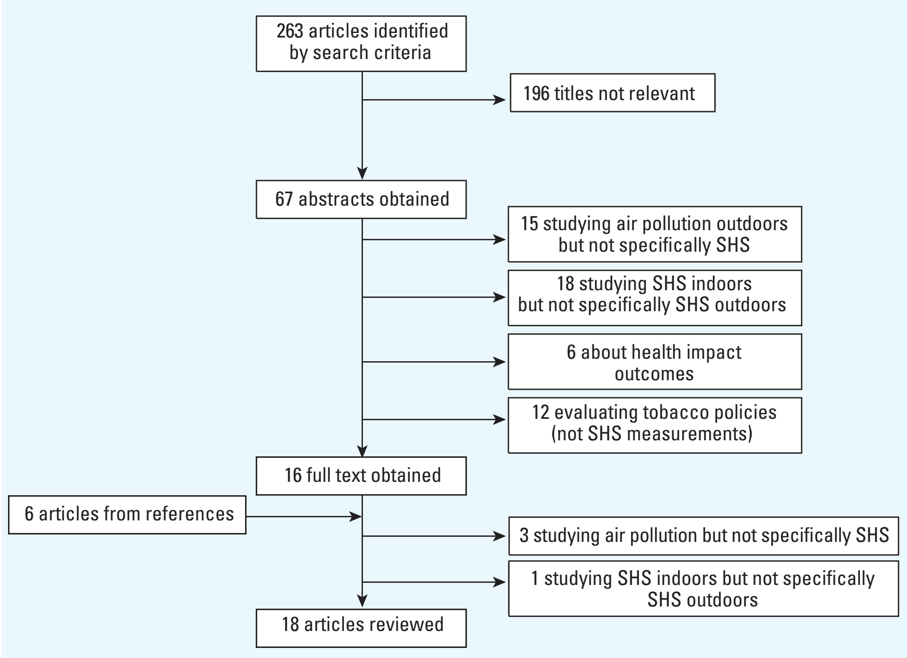

Figure 1. Flow diagram for the identification and selection of studies included in the review.

Table 1. Main characteristics of reviewed studies from before September 2012 assessing outdoor SHS exposure in hospitality venues.

Reference, location	Study design: venue type, and sample size	SHS marker	Potential confounders	SHS marker concentration: Presence of smokers	SHS marker concentration: Absence of smokers	Background concentration (control)
Klepleis et al. 2007, California, USA	Observational and experimental: 10 outdoor public places including parks, sidewalk cafés, and restaurant and pub patios. Results provided for hospitality venues and other settings combined	$PM_{2.5}$	Wind conditions, source proximity, and no. of cigarettes	Overall mean: 30 μg/m^3 (observational data). Maximum: 1,000 μg/m^3 at distances within 0.5 m (experimental data)		
Travers et al. 2007, Victoria, British Columbia, Canada	Observational: 20 smoking areas of bars and restaurants (outdoors)	$PM_{2.5}$	No. of burning cigarettes, coverage and cigarette proximity, or size	Overall mean: 96 μg/m^3. Maximum: 1,318 μg/m^3		6 μg/m^3
Wilson et al. 2007, New Zealand	Observational: 34 pubs, restaurants, and bars; 6 outdoor smoking areas of bars and restaurants. Also in this study: 10 transportation settings, 9 other indoor settings, and 6 other outdoor settings (Table 2)	$PM_{2.5}$	No. of people in room/area and no. of lit cigarettes among occupants	"Outdoor" smoking areas of bars and restaurants (n = 4): 36 μg/m^3. Relatively enclosed smoking areas attached to bars (n = 2): 124 μg/m^3. Maximum (outdoor smoking area in a bar): 284 μg/m^3	Inside hospitality venues (n = 34): 16 μg/m^3. Outside hospitality venues (n = 34): 14 μg/m^3	14 μg/m^3
Hall et al. 2009, Athens, Georgia, USA	Observational: 5 bars (n = 3) and family restaurants (n = 2) (outdoors)	SC	Proximity to smokers	Overall GM, bar: 182 μg/m^3. Overall GM, restaurant: 75 μg/m^3	Overall GM, bar: 69 μg/m^3. Overall GM, restaurant: 36 μg/m^3	Before smoking time: 43 μg/m^3. After smoking time: 49 μg/m^3
Brennan et al. 2010, Victoria, Australia	Observational: 19 pubs and bars that had at least one indoor area with an adjacent semi-enclosed outdoor eating/drinking area (5 m from the main access)	$PM_{2.5}$	No. of patrons and lit cigarettes, overhead covers, ventilation, and kitchen operating	Overall GM indoor: 61.3 μg/m^3 (pre-ban). Overall GM, outdoor: 19.0 μg/m^3 (pre-ban)	Overall GM, indoor: 17.4 μg/m^3 (post-ban). Overall GM, outdoor: 13.1 μg/m^3 (post-ban)	
Cameron et al. 2010, Melbourne, Australia	Observational: 69 visits to 54 dining areas of bars and restaurants	$PM_{2.5}$	No. of target cigarettes, no. of other lit cigarettes, and overhead cover	Overall mean: 27.3 μg/m^3. Maximum: 483.9 μg/m^3	Overall mean: 17.6 μg/m^3	8.4 μg/m^3
Stafford et al. 2010, Perth and Mandurah, Australia	Observational: 12 cafes and 16 pubs (outdoors)	$PM_{2.5}$	No. of smokers, wind level, coverage, no. of patrons, street type, and road traffic	Overall median: 8.32 μg/m^3. Maximum: 142.08 μg/m^3	Overall median: 2.56 μg/m^3	
Edwards et al. 2011, New Zealand	Observational: 7 pubs and bars (semi-enclosed outdoor area and indoor)	$PM_{2.5}$	Ventilation	Noncommunication smoking area outdoors: range, 32–109 μg/m^3. Communication smoking area outdoors: range, 29–192 μg/m^3	Noncommunication smoking area indoors: range, 14–79 μg/m^3. Communication smoking area indoors: range, 2.36–117 μg/m^3	
St.Helen et al. 2011, Athens, Georgia, USA	Observational: 2 family restaurants, 3 bars (outdoors)	$PM_{2.5}$ and CO	No. of smokers, pedestrians, and vehicles	$PM_{2.5}$: range, 16.6–63.9 μg/m^3. CO: range, 1.2–1.6 ppm		$PM_{2.5}$: 20.4 μg/m^3. CO: 1.3 ppm
Wilson et al. 2011, New Zealand	Observational: 20 outdoor smoking areas of hospitality venues, 13 inside bars adjacent to outdoor smoking areas, 10 pubs/sports bars, 18 bars, 9 restaurants, 5 cafés. Also in this study: 15 inside public buildings, 15 inside transportation settings, and 22 various outdoor street/park settings	$PM_{2.5}$	None	Outdoor smoking areas of hospitality venues (n = 20): 72 μg/m^3. Inside bars adjacent to outdoor smoking areas (n = 13): 54 μg/m^3	Inside hospitality venues (n = 42): range, 7–22 μg/m^3	11 μg/m^3
St.Helen et al. 2012, Athens, Georgia, USA	Observational: a bar and a family restaurant (outdoors), an open-air seating area with no smokers (control)	SC and NNAL	No. of lit cigarettes	SC in restaurant: 69 μg/m^3. SC in bar: 165 μg/m^3. NNAL, in restaurant: 0.774 μg/m^3. NNAL in bar: 2.407 μg/m^3	SC in restaurant: 46 μg/m^3. SC in bar: 45 μg/m^3. NNAL in restaurant: 0.041 μg/m^3. NNAL in bar: 0.037 μg/m^3	SC: 53 μg/m^3. NNAL: 0.038 μg/m^3
López et al. 2012, Europe	Observational: 48 hospitality venues (night bars, restaurants and bars)	$PM_{2.5}$ and nicotine	No. of smokers and coverage	$PM_{2.5}$ indoors (n = 42): 120.51 μg/m^3 (pre-ban). $PM_{2.5}$ outdoors (n = 42): 29.61 μg/m^3 (pre-ban). Nicotine indoors (n = 46): 3.69 μg/m^3 (pre-ban). Nicotine outdoors (46): 0.31 μg/m^3 (pre-ban)	$PM_{2.5}$ indoors (32): 36.90 μg/m^3 (post-ban). $PM_{2.5}$ outdoors (32): 36.10 μg/m^3 (post-ban). Nicotine indoors (39): 0.48 μg/m^3 (post-ban). Nicotine outdoors (39): 1.56 μg/m^3 (post-ban)	

Abbreviations: GM, geometric mean; NNAL, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol; SC, salivary cotinine.

venues and other settings combined. In the experimental component of the same study, $PM_{2.5}$ concentrations reached values of 200 μg/m^3 and 500 μg/m^3 depending on other external conditions (Klepeis et al. 2007).

Three studies (Cameron et al. 2010; Parry et al. 2011; Stafford et al. 2010) that compared outdoor SHS measurements during smoking and nonsmoking periods reported that particulate concentrations were significantly higher during active smoking. Two studies reported that $PM_{2.5}$ concentrations in outdoor smoking areas were higher than background $PM_{2.5}$ levels similarly measured in nearby, smoke-free, outdoor air (St. Helen et al. 2011; Travers et al. 2007). An additional study (Boffi et al. 2006) reported high $PM_{2.5}$ concentrations both outdoors and indoors during 1 day in a conference center where smoking was permitted.

One study used salivary cotinine to evaluate SHS exposures among nonsmokers before and after they spent 6 hr at smoking areas of outdoor bars or outdoor restaurants, or at an outdoor control site without smoking (Hall et al. 2009). Median increases in salivary cotinine from pretest to posttest were approximately 162%, 102%, and 16% for the bar, restaurant, and control sites, respectively. A similar study measured salivary cotinine

Table 2. Main characteristics of reviewed studies from before September 2012 assessing outdoor SHS exposure in non-hospitality settings.

Reference, location	Study design: venue type, and sample size	SHS marker	Potential confounders	SHS marker concentration: Presence of smokers	SHS marker concentration: Absence of smokers	Background concentration (control)
CARB 2005, California, USA	Observational: an airport, a junior college campus, a public building, an office complex, and a park	Airborne nicotine	No. of cigarettes smoked, wind speed, and direction	Range, 0.013–3.1 μg/m^3		Range, 0.009–0.12 μg/m^3
Repace 2005, Baltimore, USA	Experimental: various locations on the UMBC campus (outdoors and indoors)	$PM_{3.5}$ and PAH	Distances, number of smokers, and wind conditions	Range, 100–150 μg/m^3 outdoors in proximity to smokers		
Boffi et al. 2006, Copenhagen, Denmark	Observational: in a car park, inside a nonsmoking conference center, outdoors in front of the conference center, with smokers under a roof, along the motorway, and inside a Copenhagen restaurant where smoking was allowed	$PM_{2.5}$	None	Outside in front of a conference center: 17.8 μg/m^3. Along the motorway: 4.6 μg/m^3	Car parking area: 6.0 μg/m^3. Inside a conference center: 3.0 μg/m^3	5.7 μg/m^3
Klepeis et al. 2007, California, USA	Observational and experimental: 10 outdoor public places including parks, sidewalk cafés, and restaurant and pub patios. Results provided for hospitality venues and other settings combined	$PM_{2.5}$	Wind conditions, source proximity, and no. of cigarettes	Overall mean: 30 μg/m^3. Maximum: 1,000 μg/m^3 at distances within 0.5 m		
Wilson et al. 2007, New Zealand	Observational: 10 transportation settings, 9 non-hospitality indoor settings, and 6 non-hospitality outdoor settings. Also in this study: 34 pubs, restaurants, and bars and 6 outdoor smoking areas of bars and restaurants	$PM_{2.5}$	No. of people in room/area and no. of lit cigarettes among occupants		Transportations settings (n = 10): 13 μg/m^3. Non-hospitality indoors (n = 9): 3 μg/m^3. Non-hospitality outdoors (n = 6): 7 μg/m^3	14 μg/m^3
Kaufman et al. 2010b, Toronto, Canada	Observational: entrances to 28 office buildings both indoor and outdoor	$PM_{2.5}$	No. of cigarettes, wind direction and strength, and distance from the nearest lit cigarette to the monitor	Overall median outdoors: 11 μg/m^3 (1–4 cig); 16 μg/m^3 (≥ 5 cig). Maximum: 496 μg/m^3. Overall median indoors: 6 μg/m^3 (1–4 cig); 4 μg/m^3 (≥ 5 cig)	Overall median outdoors: 8 μg/m^3. Overall median indoors: 5 μg/m^3	8 μg/m^3
Parry et al. 2011, New Zealand	Observational: streets (no. of samples not indicated)	$PM_{2.5}$	No. of smokers, smoking proximity, and coverage	Overall mean: 14.2 μg/m^3. Maximum: 186.0 μg/m^3	Overall mean: 5.9 μg/m^3	
Sureda et al. 2012, Barcelona, Spain	Observational: 47 public building main entrances (both outdoors and indoors)	$PM_{2.5}$ and airborne nicotine	No. of lit cigarettes, coverage, and distance to roadways	Overall $PM_{2.5}$ concentration outdoor: 17.16 μg/m^3. Overall $PM_{2.5}$ concentration indoor: 18.20 μg/m^3. Nicotine concentration in 28 main entrances outdoors: 0.81 μg/m^3. Maximum value $PM_{2.5}$ (outdoor): 128.44 μg/m^3	Overall $PM_{2.5}$ concentration Control point indoor: 10.40 μg/m^3	$PM_{2.5}$ concentration: 13.00 μg/m^3
Wilson et al. 2011, New Zealand	Observational: 15 inside public buildings, 15 inside transportation settings, and 22 various outdoor street/park settings. Also in this study: 20 outdoor smoking areas of hospitality venues, 13 inside bars adjacent to outdoor smoking areas, 10 pubs/sports bars, 18 bars, 9 restaurants, and 5 cafés	$PM_{2.5}$	None		Inside non-hospitality settings (n = 30): range, 2–13 μg/m^3. Non-hospitality outdoor settings: range, 2–11 μg/m^3	11 μg/m^3

cig, cigarettes.

in saliva and NNAL in urine samples from non-smokers before and after being at an outside bar or restaurant or at a control site (St. Helen et al. 2012). Cotinine in samples collected both immediately after and the morning after 3-hr visits to the outside bar and restaurant sites were significantly higher than in the control samples, and NNAL was significantly higher in first morning urine samples after bar and restaurant site visits. Another study used airborne nicotine to assess SHS exposure; the mean 8-hr concentrations ranged from 0.013 to 3.1 μg/m^3 (higher than the mean 8-hr background concentrations of 0.009–0.12 μg/m^3) (CARB 2005).

Factors influencing outdoor SHS levels. Atmospheric conditions, including wind direction, wind speed, and atmospheric stability, can modify outdoor SHS levels. Other factors are the density and distribution of the smokers and the structure of the outdoor location (completely open or semi-open). All of the studies that evaluated possible modifiers of SHS concentrations reported that the density of smokers and/or number of lit cigarettes predicted outdoor SHS (Brennan et al. 2010; Cameron et al. 2010; CARB 2005; Edwards and Wilson 2011; Kaufman et al. 2010b; Klepeis et al. 2007; López et al. 2012; Parry et al. 2011; Repace 2005; St.Helen et al. 2011, 2012; Stafford et al. 2010; Sureda et al. 2012). Most of these studies also found the degree of enclosure of the outdoor area as a determinant factor (Brennan et al. 2010; Cameron et al. 2010; López et al. 2012; Parry et al. 2011; Stafford et al. 2010; Sureda et al. 2012; Travers et al. 2007). For example, Cameron et al. (2010) reported that $PM_{2.5}$ increased by approximately 30% with each additional active smoker within 1 m of the point of measurement, and by 50% if measured under an overhead cover.

Some studies on wind conditions (speed and direction) and proximity to smokers found that these were not associated with SHS levels (Kaufman et al. 2010b; Travers et al. 2007). However, the CARB study (2005) and two experimental studies (Klepeis et al. 2007; Repace 2005) in public outdoor locations that controlled smoking activity at precise distances from monitored positions reported that outdoor SHS levels were highly dependent on wind direction and source proximity. Klepeis et al. (2007) demonstrated that upwind $PM_{2.5}$ concentrations are likely to be very low, whereas downwind levels during periods of active smoking can be very high. They also reported that $PM_{2.5}$ levels decreased by half or more as the distance from a lit cigarette increased from 0.25–0.5 m to 1–2 m, and that levels were generally close to background. However, Repace (2005) reported that outdoor $PM_{3.5}$ and PAH concentrations did not approach background levels until about 7 m.

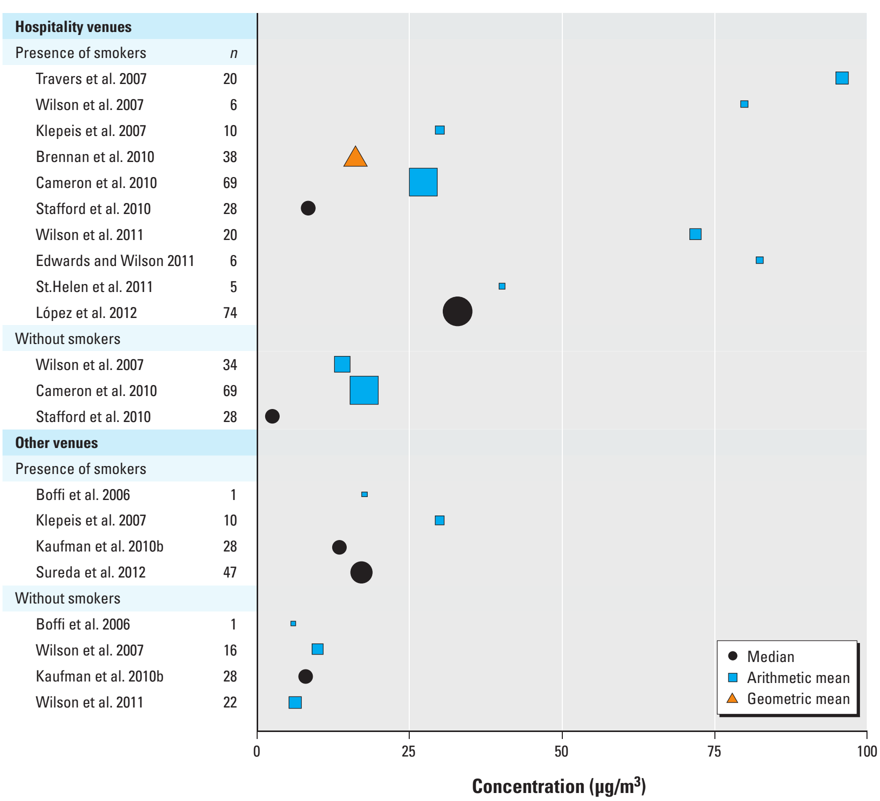

Figure 2. Outdoor $PM_{2.5}$ concentrations reported for hospitality venues and other settings according to the presence or absence of smokers. Klepleis et al. (2007) included hospitality and non-hospitality venues without distinguishing the mean value between them, and hence it has been included both in "hospitality venues" and "other venues." Wilson et al. (2011) and Edwards and Wilson (2011) provided the individual values for each measurement, and we have computed the arithmetic mean for the figure. Brennan et al. (2010) and López et al. (2012) provided mean and median values, respectively, for venues before and after a smoking ban. We have computed the average values for each study to include them in the figure.

Outdoor smoking areas and indoor air quality. $PM_{2.5}$ concentrations in indoor settings where smoking was banned but near outdoor smoking areas varied from 4 μg/m^3 (Kaufman et al. 2010b) to 120.51 μg/m^3 (López et al. 2012); both studies were carried out in hospitality venues. Indoor $PM_{2.5}$ levels far away from outdoor tobacco sources were lower (Sureda et al. 2012; Wilson et al. 2011).

Two studies specifically examined SHS in main entrances of public buildings. Kaufman et al. (2010b) simultaneously measured $PM_{2.5}$ concentrations inside and outside of 28 office building entrances. Outdoor SHS levels within 9 m of building entrances were significantly higher in the presence of smoking (11 μg/m^3 with 1–4 cigarettes, and 16 μg/m^3 with ≥ 5 cigarettes) compared to occasions when there was no smoking (8 μg/m^3). $PM_{2.5}$ median indoor concentrations ranged from 4 to 6 μg/m^3. Sureda et al. (2012) showed higher median $PM_{2.5}$ concentrations in the presence of smoking, both outdoors near main entrances (17.16 μg/m^3) and in indoor halls near outdoor smoking areas (18.20 μg/m^3), compared with those in control locations without smoking, both indoors (10.40 μg/m^3) and outdoors (13.00 μg/m^3).

Several articles reported positive associations between SHS levels ($PM_{2.5}$ concentrations) measured indoors and outdoors (Brennan et al. 2010; Edwards and Wilson 2011; Kaufman et al. 2010b; López et al. 2012; Sureda et al. 2012; Wilson et al. 2011). Indoor SHS levels are higher when smoking occurs in the adjacent outdoor setting, especially when the outdoor area is semi-enclosed. For example, Sureda et al. (2012) showed that $PM_{2.5}$ concentrations in indoor halls were more closely correlated with outdoor concentrations measured near main entrances (outdoors) than with the indoor control (a nonsmoking area far from the main entrance). Brennan et al. (2010) estimated that a 100% increase in the geometric mean of the outdoor $PM_{2.5}$ concentration was associated with a 36.1% rise in the geometric mean of the indoor $PM_{2.5}$ concentration in smoke-free pubs and bars.

Factors influencing indoor SHS from outdoor areas. Factors such as wind speed and direction that modify outdoor SHS levels also may influence indoor air quality. The effects of structural barriers between outdoor smoking areas and indoor locations were also considered in some articles (Brennan et al. 2010; Edwards and Wilson 2011). Brennan et al. (2010)

observed that open access between indoors and outdoors was associated with lower $PM_{2.5}$ levels indoors. However, an Australian study (Edwards and Wilson 2011) showed higher indoor $PM_{2.5}$ concentrations when doors to outdoor smoking areas were left open.

Smoking bans and SHS exposures. One study evaluated the impact of laws prohibiting indoor smoking (Brennan et al. 2010) by measuring $PM_{2.5}$ concentrations before and after indoor smoking bans were implemented in pubs and bars that had at least one indoor area with an adjacent semi-enclosed outdoor eating/drinking area, and showed reduced $PM_{2.5}$ concentrations both indoors and outdoors (65.5% and 38.8%, respectively) from pre-ban to post-ban. Two other studies evaluated indoor and outdoor SHS in different settings after the implementation of indoor smoking bans (Wilson et al. 2007, 2011). Both reported higher concentrations of fine particulates in outdoor smoking areas, especially those that were partly enclosed, as well as indoor areas adjacent to outdoor smoking areas compared to other smoke-free indoor settings. Finally, a multicenter study carried out in hospitality venues of eight European countries compared SHS concentrations between venues where indoor smoking was allowed and venues where it was banned (López et al. 2012). The authors reported that median indoor $PM_{2.5}$ and airborne nicotine concentrations were significantly higher in venues where smoking was allowed than in those where it was banned. Conversely, the outdoor nicotine concentration was significantly higher for venues where indoor smoking was banned than outdoor areas of venues where indoor smoking was allowed (López et al. 2012).

Tobacco smoke levels compared to background levels. Maximum mean or median outdoor $PM_{2.5}$ concentrations ranged from 128 μg/m^3 (Sureda et al. 2012) to 496 μg/m^3 (Kaufman et al. 2010b), with some point measurements exceeding 1,000 μg/m^3 (Klepeis et al. 2007; Travers et al. 2007). The maximum peak indoor $PM_{2.5}$ concentration reported for a smoke-free setting was 239 μg/m^3 (Wilson et al. 2011). In contrast, mean or median background $PM_{2.5}$ concentrations varied from 6 μg/m^3 (Travers et al. 2007) to 20.4 μg/m^3 (St.Helen et al. 2011).

SHS markers other than $PM_{2.5}$. Three studies evaluated different SHS markers to determine which would be most appropriate to describe SHS levels in outdoor areas. Sureda et al. (2012) reported a Spearman correlation coefficient between outdoor $PM_{2.5}$ and airborne nicotine concentrations of 0.365 (95% CI: 0.009, 0.650). Hall et al. (2009) reported that the number of smokers present had a strong positive association with outdoor $PM_{2.5}$ concentrations but not CO concentrations. Moreover, CO levels measured outside restaurants and bars did not differ significantly from concentrations measured at a control location, in contrast with findings for $PM_{2.5}$ concentrations. Other studies used biological markers such as cotinine or NNAL to show SHS exposure (Hall et al. 2009; St.Helen et al. 2012).

Discussion

We found only 18 studies that met our criteria, but these indicated that SHS levels in some outdoor smoking areas are not negligible, especially in areas that are semi-enclosed.

SHS levels and air quality standards. In general, SHS levels measured in outdoor smoking areas were high, particularly in hospitality venues where $PM_{2.5}$ concentrations ranged from 8.32 μg/m^3 (Stafford et al. 2010) to 182 μg/m^3 (Hall et al. 2009) when smokers were present. SHS levels were also increased in indoor areas adjacent to outdoor smoking areas. Hall et al. (2009) and St.Helen et al. (2012) reported that saliva cotinine concentrations were higher in study participants following exposure to SHS at outdoor bars and restaurants when smoking was allowed than after exposure to smoke-free terraces. These results suggest that hospitality workers and patrons may be exposed to high SHS levels under certain conditions. Although outdoor SHS levels are more transient than indoor levels, and can quickly drop to background levels in the absence of active smoking, potential health effects of these exposures merit consideration and need to be further studied.

According to the WHO, there is no safe level of SHS (WHO 2000). The WHO guidelines indicate that the lower range of concentrations at which adverse health effects have been demonstrated is not greatly above background concentrations (estimated at 3–5 μg/m^3 in the United States and Western Europe for $PM_{2.5}$). In the updated WHO Air Quality Guidelines, an annual outdoor average value of 10 μg/m^3 for $PM_{2.5}$ was selected as the lower end of the range over which significant effects on survival have been observed (Gorini et al. 2005; WHO 2000, 2005). These are the lowest levels at which total, cardiopulmonary, and lung cancer mortality have been shown to increase with more than 95% confidence in response to $PM_{2.5}$. Most of the reviewed studies of $PM_{2.5}$ concentrations in outdoor smoking areas reported levels higher than the annual mean guideline value of 10 μg/m^3 recommended by WHO

Influences of outdoor SHS on indoor air quality. Indoor smoke-free areas near outdoor smoking areas showed higher levels than smoke-free indoor areas that were farther away from outdoor SHS sources, suggesting that SHS from outdoor smoking areas can enter adjacent buildings. Some findings also suggested that although outdoor SHS concentrations dropped immediately to background levels when the SHS sources were extinguished, indoor SHS concentrations persisted at relatively high levels and slowly decayed over several hours until doors were opened to ventilate the building (Klepeis et al. 2007). SHS levels in outdoor locations are more susceptible to variation due to the proximity of active smoking and wind conditions. During periods of active smoking, outdoor SHS levels can be comparable to levels in indoor smoking areas, but outdoor levels dropped rapidly after smoking activity ceased.

Other factors influence SHS levels. Some factors can influence SHS levels both indoors and outdoors (Brennan et al. 2010; Cameron et al. 2010; Edwards and Wilson 2011; Kaufman et al. 2010b; Klepeis et al. 2007; López et al. 2012; Repace 2005; St.Helen et al. 2011, 2012; Stafford et al. 2010; Sureda et al. 2012). Smoker density and enclosure of the outdoor locations are determinant modifiers. Some studies also suggest that wind speed and direction, as well as proximity to smokers, are associated with SHS levels outdoors.

SHS airborne markers other than $PM_{2.5}$. Particulate matter was the most common airborne marker used in the presently reviewed articles. However, $PM_{2.5}$ is not a specific marker; markers such as airborne nicotine are specific to SHS (Gorini et al. 2005; Ott et al. 2006). Biological markers have been scantily used. However, cotinine has been proposed as a very sensitive and specific biological marker of SHS exposure (Benowitz 1999), and total NNAL has been used to characterize human exposure to carcinogenic tobacco-specific nitrosamines among nonsmokers exposed to SHS (Anderson et al. 2001). Further research is necessary to evaluate which SHS marker would be most appropriate to measure SHS levels in outdoors settings and whether it would be necessary to combine more than one marker.

Limitations. Some of the reviewed studies did not control for important factors that can influence SHS levels, such as wind conditions, the structural characteristics of outdoor area (semi-enclosed vs. totally open), or proximity to active smokers. Future studies should control for these factors to enable a better understanding of the results. Additionally, some studies used $PM_{2.5}$ concentrations to estimate SHS levels in outdoor areas, but did not control for other sources of $PM_{2.5}$, such as cooking or traffic-related air pollution (Gorini et al. 2005). Further studies should record the presence of other sources of combustion, such as cooking facilities, proximity to roadways, or traffic density; measure and report background levels of $PM_{2.5}$; and/or use specific SHS markers such as airborne nicotine.

Publication bias is a potential source of error in systematic reviews. We searched the available literature in PubMed, the main biomedical database, and Google Scholar and checked references to identify documents not published in academic journals. However, we cannot rule out the possibility that some unpublished manuscripts or other documents addressing the topic of interest may have been missed. Direct comparisons of results among studies were hampered by the use of different statistics (medians, means, or geometric means) and sampling strategies; the use of standardized methods could strengthen the validity of results and facilitate comparisons among different populations and locations. Furthermore, the number of venues measured in each study was limited. Future studies should consider including representative samples of locations selected using standard statistical sampling procedures and sample size computations.

Strengths. The reviewed studies included a variety of venue types (e.g., entrances to public buildings, hospitality venues, transportation settings) and characteristics. Most of the reviewed studies were observational, and thus provide information that reflects smoking behaviors and exposures under normal real-life conditions. However, experimental studies provide the opportunity to control for unpredictable variables, such as the proximity of smokers or wind conditions. The use of real-time monitoring permits determination of the precise magnitude of extremely transient (short-term) concentrations and exposures, while retaining the flexibility of exploring concentrations and exposure across a variety of averaging times and time series and calculating mean concentrations and exposures (Klepeis et al. 2007).

Conclusion

Only limited evidence is available regarding SHS exposure in outdoor settings as determined by environmental and biological markers; therefore, the existing evidence must be interpreted carefully. However, our review clearly indicates the potential for high SHS exposures at some outdoor settings and indoor locations adjacent to outdoor smoking areas. This review shows that high smoker density, highly enclosed outdoor areas, low wind conditions, and close proximity to smokers generate higher outdoor SHS concentrations. Accounting for these factors is important for future studies on the relationship between outdoor SHS exposure and health outcomes.

The WHO Framework Convention on Tobacco Control has concluded that 100% smoke-free environments are required to adequately protect the public's health from the harmful effects of SHS (WHO 2003). The present review indicates that further research using standardized methodology is needed to better characterize outdoor SHS exposure levels and determine whether smoke-free legislation should be extended to outdoor areas.

Future studies should include representative samples of different locations; use standardized statistical analyses and report multiple measures of central tendency and measures of variability (standard errors, confidence intervals, or quartiles); and consider potential modifiers of SHS levels including smoker density, degree of enclosurement of outdoor locations, wind speed and direction, and proximity to smokers. Finally, further research is needed to determine the most appropriate marker or combination of markers to assess SHS exposure, which may include more specific environmental and individual markers of exposure (e.g., airborne nicotine and cotinine in saliva) in addition to $PM_{2.5}$ concentration.

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Secondhand smoke in outdoor settings: smokers' consumption, non-smokers' perceptions, and attitudes toward smoke-free legislation in Spain.

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Secondhand smoke in outdoor settings: smokers' consumption, non-smokers' perceptions, and attitudes toward smoke-free legislation in Spain

Xisca Sureda[a,b,c], Esteve Fernández[a,b,c,d], Jose M Martínez-Sánchez[a,b,e], Marcela Fu[a,b,c], María J. López[f,g,h], Cristina Martínez[a,b,d,i], Esteve Saltó[j,k].

[a]*Tobacco Control Unit, Cancer Control and Prevention Programme, Institut Català d'Oncologia-ICO. Gran Via de L'Hospitalet 199-201, 08908 L'Hospitalet de Llobregat (Barcelona), Spain*

[b]*Cancer Control and Prevention Group, Institut d'Investigació Biomèdica de Bellvitge-IDIBELL, Gran Via de L'Hospitalet 199-201, 08908 L'Hospitalet de Llobregat (Barcelona), Spain*

[c]*Department of Clinical Sciences, School of Medicine, Universitat de Barcelona, Carretera de la Feixa llarga s/n. 08908 L'Hospitalet del Llobregat (Barcelona), Spain*

[d]*Catalan Network of Smoke-free Hospitals, Insitut Català d'Oncologia. Gran Via de L'Hospitalet 199-201, 08908 L'Hospitalet de Llobregat, Barcelona, Spain*

[e]*Biostatistic Unit, Department of Basic Science, School of Medicine and Health Sciences, Universitat Internacional de Catalunya, Carrer Josep Trueta s/n. 08915 Satn Cugat del Valles,*

[f]*Evaluation and Interventions Methods Service, Agència de Salut Pública de Barcelona, Pça Lesseps 1, 08023 Barcelona, Spain*

[g]*Biomedical Research Centre Network for Epidemiology and Public Health (CIBERESP), Agència de Salut Pública de Barcelona, Pça Lesseps 1, 08023 Barcelona, Spain*

[h]*Institut d'Investigació Biomèdica-IBB Sant Pau, Sant Antoni Maria Claret, 167, 08025 Barcelona, Spain*

[i]*Department of Nursing, School of Medicine and Health Sciences, Universitat Internacional de Catalunya, Carrer Josep Trueta s/n. 08915 Sant Cugat del Valles, Spain*

[j]*Direcció General de Planificació i Recerca en Salut, Generalitat de Catalunya, Travessera de les Corts, 131-159, 08028 Barcelona, Spain*

[k]*Department of Public Health, School of Medicine, Universitat de Barcelona, Carrer Casanova 143, 08036 Barcelona, Spain.*

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Correspondence to:

Xisca Sureda Llull, BPharm, MPH

Tobacco Control Research Unit.

Institut Català d'Oncologia.

Av. Gran Via de l'Hospitalet, 199-203.

08908 l'Hospitalet de Llobregat (Barcelona), Spain

E-mail: fsureda@iconcologia.net

ABBREVIATIONS

SHS: Secondhand smoke

PM: Particulate Matter

ABSTRACT

Objective: To describe where smokers smoke outdoors, where non-smokers are exposed outdoors to SHS, and attitudes toward smoke-free outdoor areas after the implementation of national smoke-free legislation.

Design: This cross-sectional study. The survey was conducted between June 2011 and March 2012 (n=1,307 participants).

Setting: Barcelona, Spain

Participants: Representative, random sample of the adult (≥16 years) population

Primary and secondary outcome: Proportion of smoking and prevalence of exposure to SHS in the various settings according to type of enclosure. Percentages of support for outdoor smoke-free policies according to smoking status.

Results Smokers reported smoking most in bars and restaurants (54.8%) followed by outdoor places at work (46.8%). According to non-smokers, outdoor SHS exposure was highest at home (42.5%) and in bars and restaurants (33.5%). Among non-smoking adult students, 90% claimed exposure to SHS on university campuses. There was great support for banning smoking in the majority of outdoor areas, which was stronger among non-smokers than smokers. Over 70% of participants supported smoke-free playgrounds, schol and high school courtyards, and the grounds of healthcare centers.

Conclusion Extending smoking bans to selected outdoor settings should be considered in further tobacco control interventions to protect non-smokers from SHS exposure and to establish a positive model for youth. The majority of public support for some outdoor smoke-free areas suggests that it is feasible to extend smoking bans to additional outdoor settings.

STRENGTHS AND LIMITATIONS OF THE STUDY

This study is the first to describe together tobacco consumption, SHS smoke exposure, and attitudes towards smoke-free policies in a number of outdoor settings, thus providing an overall picture of these related aspects of tobacco control.

This study included representative, random samples of the population of Barcelona (Spain).

This study included information obtained after the implementation of Spanish comprehensive smoke-free legislation (Law 42/2010). It would have been of great interest to have data before that law, and also before and after previous legislation (Law 28/2010) to evaluate possible changes.

INTRODUCTION

Smoke-free policies have been demonstrated to be an effective way to protect people from the adverse effects of secondhand smoke (SHS) exposure[1, 2]. Such policies have been successfully implemented in indoor public places and workplaces in several countries during the last decade, in accordance with Article 8 of the Framework Convention on Tobacco Control as recommended by the World Health Organization[3]. Reported impacts of these smoke-free laws after their implementation include reductions in SHS exposure by 80-90% in high-exposure settings[4], reductions in respiratory symptoms[5], an immediate decrease in the incidence of heart attacks[6], an increase in the number of smokers who want to quit[7], the encouragement of smoke-free homes[8], and even a neutral or positive effect on business in the hospitality sector and elsewhere[9].

However, smoke-free policies in indoor work places and public places may motivate smokers to relocate to outdoor settings[10, 11]. In recent years, several countries have extended smoke-free legislation to various outdoor settings, including healthcare centers, children's playgrounds, beaches, dining areas, sporting venues, public building entrances, transport settings, partly enclosed streets, and university campuses[10, 12, 13].

These policies are becoming popular and socially accepted, with public support increasing over time[14], but they are not free of criticism[15-17]. Those who oppose outdoor smoke-free legislation claim that it is ethically unsustainable because it does not respect the principle of freedom and autonomy of individuals, and that there is insufficient evidence that SHS in these environments impacts health[15, 16]. Supporters of these policies argue that outdoor smoking bans reduce the visibility of smoking, that they are associated with denormalization of smoking, that they establish a positive smoke-free model for youth, and that they reduce smoking opportunities and SHS exposure. Furthermore, smoking bans may be accompanied by environmental benefits such as reducing fire risk and pollution from butts[14, 16-21].

On January 2, 2011, Spain implemented a new smoke-free law (Law 42/2010), the first time in Europe [22] that smoking was prohibited in some outdoor areas, including hospital premises, school and high school courtyards, and children's playgrounds [23]. In this context, the objectives of the present study were to describe: 1) the outdoor settings in which smokers smoke, 2) the outdoor settings in which non-smokers are exposed to SHS, and 3) the attitudes toward smoke-free outdoor policies after implementation of Law 42/2010.

METHODS

Study design and selection of study participants

This cross-sectional study included a representative, random sample of the adult (≥16 years) population of Barcelona, Spain. The survey was conducted between June 2011 and March 2012, after implementation of national, comprehensive smoke-free legislation (on January 2, 2011). A detailed description of the methods has been provided elsewhere[24]. In brief, we determined a sample size of 1,560 people with standard procedures (error of 5%, error of 20%, and 20% losses for independent samples); our final sample included 1,307 individuals. Sample size calculations were performed with GRANMO MS Windows 5.2 (http://www.imim.es/media/upload/ arxius/grmw52.zip).

We obtained data and addresses for Barcelona residents from the updated official city census (year 2010) provided by the Municipal Institute of Statistics of Barcelona. Individuals aged 16 years and older were eligible to participate in this study. A letter was mailed to eligible individuals to describe the purpose of the study and to inform them that they had been selected at random. The letter also indicated that the study required a visit from an interviewer that would administer the questionnaire and collect a saliva sample. The individuals were informed that they were free to decline participation, and that they could access more information about the study on a website, by telephone, or by email; contact information was provided in the letter. Participants that could not be located after several attempts (at different times of day and different days of the week) and those that declined to participate in the study were replaced at random. Replacements were chosen from eligible individuals of the same sex, within a 5-year age group, and within the same district of residence. Substitutions accounted for 54.6% of the survey respondents.

Individuals that agreed to participate were interviewed at home by trained interviewers. Participants were asked to sign an informed consent form before proceeding with the face-to-face, computer-assisted interview. The questionnaire included information on sociodemographics, tobacco consumption, self-assessed exposure to SHS in various settings (at home, work/educational venues, during leisure time, and in public and private transportation), and attitudes toward smoking restrictions. After completing the questionnaire, respondents were asked to provide a sample of saliva for cotinine analysis, and weight and height were measured. The Research and Ethics Committee of Bellvitge University Hospital approved the study protocols and the informed consent forms.

Smokers' tobacco consumption in outdoor settings

Smokers were defined as individuals that, at the time of the interview, reported that they smoke at least one cigarette per day (daily smokers), that they smoke occasionally (occasional smokers), or that had a salivary cotinine concentration >10 ng/mL[25].

Tobacco consumption outdoors was determined with the same questions for home, work, bars/restaurants, and discotheques/pubs. The question was, "How many cigarettes (per day) do you normally smoke at (home/work/bars and restaurants/discotheques/pubs)?" Based on this question, we established four categories of tobacco consumption: (1) no consumption, which included subjects who reported smoking cigarettes neither indoors nor outdoors; (2) tobacco consumption only indoors, which included individuals who reported smoking one or more cigarettes indoors only; (3) tobacco consumption only outdoors, which included individuals who reported smoking one or more cigarettes outdoors only; and (4) tobacco consumption both indoors and outdoors, which included individuals who reported smoking one or more cigarettes both indoors and outdoors.

Non-smoker SHS exposure in outdoor settings

Non-smokers were defined as individuals that, at the time of the interview, reported that they did not smoke and had a salivary cotinine concentration ≤10 ng/mL[25]. This group included individuals that had never smoked as well as former smokers.

Exposure to SHS was evaluated with different questions depending on the setting studied. We determined exposure at home, at work, at education venues (including the following places: in the classroom, in the corridor or hall, in the bar or cafeteria, in the study room, in the photocopying room, in the main building entrances (outdoors), and in other outdoor locations on campus), during leisure time (including bars, restaurants, discotheques, and pubs), on public transportation (including subway or tram, subway or tram station, train, train station, bus, and bus station). Based on the responses regarding SHS exposure in those settings, we established four categories of SHS exposure for each setting: (1) non-exposed individuals, which included individuals with no exposure according to their answers; (2) individuals exposed only indoors, which included individuals who declared that they were only exposed in some of the indoor places; (3) individuals exposed only outdoors, which included individuals who reported that they were only exposed in some of the outdoor places; and (4) individuals exposed both indoors and outdoors, which included individuals who reported exposure in any of the indoor and outdoor places.

Public support for outdoor smoke-free policies

We included information about public support for outdoor smoke-free policies from smokers and non-smokers. Public support for outdoor smoke-free policies was determined using the question, “To what extent do you agree or disagree with the prohibition of smoking in the following outdoor settings?” Five responses were possible (totally agree, agree, neither agree nor disagree, disagree, totally disagree). We recorded information about outdoor locations in schools/high schools, university campuses, healthcare centers, public transportation, playgrounds, shopping centers, sport centers, and swimming pools and beaches. For the analysis, we derived a variable for each setting with three categories: (1) “Agree,” which included individuals who reported total agreement or agreement with implementing outdoor smoke-free legislation; (2) “Neither agree nor disagree,” which included subjects who described themselves as neither in favor nor against the prohibition of smoking outdoors; and (3) “Disagree,” which included individuals who disagreed or totally disagreed with implementing outdoor smoke-free legislation.

Statistical analysis

For smokers, we computed the proportion of smoking in the various settings according to type of enclosure. For non-smokers, we computed the prevalence of exposure to SHS in various settings and according to the type of enclosure. We also computed percentages of support for outdoor smoke-free policies according to smoking status. Analyses were stratified by sex, age (16-44, 45-64, and ≥65 years), and educational level (less than primary and primary school, secondary school, and university). Statistical analyses were performed with SPSS v17.0.

RESULTS

A total of 1,307 participants were interviewed (615 males and 692 females); 947 participants were self-reported non-smokers (409 males and 538 females) and 360 were self-reported smokers (206 males and 154 females). Of the non-smokers, 19 had cotinine concentrations consistent with active smoking (>10 ng/mL) and thus were classified as smokers [25]. Of self-reported non-smokers, 48 did not provide a saliva sample and in 2 cases the cotinine analysis was not possible (i.e., insufficient sample), and thus these cases were considered missing data.

Table 1 shows the proportion of smokers who reported smoking outdoors in various settings. Nearly 18% of smokers reported that they smoked at home in outdoor areas alone, while 18.1% smoked both indoors and outdoors. Forty-six percent of smokers said that they only smoked outdoors while at work. Smoking participants smoked outdoors most often in bars and restaurants (54.8%) and outdoors in discotheques and pubs (34.6%).

Table 1. Distribution of 379 smokers (≥ 16 years) according to where they smoke and type of enclosure. Barcelona, 2011-2012.

	No consumption	**Only indoors**	**Only outdoors**	**Both indoors and outdoors**
	n (%)	n (%)	n (%)	n (%)
Home (n=360)	58 (16.1)	173 (48.1)	64 (17.8)	65 (18.1)
Work (n=250)	122 (48.8)	11 (4.4)	115 (46.0)	2 (0.8)
Bars and restaurants (n=338)	134 (39.6)	19 (5.6)	174 (51.5)	11 (3.3)
Discotheques and pubs (n=173)	109 (63.0)	4 (2.3)	57 (32.9)	3 (1.7)

At home, 42.5% of non-smokers reported SHS exposure only outdoors (18.8%) or both indoors and outdoors (23.7%). At work, SHS exposure in outdoor settings was self-reported by 15% of non-smokers; 83.7% of non-smokers claimed that they were not exposed to SHS in any setting during work. Most adult students interviewed were exposed to SHS in education venues outdoors only (70.2%) or both indoors and outdoors (20.2%). Non-smokers were exposed to SHS outdoors in bars and restaurants (33.5%) and outdoors in discotheques and pubs (14.4%). The rate of self-reported exposure outdoors on public transportation was 2.8% (Table 2).

Table 2. SHS exposure among 878 non-smokers (≥ 16 years) according to the setting of exposure and the type of enclosure. Barcelona 2011-2012.

	Not exposed	**Only indoors**	**Only outdoors**	**Both indoors and outdoors**
	n (%)	n (%)	n (%)	n (%)
Home (n=876)	444 (50.7)	59 (6.7)	165 (18.8)	208 (23.7)
Work (n=489)	386 (83.7)	6 (1.3)	69 (15.0)	-
Education venues (n=134)	12 (9.7)	-	87 (70.2)	25 (20.2)
Bars and restaurants (713)	458 (64.2)	16 (2.2)	234 (32.8)	5 (0.7)
Discotheques and pubs (n=297)	250 (84.2)	4 (1.3)	39 (13.1)	4 (1.3)
Public transport (n=724)	644 (96.3)	6 (0.9)	2 (0.3)	17 (2.5)

Table 3 contains the percentages of support of the smoking ban in various outdoor settings after implementation of the new Spanish smoke-free legislation. Overall, 80.8% of participants supported smoke-free playgrounds, 71.8% grounds of healthcare centers, 70.5% school and high school courtyards, 56.1% public transportation outdoors, 53.5% sport centers outdoors, 52.7% university campuses, 43.0% open swimming pools and beaches, and 38.4% outdoor areas in shopping centers. The respective proportions of non-smokers who supported outdoor smoking bans were higher than these overall figures, but the respective proportions of agreement among smokers were 15-30 percentage points lower (Table 3); these differences were statistically significant ($p<0.05$). Similar patterns were observed for men and women in terms of the agreement on outdoor smoke-free policies. Participants aged 65 years and older were more supportive of the prohibition of smoking in outdoor settings than people aged 16-44 years and people aged 45-65 years. There was no clear, specific pattern according to educational level.

Table 3. Agreement with the smoking ban in various outdoor settings (n=1,307 participants) according to smoking status, sex, age, and educational level. Barcelona 2011-2012.

	School/high school		**University**		**Healthcare centers**		**Public transportation**		**Playgrounds**		**Shopping centers**		**Sport centers**		**swimming pool/beach**	
	n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value
All	1302 (70.5)		1300 (52.7)		1301 (71.8)		1305 (56.1)		1301 (80.8)		1298 (38.4)		1289 (53.5)		1296 (43.0)	
Smoking status																
Smokers	378 (56.6)		377 (34.7)		378 (57.9)		378 (39.4)		375 (69.9)		378 (20.6)		375 (32.0)		378 (21.4)	
Non-smokers	874 (76.1)	<0.001	874 (60.2)	<0.001	873 (77.8)	<0.001	877 (63.3)	<0.001	876 (84.9)	<0.001	870 (45.5)	<0.001	866 (62.4)	<0.001	868 (51.6)	<0.001
Sex																
Men	612 (70.1)		614 (52.8)		613 (71.8)		613 (56.6)		613 (80.9)		613 (40.1)		614 (54.6)		614 (41.2)	
Women	690 (70.9)	0.761	686 (52.6)	0.958	688 (71.8)	0.992	692 (55.6)	0.724	688 (80.7)	0.911	685 (36.8)	0.216	675 (52.6)	0.479	682 (44.6)	0.221
Age in years																
16-44	595 (70.9)		594 (49.5)		596 (73.8)		595 (55.8)		594 (83.5)		595 (36.5		593 (53.0)		593 (39.8)	
45-65	388 (66.5)		386 (49.2)		385 (65.5)		390 (54.1)		389 (77.4)		388 (34.5)		384 (49.7)		389 (41.4)	
≥65	319 (74.6)	0.060	320 (62.8)	0.001	320 (75.6)	0.004	320 (59.1)	0.408	318 (79.9)	0.052	315 (46.7)	0.002	312 (59.3)	0.039	314 (51.0)	0.004
Educational level																
Less than secondary	348 (74.1)		349 (65.0)		347 (75.5)		349 (57.9)		348 (82.8)		347 (47.0)		345 (56.5)		344 (49.7)	
Secondary	521 (66.6)		519 (48.4)		522 (72.4)		522 (54.6)		518 (77.4)		520 (34.4)		516 (49.4)		520 (40.2)	
University	431 (72.2)	0.037	430 (47.9)	<0.001	430 (67.9)	0.059	432 (56.5)	0.621	433 (83.1)	0.045	429 (35.9)	<0.001	426 (55.9)	0.058	430 (40.9)	0.013

DISCUSSION

This is the first study to evaluate where smokers smoke outdoors, where non-smokers receive outdoor exposure to SHS, and attitudes toward smoke-free outdoor areas after the implementation of national, comprehensive smoke-free legislation, thus providing an overall picture of these related aspects of tobacco control.

Where smokers smoke and where non-smokers are exposed to SHS outdoors

Our results reveal that both consumption and self-reported SHS exposure were very low, if not absent, in all settings regulated by national, comprehensive smoke-free legislation. However, non-smokers reported SHS exposure in most outdoor settings in which smokers reported smoking. These results are population-level confirmation of the relocation described in *in situ* early observational studies[10, 11] after implementation of smoke-free policies affecting indoor public places and workplaces.

In the present investigation, more smokers (49.2%) reported smoking in the outdoor areas of bars and restaurants after the smoke-free legislation took effect. Accordingly, 33.5% of the non-smokers interviewed reported SHS exposure in those settings. In Spain, bars and restaurants were exempted from the smoking ban before Law 42/2010, and people could smoke indoors in some venues; the current smoke-free law prohibits smoking in those places with no exceptions. In a country like Spain, which has a popular culture of socialization, it is understandable that smokers relocated to the outdoor areas of bars and restaurants. A recent study of the impact of the Spanish smoke-free law demonstrated that the presence of outdoor smoking may be reducing the effectiveness of the indoor smoking ban at protecting hospitality workers and patrons from SHS exposure[26]. A previous investigation of outdoor smoking behavior before and after implementation of France's national smoke-free law suggested that smokers relocated to outdoor environments based on an increase in reported smoking at hospitality venues, including both restaurants and cafés/pubs/bars[27].

In the present study, self-reported exposure in outdoor areas at home constituted ~40% of positive responses. Moreover, 84% of smokers reported smoking at home, and 35.9% of them smoked in outdoor areas. Although recent studies of the effects of stepped smoke-free legislation (Laws 28/2005 and 42/2010) in Spain observed significant relative reductions (15.1%[24] and 43.1%[28]) in self-reported SHS exposure in the home, it is important to consider the results of the present investigation to focus new strategies on increasing the percentage of smoke-free homes.

Among non-smoking adult students, 90% reported SHS exposure on university campuses, higher than the 79.5% reported in a previous study of staff and students in an Australian University[29]. In the same study, respondents supported a smoke-free policy on campus, and 65.7% of respondents felt that the campus should be completely smoke-free. Another investigation of university students in Beirut, Lebanon indicated that after establishing a smoke-free campus, most students were satisfied with the extension of the ban, and some smokers reduced smoking or declared that the ban could help them to quit[30]. In our study, 52.7% of respondents favored smoke-free university campuses. Together with the high percentage of respondents exposed in this setting and the results of other studies, our investigation suggests the need to consider making university campuses smoke-free.

Attitudes toward outdoor smoke-free legislation

Our findings suggest that there is great support for outdoor smoke-free areas, support that is stronger among non-smokers than smokers. The highest support was for areas in which children are present (playgrounds and school/high school courtyards) and the grounds of healthcare centers. Moreover, more than half of respondents supported smoke-free outdoor areas for public transportation (bus stops, stations), sport centers, and university campuses. Less support was observed for smoke-free outdoor areas in shopping centers and swimming pools/beaches. A review of public attitudes toward smoke-free outdoor areas also found a majority support for restricting smoking in a variety of outdoor places that in general was higher for places in which children were present, ranging from 72% in a survey in Minnesota (USA) in 1998 to 91% in California (USA) and British surveys conducted in 2002 and 2007, respectively[14]. A study conducted in Italy revealed that 64.6% of Italians supported smoke-free policies in public parks, 68.5% in sports stadiums, 62.1% in beaches, 79.9% in outdoor areas surrounding hospitals, and 85.9% (the strongest support) in school courtyards[31]. In California[32], a survey conducted in 2002 uncovered 91% support for smoke-free policies for children's play yards, 63% for outside buildings entrances and outdoor restaurant dining patios, 40% for outdoor bars/clubs, and 52% for outdoor public places including parks, beaches, and sport stadiums. This support increased in the survey conducted in California in 2005[33].

When we evaluated our results according to smoking status, we observed that non-smokers reported stronger support for smoke-free outdoor areas than smokers. These differences were consistently observed for all outdoor settings considered. The largest gaps between smokers and non-smokers occurred in support for sport centers (32.0% for smokers vs. 62.4% for non-smokers) and swimming pools/beaches (21.4% for smokers vs. 51.6% for non-smokers). The smallest gap was associated with support for smoke-free outdoor areas in public parks (69.9% for smokers vs. 84.9% for non-smokers) followed by school/high school courtyards (56.6% for smokers vs. 76.1% for non-smokers) and the grounds of healthcare centers (57.9% for smokers vs. 77.8% for non-smokers). Stronger support among non-smokers than smokers for restricting smoking in outdoor areas is consistent across countries[14, 31]. However, more than half of the smokers interviewed here supported the restriction of smoking in outdoor areas where children are present (public park and school/high school courtyards) and the grounds of healthcare centers, as also reported in Italy[31] and New Zealand[31, 34].

Policy and research implications

Outdoor smoke-free areas are not as common as indoor smoke-free areas. However, our study indicates that non-smokers reported SHS exposure in some outdoor settings, including outdoor areas at home, at education venues, and during leisure time. A review of 18 studies of SHS levels in outdoor areas reported mean PM2.5 concentrations ranging from 8.32 µg/m^3 to 124 µg/m^3 at hospitality venues and from 4.60 µg/m^3 to 17.80 µg/m^3 in non-hospitality venues when smokers were present[35]. Although there is some controversy about the adverse health effects of SHS exposure in outdoor settings, several recent studies have reported evidence of the effects of short-term exposure to tobacco smoke, such as eye irritation and respiratory irritation in non-smokers[36, 37] and even adverse effects on the cardiovascular system[38].

The high percentage of non-smokers in the current investigation who reported SHS exposure at home and the percentage of smokers who reporting smoking both indoors and outdoors at home highlight the need to develop health-education interventions to implement voluntary smoke-free rules in those settings[39]. Previous studies demonstrated that restrictions at home are more common when smokers live with other non-smoking adults and where children are present[40]. In the current study, we were not able to determine whether the smokers who reported smoking at home lived with other non-smokers and/or children. However, the high percentage of non-smokers exposed at home indicates that further research is necessary to identify the most effective measures for promoting smoke-free homes as a key element of tobacco-control programs.

The high percentage of non-smokers exposed to SHS in bars and restaurants is also of concern, as is our observation that more than half of the smokers reported smoking in those settings. A previous investigation of a sample of bars and restaurants in various European cities measured nicotine and PM as SHS markers and detected significant SHS levels in outdoor areas, indicating a significant health risk for individuals exposed in those settings[41]. It would have been interesting to describe the support for prohibiting smoking in bars and restaurants outdoors, but we did not collect that information in this survey. Surveys in California (USA)[33] and New South Wales (Australia)[42] reported 72% and 69%, respectively, support for smoke-free outdoor restaurant patios. Terraces and patios will surely be the focus of new smoke-free legislation[26].

The strong support for some outdoor smoke-free areas should be considered by policy makers and tobacco-control researchers for future interventions. This support indicates an important process of denormalization of smoking, and policy makers should consider it to be a determinant for reinforcing tobacco-control measures. The strongest support for smoke-free outdoor settings was obtained for children's playgrounds, the grounds of healthcare centers, and school/high school courtyards. Those places were included in the last Spanish smoke-free law (Law 42/2010). It would have been interesting to compare the current results with data gathered prior to the implementation of Law 42/2010 to evaluate whether support for smoke-free areas increased after its implementation, confirming its positive effect on the attitudes of the population. Although we did not have those data, other studies suggest that support for smoke-free bans increased after the adoption of legislation and over time[14, 31].

Strengths and limitations

A potential limitation of the current study derives from the self-reported nature of the data obtained through questionnaires. This potential information bias was minimized by asking the participants for specific settings where they smoke and where they were exposed to SHS, and recording the participants' support for making specific outdoor places smoke-free on a five-point scale. This cross-sectional study included information obtained after the implementation of Spanish comprehensive smoke-free legislation (Law 42/2010). It would have been of great interest to have conducted a similar survey before that law, and also before and after previous legislation (Law 28/2010) to evaluate the effects of each law on tobacco consumption and SHS exposure in outdoor settings, as well as the changes in support for some smoke-free outdoor areas. Our previous survey (in 2004-05, before Law 28/2005 was implemented) included information on smokers' consumption and SHS exposure in various settings[43, 44]. However, we did not enquire separately about tobacco consumption and SHS exposure indoors and outdoors, nor did we investigate attitudes toward smoke-free outdoor places, as we did in the present study.

CONCLUSION

Our results show that the exposure of non-smokers to SHS mostly occurs in outdoor areas where smoking is allowed. The strong support for some smoke-free areas, including areas that are already smoke-free according to a national law, suggests the feasibility of extending smoking bans to several outdoor settings. Factors that influence support for smoke-free areas should be considered when deciding which policy interventions best promote the extension of smoking bans to outdoor settings. Awareness of the hazards of SHS exposure, the need to protect children and other non-smokers from this exposure, and/or establishing a positive model for youth should be on the agenda for interventions that favor the denormalization of smoking and increased support for new smoke-free areas.

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Contributors: EF and XS designed the study to which all the authors contributed. XS, MF, and CM collected the data. XS, JMMS, MF and MJL prepared the database. XS and JMMS analyzed the data and MF, ES and EF revised with her the results. All the authors contributed to

the interpretation of results. XS drafted the manuscript, which was critically revised by all authors, who also approved the final version. EF is the guarantor.

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6. DISCUSIÓN CONJUNTA

Después de la implementación de medidas sanitarias para la prevención y control de tabaquismo es necesario evaluar de forma global su impacto para determinar si se han obtenido los resultados esperados. Además, es necesario monitorizar de forma continua en el tiempo los cambios en la epidemia del tabaco, tanto en el consumo como en la exposición al HAT de los no fumadores para poder desarrollar intervenciones de control del tabaquismo más eficientes, incluyendo recomendaciones para la población general.

6.1. Cambios en la exposición al HAT en la población no fumadora

En la presente tesis doctoral se incluyen los resultados de la evaluación de las leyes de medidas sanitarias para la prevención y control del tabaquismo introducidas en España el 1 de enero de 2006 (Ley 28/2005) y el 2 de enero de 2011 (Ley 42/2010) con datos obtenidos antes de la implementación de la Ley 28/2005 y datos obtenidos después de la Ley 42/2010. Los resultados muestran que tanto la exposición autopercibida como objetiva mediante las concentraciones de cotinina en saliva de la población adulta no fumadora disminuyen significativamente después de la entrada en vigor de la legislación. Esta disminución se observa tanto en los lugares de trabajo, durante el tiempo libre e incluso en lugares no regulados por la ley, como en el transporte público y el hogar. Esta disminución en el hogar se ha observado en estudios previos que, importante, contradicen los resultados previstos por la industria que argumentaba que leyes más restrictivas que prohibiesen fumar en los lugares de restauración y hostelería implicarían un desplazamiento de los fumadores al hogar y de esta manera aumentaría la exposición al HAT en los menores(78;83-87).

Un estudio realizado en Escocia que evaluaba los cambios en la exposición autoreportada y evaluada mediante cotinina después de la implantación de políticas libres de humo observó una disminución de la exposición al HAT de manera global y para todos los lugares estudiados(78). Nuestros resultados indican una disminución global de la exposición autoreportada al HAT entre la población no fumadora de un 25,1%. Esta disminución observada en la exposición al HAT vendría determinada por la implementación de ambas leyes (Ley 28/2005 y Ley 42/2010), lo que demuestra la importancia de las políticas de control del tabaquismo para la protección de los no fumadores a la exposición al HAT. Sin embargo no podemos discernir los efectos propios de cada una de ellas, lo cual hubiera sido de gran interés. Aún así, algunos estudios previos que evaluaban los efectos de la Ley 28/2005, observaron una disminución importante en la exposición al HAT en los lugares de trabajo(69), pero no durante el tiempo libre ni el hogar(66;88), ni en bares ni en restaurantes(69;70). En nuestro estudio, una de las mayores reducciones de exposición al HAT observadas tuvo lugar durante el tiempo libre. Un estudio previo realizado en España observó una reducción de los niveles de nicotina aérea y de $PM_{2.5}$ de más del 90% en bares y restaurantes después de la implementación de la ley 42/2010(89). Además, otro estudio de base poblacional realizado en Galicia también observó una reducción importante de la exposición al HAT durante el tiempo libre después de la implementación de la Ley 42/2010(90). Nuestros resultados, y los obtenidos en los otros estudios, demuestran la importancia de la implementación de la nueva legislación que fortalece la anterior ley con la prohibición de fumar en todos los locales de hostelería, sin excepción. Estos lugares son donde la gente joven no fumadora ha estado expuesta mayoritariamente durante el tiempo libre. Al igual que estudios publicados con anterioridad en otros países(78;83;85-87), no se observa un desplazamiento de los fumadores al hogar. Al contrario, nuestros resultados muestran una disminución de la exposición al HAT en el hogar, mientras que los estudios que evaluaban propiamente la Ley 28/2005(7) no mostraban diferencias en la exposición al HAT en el hogar antes y después de su implementación. Esta disminución observada podría estar relacionada con el proceso de desnormalización del tabaco favorecido tanto por el paso del tiempo desde la implementación de la ley 28/2005 como por la implementación de una ley más restrictiva.

La proporción de adultos no fumadores con concentraciones no detectables de cotinina en saliva aumentó del 7,3% antes de la Ley 28/2005 al 53,2% después de la implementación de la Ley 42/2010. Este resultado, junto con la disminución observada en las concentraciones de cotinina en saliva (del 87,6%) y la disminución de la exposición autoreportada al HAT (del 25.1%), son la prueba de los efectos positivos de la implementación de las medidas legislativas. Estudios realizados en otros países después de la implementación de leyes de espacios sin humo muestran resultados igualmente satisfactorios si bien la disminución de las concentraciones de cotinina en saliva en los no fumadores no es tan pronunciada como la observada en nuestro estudio (reducciones del 47% en Nueva York, 39% en Escocia, y del 27% en Inglaterra)(78;91;92). Esto vendría explicado por las altas concentraciones de cotinina en saliva obtenidas en la población española no fumadora antes de la implementación de la Ley 28/2005 y 42/2010, que eran hasta 9 veces superiores a las obtenidas en los estudios de Nueva York, Escocia e Inglaterra antes de la implementación de sus respectivas legislaciones. Sin embargo las concentraciones obtenidas después de implementar las medidas de control de tabaquismo fueron similares en todas las poblaciones estudiadas. Podríamos explicar la alta concentración de cotinina en saliva obtenida en nuestra población en 2004-2005 si pensamos que la prevalencia de fumadores en España en ese momento era superior a la de los países comparados. Una vez implementadas las leyes de medidas de control del tabaquismo que en 2011 prohibía fumar en todos los espacios públicos cerrados, sin excepciones, esta prevalencia de exposición entre los no fumadores disminuye independientemente de la prevalencia de fumadores, que continua siendo superior comparada con la de estos países.

6.2. Cambios en la prevalencia de consumo de tabaco y patrón de consumo

Los resultados obtenidos en la presente tesis doctoral indican una disminución de la prevalencia de fumadores diarios entre el 2004-2005 y 2011-2012, del 26,6 al 24,1%, disminución que no es estadísticamente significativa. Esta reducción se observa tanto en mujeres como en hombres, en los que sí fue estadísticamente significativa. Como ya se ha demostrado en otros estudios, los cambios en la prevalencia de consumo del tabaco no dependerían sólo de la implementación de las políticas de espacios libre de humo sino que deberían explicarse según las tendencias seculares que sigue la epidemia del tabaquismo(73;93). En nuestro caso, los cambios observados coinciden con los datos reportados por la Encuesta Nacional de Salud entre 1987 y 2006 con una disminución de la prevalencia de fumadores del 2,2% por año en hombres fumadores (diarios y ocasionales) y la disminución observada en mujeres entre el período 2001 y 2006 de un 2,9% de disminución anual(7).

Los resultados indican una mayor reducción de la prevalencia del consumo de tabaco entre la gente joven, con edades comprendidas entre 16 y 44 años. También se observa una disminución importante de los "grandes fumadores" o "heavy smokers" en su acepción inglesa (fumadores de >20 cigarrillos al día), aunque no se observan cambios en las puntuaciones del Test de Fagerström de dependencia de la nicotina ni en los estados de cambio en los fumadores diarios antes y después de la implementación de las legislaciones.

Se observa una importante reducción de la prevalencia de consumo de tabaco manufacturado entre la población fumadora diaria en el período estudiado. Por el contrario, los resultados muestran un aumento considerable del consumo de cigarrillos de liar exclusivo o combinado con cigarrillos manufacturados, sobre todo entre la gente joven. Estos datos coinciden con cambios observados en las ventas de cigarrillos per cápita en España que indican una disminución de la venta de los cigarrillos manufacturados junto con el aumento en la venta de los cigarrillos de liar(8). El aumento observado de la prevalencia de consumo de tabaco de liar coincide con el aumento que se viene observando en otros estados (Australia, Canada, Reino Unido, Estados Unidos o Italia) del consumo exclusivo de este tipo de tabaco o de su consumo mixto con los cigarrillos manufacturados, en menor o mayor proporción (94;95). Al igual que en estos estudios, los datos de la encuesta realizada en el año 2011-2012 indican que el patrón del consumidor de tabaco de liar correspondería a hombres, de edades jóvenes y con niveles de estudio más elevados.

El aumento del consumo del tabaco de liar se ha relacionado con la crisis económica actual que ha afectado a tantos países europeos, incluido España(96;97). El endurecimiento de las políticas de control del tabaco que regulan las tasas del tabaco en España ha afectado principalmente al tabaco manufacturado, mientras que otros tipos de tabaco se han convertido en alternativas más económicas y asequibles para los fumadores(97). Se ha demostrado que el aumento del precio del tabaco conlleva una disminución de la prevalencia de consumo y de la intensidad(96;98). En 2009, el precio de los cigarrillos manufacturados era aproximadamente un 50% mayor al del tabaco de liar. La industria también ha aprovechado estas diferencias en los impuestos de los productos del tabaco para promocionar el tabaco de liar a precios más asequibles. Por ello, no es de extrañar que en tiempos de crisis se observe este aumento de la prevalencia de consumo del tabaco de liar en detrimento del cigarrillo manufacturado, y más entre la gente joven.

Aunque las razones económicas parecen ser la principal razón que motiva a los fumadores de cigarrillos manufacturados a cambiar al tabaco de liar, éstas no son las únicas. De acuerdo a las características de consumo declaradas por los usuarios de tabaco de liar podríamos definir a estos fumadores como poco dependientes a la nicotina y que no se plantean dejar de fumar en un futuro próximo. Además se trata de fumadores que consumen pocos cigarrillos al día aunque inhalan más profundamente que los consumidores de cigarrillos manufacturados. Estas características junto a su menor edad se combinan con la creencia de que el tabaco de liar es menos perjudicial que otros tipos de tabaco, y que la cantidad fumada se reduce junto a una percepción más positiva y una sensación de satisfacción de su consumo(95;99). Sin embargo nuestros resultados indican que los usuarios de tabaco de liar tienen concentraciones de cotinina similares a los usuarios de cigarrillos manufacturados, para las mismas características de consumo. Esto podría explicarse por el hecho de que los fumadores regulan la ingesta de nicotina para alcanzar la dosis deseada(100) y también porque el contenido de nicotina de los cigarrillos de liar es superior al de los manufacturados, al igual que el de alquitrán y monóxido de carbono(95;101-103). Esto también pone en evidencia las consecuencias para la salud del consumo de este tipo de tabaco. El consumo de tabaco de liar estaría incluso relacionado con un mayor riesgo de cáncer de pulmón y otras enfermedades (99).

Para poder desarrollar medidas eficientes para el control del tabaquismo debemos monitorizar de manera continua los cambios en la prevalencia de consumo de tabaco así como las características y el patrón de consumo es necesario. Teniendo en cuenta el aumento observado en la prevalencia de fumadores de cigarrillos de liar, se deberían revisar las políticas reguladoras de las tasas del tabaco de manera que se igualara el precio de los diferentes productos del tabaco. Además, se necesitan más estudios para determinar la exposición a biomarcadores del tabaco y los efectos en salud del consumo de los cigarrillos de liar.

6.3. Exposición al HAT en espacios al aire libre medida con marcadores del tabaco

Las políticas de espacios libres de humo implementadas desde la aprobación del Convenio Marco de la OMS para el Control del Tabaquismo (CMCT) se han centrado típicamente en los espacios públicos cerrados. Sin embargo en algunos países estas políticas se han extendido recientemente a determinados espacios exteriores, siguiendo las recomendaciones de la revisión del artículo 8 del CMCT. La Ley 42/2010 se suma a estas recomendaciones extendiendo la prohibición de fumar a parques y lugares de ocio infantil al aire libre, así como a las zonas exteriores de colegios y recintos hospitalarios. Este tipo de prohibiciones han sido criticadas por una parte de la opinión pública por carecer de evidencia científica que demuestre los efectos en salud de la exposición al HAT en estos espacios y por atentar contra la libertad individual.

La revisión bibliográfica que forma parte de la presente tesis doctoral incluye 18 estudios dónde se evaluaba la exposición al HAT en espacios al aire libre y en sus zonas interiores adyacentes, muestra que los niveles obtenidos de HAT en determinados espacios exteriores deberían considerarse, sobre todo en los espacios semiabiertos.

Los niveles de HAT obtenidos en espacios exteriores fueron más elevados en el sector de la hostelería, con concentraciones de $PM_{2.5}$ que sobrepasaban los 10 µg/m^3 en la mayoría de los casos cuando había fumadores presentes. Además los resultados de dos de esos estudios (104;105) muestran que las concentraciones de cotinina en no fumadores después de haber estado expuestos en terrazas de bares y restaurantes donde se permitía fumar son más elevadas que las obtenidas en no fumadores después de haber estado en terrazas libres de humo.

De acuerdo con la OMS, no existe ningún nivel seguro de exposición al HAT(25). La OMS determina un valor guía anual para exposiciones prolongadas de $PM_{2.5}$ de 10 µg/m^3 para espacios exteriores(9;25;106). Este valor representa el extremo inferior del rango en el que se observaron efectos significativos en la supervivencia. Sin embargo, se ha estimado que concentraciones de 3-5 µg/m^3 para las partículas de menos de 2.5 µm ($PM_{2.5}$) ya pueden producir efectos adversos para la salud. La OMS también ha determinado un valor guía para exposiciones a $PM_{2.5}$ a corto plazo (24 h), que es de 25µg/m^3. Si bien para espacios exteriores podríamos pensar que sería más lógico utilizar el límite de exposiciones a corto plazo de 25 µg/m^3, se suele recomendar que se dé preferencia al promedio anual sobre el de 24 horas.

Los resultados obtenidos en la revisión sistemática sugieren que un sector de la población, especialmente los trabajadores de la hostelería, estarían expuestos a niveles elevados de HAT en determinadas condiciones, por encima de los niveles recomendados por la OMS de 10µg/m^3 para exposiciones prolongadas, que sería el preferible a utilizar en estos casos, teniendo en cuenta el número de horas laborales a las que pueden estar expuestos esta población.

La revisión pone en evidencia que las zonas interiores adyacentes a espacios exteriores en los que se fuma también presentan niveles de exposición al HAT más elevados que los observados en espacios interiores alejados de las zonas de fumadores exteriores. Además, si bien en los espacios exteriores los niveles de HAT que se registran después de fumar descienden inmediatamente a niveles basales, en los espacios interiores en los que se ha fumado en zonas adyacentes exteriores, estos niveles se mantienen relativamente altos y disminuyen lentamente con el tiempo y con la ayuda de la ventilación del espacio(107).

Igualmente, los niveles de exposición al HAT en los espacios exteriores dónde se fuma y en sus zonas anexas interiores dependerá de algunos otros factores, algunos de los cuales no podemos controlar. Además, en el caso de los espacios exteriores estos factores hacen que los niveles de exposición al HAT sean transitorios y muy susceptibles a variaciones pudiendo pasar de niveles considerables y muy por encima de los recomendados por la OMS a niveles prácticamente indetectables. Algunos de los factores principales que determinan los niveles de HAT en estas localizaciones son el número de fumadores y características estructurales del lugar (con paredes laterales y/o techo). Otros estudios también sugieren que la dirección y velocidad del viento y la proximidad a los fumadores determinan los niveles de HAT en el momento de su medición mediante marcadores. A más densidad de fumadores, más paredes laterales y/o techo, más proximidad de fumadores y poco viento, se generan concentraciones más elevadas de HAT.

La variabilidad de los niveles de HAT en espacios exteriores y el hecho de que existen relativamente pocos estudios que miden la exposición al HAT en estas localizaciones y que los estudios existentes no siguen una metodología estándar dificulta poder determinar la existencia y magnitud de los efectos en la salud que supone la exposición al HAT en estos espacios.

Por todo ello recomendamos realizar nuevos estudios utilizando una metodología estándar para poder caracterizar mejor la exposición en estas localizaciones. Para ello se debería determinar qué marcador de la exposición al HAT sería el más adecuado para medir objetivamente los nivel de HAT en estos espacios y si sería necesario combinar más de un marcador. Además futuros estudios deberían incluir muestras representativas de diferentes localizaciones exteriores; deberían tener en cuenta los factores que pueden modificar estos niveles, sobretodo características estructurales del espacio y la densidad de fumadores, pero también condiciones meteorológicas y proximidad a los fumadores; y deberían utilizar métodos estadísticos estandarizados. Todo esto ayudaría a dar mayor validez a los resultados y facilitaría la comparación entre diferentes poblaciones y localizaciones estudiadas para después poder establecer medidas adecuadas para proteger a la población no fumadora de la exposición al HAT en dónde fuera necesario.

6.4. Espacios al aire libre: exposición percibida al HAT, consumo autoreportado y aceptabilidad de las políticas libres de humo.

También es importante tener en cuenta la aceptabilidad que tienen las políticas libres de humo en espacios abiertos entre la población general así como conocer la situación en estos espacios mediante la información autorreportada de consumo de tabaco y de exposición al HAT en la población no fumadora, para poder diseñar las intervenciones más eficaces para la prevención y control del tabaquismo. Los resultados obtenidos en el estudio 2011-2012, después de la implementación de la Ley 42/2010 que ya prohíbe fumar en algunos espacios abiertos, muestran que en aquellos espacios en que la ley prohíbe fumar, tanto el consumo de tabaco como la exposición al HAT reportada por los no fumadores son prácticamente inexistentes. Estos resultados demuestran un gran cumplimento de la ley por parte la población general. Sin embargo, también se confirma el desplazamiento de los fumadores a localizaciones exteriores que ya se había discutido en otros estudios publicados anteriormente(34;48). Alguna de las localizaciones más afectadas serían las terrazas de bares y restaurantes en las que casi la mitad de los fumadores entrevistados declara fumar en estos espacios y un 33,5% de la población no fumadora declara haber estado expuesta después de la entrada en vigor de la Ley 42/2010. Estos resultados deberían tenerse en cuenta junto con los obtenidos en nuestra revisión sistemática que indica que las concentraciones de $PM_{2.5}$ obtenidas en terrazas de bares y restaurantes donde se permitía fumar eran más elevadas a los niveles recomendados por las guías de calidad de aire de la OMS para exposiciones prolongadas. Otro estudio realizado en una muestra de bares y restaurantes en diferentes ciudades europeas encontró niveles elevados de nicotina aérea y material particulado en sus espacios exteriores, indicando un posible riesgo para la salud de los individuos expuestos en estas localizaciones(108). Aunque existe cierta controversia sobre los efectos adversos para la salud en localizaciones al aire libre, algunos estudios recientes han reportado evidencia de efectos de la exposición al HAT a corto plazo, como irritación de los ojos y de las vías respiratorias en no fumadores(16;17), e incluso sobre el sistema cardiovascular(18).

Los resultados mencionados sugieren que la efectividad de la ley 42/2010 para proteger a la población de la exposición al HAT en el sector de la hostelería podría estar reducida por la presencia de fumadores en los espacios exteriores de estas localizaciones donde sí se permite fumar, tal como ya sugiere un estudio previo de nuestro grupo de investigación(89). Hubiese sido interesante poder reportar la aceptabilidad de la población general (tanto población fumadora como no fumadora) sobre la prohibición de fumar en estos espacios pero en la encuesta realizada para este estudio no se registraba esta información. Sin embargo, una encuesta realizada en el 2002 en California(109) indicaba que un 63% de la población general estaba de acuerdo con la prohibición de fumar en espacios exteriores de restaurantes y un 40% en los exteriores de bares y pubs. La misma encuesta realizada tres años después(110) mostraba un aumento del apoyo a este tipo de políticas libres de humo.

Otro aspecto a destacar es el consumo de tabaco y la exposición al HAT entre la población no fumadora en los espacios exteriores del hogar. Si bien, los resultados obtenidos de las encuestas realizadas antes de la Ley 28/2005 y después de la Ley 42/2010 muestran una reducción relativa de la exposición al HAT autoreportada en el hogar al 15,1% después la introducción de ambas legislaciones, aproximadamente un 40% de los no fumadores declaran estar expuestos al HAT en los espacios exteriores del hogar después de la implementación de las leyes. Estos resultados ponen de relieve la necesidad de desarrollar nuevas estrategias e identificar las medidas más efectivas para aumentar la proporción voluntaria de hogares libres de humo.

En nuestro estudio, el 90% de los estudiantes no fumadores entrevistados declararon estar expuestos al HAT en los espacios exteriores de los campus universitarios, porcentaje mayor al 79,5% obtenido en un estudio previo realizado entre el personal universitario y los estudiantes de una universidad australiana(111). Este alto porcentaje de exposición al HAT debería considerarse no sólo para proteger a los no fumadores de la exposición al HAT sino también para prevenir el inicio de consumo de tabaco en la población más joven, reducir el consumo en la población joven fumadora o para ayudarles a dejar de fumar. Estos efectos positivos ya se observaron en un estudio realizado entre estudiantes universitarios en Beirut después de establecer un campus universitario libre de humo, en el que además, la mayoría de los estudiantes se mostraron satisfechos con la nueva normativa(112). El alto porcentaje de exposición al HAT obtenido en nuestro estudio entre la población no fumadora universitaria y considerando que un 52,7% de la población general entrevistada está a favor de los campos universitarios sin humo, nos sugieren la necesidad y factibilidad de implementar este tipo de políticas.

El alto porcentaje de apoyo a las políticas libres de humo en espacios exteriores no sólo se observó para los campus universitarios. Se observó un gran apoyo para la mayoría de localizaciones estudiadas que fue mayor para aquellas localizaciones dónde la presencia de menores es común (parques, lugares de ocio infantil y colegios) y recintos hospitalarios, con más de un 70% de apoyo de toda la población estudiada para estas localizaciones. El apoyo a la prohibición de fumar en estos espacios fue mayor entre la población no fumadora respecto a los fumadores para todas las localizaciones estudiadas. Sin embargo, las diferencias reportadas entre grupos fueron menores igualmente para los parques infantiles, seguido de los colegios y de los recintos hospitalarios. De hecho estos espacios son los ya incluidos en la Ley 42/2010 como espacios libres de humo lo que sugiere la aceptabilidad de la Ley tanto entre la población no fumadora como la fumadora, y el proceso de desnormalización del tabaco que acompaña a la aplicación de normativas para el control de tabaquismo. Resultados similares a los nuestros se han observado en otros estudios que también evaluaban las actitudes y creencias de la población general para los espacios exteriores libres de humo(46;47;113). El gran apoyo obtenido en otros estudios y en el nuestro para la mayoría de localizaciones sugiere la factibilidad de extender las políticas libres de humo a estos espacios.

6.5. Ventajas y limitaciones de esta investigación

Una de las principales limitaciones del estudio vendría determinada por el uso del cuestionario que comporta un posible sesgo de información. Sin embargo, los datos obtenidos de prevalencia de consumo de tabaco coinciden con los datos obtenidos en 2006 y 2011 por la Encuesta Nacional de Salud (Ministerio de Sanidad y Consumo:Encuesta Nacional de Salud, 2006, 2013). Además, el sesgo asociado a la utilización de cuestionarios vendría limitado en nuestro caso por la utilización de un marcador objetivo y específico del tabaco como es la cotinina medida en saliva.

Por otra parte al tratarse de un estudio con dos encuestas transversales de una muestra representativa de la población es posible que exista un cierto sesgo de selección, pues la no-respuesta puede estar asociada a las variables de estudio. Para evaluar este posible sesgo se analizó la distribución por sexo, edad y distrito de residencia de los participantes y no participantes (información derivada del Padrón Municipal de habitantes) y se comparó la distribución por estas mismas variables con el Padrón Municipal. No se observaron diferencias entre participantes y no participantes, y las distribuciones de las muestras de participantes siguieron sin desviaciones significativas las de las correspondientes poblaciones padronales.

Otra limitación que encontramos es el no poder discernir los efectos que tendrían la Ley 28/2005 y la Ley 42/2010 por separado, al no disponer de datos después de la implementación de la primera ley y antes de la segunda. Tampoco disponemos de datos previos a la Ley 28/2005 sobra las actitudes y creencias de la población sobre la prohibición de fumar en los espacios exteriores, por lo que sólo se utilizaron los datos obtenidos en la segunda encuesta transversal realizada. Sin embargo, la interpretación de los resultados conjuntamente con los resultados obtenidos en los estudios previos que evaluaban la Ley 28/2005 y otros estudios publicados en otros países nos permiten evaluar globalmente los efectos de las medidas de prevención y control del tabaquismo implementadas en España.

Finalmente, al tratarse de un estudio de naturaleza transversal podría estar sometido a más sesgos de lo que lo estaría un estudio de cohortes. Sin embargo, los estudios longitudinales pueden presentar importantes sesgos por pérdidas de seguimiento de los sujetos, lo que reduce sus ventajas. Además, los estudios con encuestas transversales realizadas antes y después de la implementación de políticas libre de humo que incluyen un marcador biológico objetivo han demostrado ser un método válido y de elección para evaluar estas políticas (114-116).

La principal fortaleza de este trabajo radica en que se trata del primero que evalúa los cambios en la exposición al HAT y en el patrón de consumo de tabaco en la población general mediante biomarcadores antes y después de la implementación de las leyes de medidas sanitarias para el control del tabaquismo implementadas en España en 2006 y 2011. Además se trata del primer estudio en España que estudia los cambios de patrón de consumo según el tipo de tabaco fumado describiendo las características de los fumadores de tabaco de liar y la de los fumadores de cigarrillo manufacturado. Por lo que sabemos, este es el primer trabajo que considera los niveles de cotinina en saliva en los fumadores para evaluar el patrón de consumo según tipo de tabaco fumado. Finalmente, es la primera vez en España que se describen las actitudes de la población general hacia las políticas libres de humo en espacios exteriores.

7. CONCLUSIONS

This thesis evaluates the implementation of tobacco control policies in Spain (Law 28/2005 and Law 42/2010), and its results are discussed in the context of the evidence in countries that have implemented similar regulations. From the scientific articles included in this thesis we can draw the following conclusions:

1) The implementation of a stepped smoke-free legislation was accompanied by a large reduction in second-hand smoke, both self-reported and assessed by means of salivary cotinine concentrations, in the adult non-smoking population in Barcelona, Spain. This reduction was observed in workplaces, during leisure time, and even in settings not regulated by the law, like in the home and public transportation.

2) The prevalence of smoking is decreasing according to the trends of tobacco epidemic in Spain and together with the tobacco smoke free policies implemented in the last decade.

3) It has been observed an important increase on roll-your-own cigarettes use that it is especially remarkable among people in younger ages.

4) The review on second-hand smoke exposure in outdoor settings indicates the potential for high second-hand smoke exposure at some outdoor settings and indoor locations adjacent to outdoor smoking areas.

5) This review shows that high smoker density, highly enclosed outdoor areas, low wind conditions, and close proximity to smokers generate higher outdoor second-hand smoke concentrations. Accounting for these factors is important for future studies on the relationship between outdoor SHS exposure and health outcomes.

6) Non-smokers reported second-hand smoke exposure in most outdoor settings in which smokers reported to smoke.

7) There is great support for outdoor smoke-free areas that is stronger among non-smokers than among smokers. The highest support was for areas in which children are present (playgrounds and school/high school courtyards) and the grounds of healthcare centers.

7.1 Policy and research implication

This is the first study evaluating, using both self-reports and a personal biomarker of exposure to second-hand smoke (SHS), the impact of the stepped Spanish smoke-free legislation (Law 28/2005 and Law 42/2010) on second-hand smoke exposure in different settings among adult non-smokers from the general population; on tobacco consumption and smoking attributes among smokers; as well as attitudes towards smoke-free legislation in outdoor settings.

Based on the results and the conclusions derived from the study we may derive the following research and policy implications:

1) The strategy of strengthening Law 28/2005 to hospitality venues without exceptions was clearly effective. We observed a high reduction in SHS exposure during leisure time and a reduction in SHS exposure at home contrary to the speculative tobacco industry hypothesis of displacement of smoking from public to private places. Over time, the law will result in a reduction in morbidity (already observed for cardiovascular diseases) and mortality among non-smoking adults.

2) This is the first study in Spain that systematically evaluates smoking prevalence and smokers' attributes focusing in the type of tobacco consumed, manufactured or roll-your-own cigarettes (RYO), before and after the implementation of a stepwise smoke-free legislation. The increase in the proportion of RYO cigarettes users and the consequences on health of their use suggest the need by policymakers to implement tax policies to equalise the prices of different types of tobacco products.

3) Further research is needed to determine exposure to tobacco biomarkers and the health effects of RYO cigarettes use. New tobacco control strategies should be developed to tackle new forms of tobacco consumption, especially among RYO cigarettes users that are predominantly young people.

4) The WHO Framework Convention on Tobacco Control has concluded that 100% smoke-free environments are required to adequately protect the public's health from the harmful effects of SHS (WHO 2003). High SHS levels obtained in some outdoor locations included in the systematic review, especially in outdoor hospitality venues, suggest that these areas should be considered when deciding which policy interventions best promote the extension of smoking bans to outdor settings.

5) Further research using standardized methodology is needed to better characterize SHS exposure levels in outdoor areas and determine whether smoke-free legislation should be extended to these areas.

6) The strong support of the population for some smoke-free areas, including areas that are already smoke-free according to a national law, sugests the feasibility of extending smoking bans to other outdoor settings. This support indicates an important process of denormalization of smoking, and policy makers should take it into account for reinforcing and extending tobacco control measures.

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ANEXOS

Anexo 1. Artículo: Impact of Tobacco Control Policies in Hospitals: Evaluation of a National Smoke-Free Campus Ban in Spain

Impact of Tobacco Control Policies in Hospitals: Evaluation of a National Smoke-Free Campus Ban in Spain

Xisca Sureda[a,b,c], Montse Ballbè[a,b,d], Cristina Martínez[a,b,d,e], Marcela Fu[a,b,c], Esther Carabasa[a,b,d], Esteve Saltó[f,g], Jose M Martínez-Sánchez[a,b,c], Esteve Fernández[a,b,c,d]

[a]*Tobacco Control Unit, Cancer Control and Prevention Programme, Institut Català d'Oncologia-ICO, L'Hospitalet de Llobregat (Barcelona), Spain.*

[b]*Cancer Control and Prevention Group, Institut d'Investigació Biomèdica de Bellvitge-IDIBELL, L'Hospitalet de Llobregat (Barcelona), Spain*

[c]*Department of Clinical Sciences, School of Medicine, Universitat de Barcelona, L'Hospitalet del Llobregat (Barcelona), Spain.*

[d]*Catalan Network of Smoke-free Hospitals, L'Hospitalet de Llobregat, Barcelona, Spain*

[e]*Medicine and Health Sciences School, Universitat Internacional de Catalunya, Barcelona, Spain*

[f]*Public Health Agency, Ministry of Health, Generalitat de Catalunya, Spain*

[g]*Department of Public Health, Universitat de Barcelona, Barcelona, Spain.*

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CORRESPONDENCE

Xisca Sureda Llull, BPharm, MPH
Tobacco Control Research Unit.
Institut Català d'Oncologia.
Av. Gran Via de l'Hospitalet, 199-203.
08908 l'Hospitalet de Llobregat (Barcelona), Spain
E-mail: fsureda@iconcologia.net

Abbreviations

ENSH: European Network of Smoke-free Hospitals

FCTC: Framework Convention on Tobacco Control

IARC: International Agency of Research on Cancer

IQR: Interquartile Ranges

PM: Particulate Matter

SHS: Second-hand Smoke

XCHsF: Catalan Network of Smoke-free Hospitals

WHO: World Health Organization

Abstract

Introduction: On January 2nd, 2011, the Spanish government passed a new smoking law that banned smoking in hospital campuses. The objective of this study was to evaluate the implementation of smoke-free campuses in the hospitals of Catalonia based on both airborne particulate matter ($PM_{2.5}$) and observational data.

Methods: This cross-sectional study included the hospitals registered in the Catalan Network of Smoke-free hospitals. We measured $PM_{2.5}$ (µg/m^3) at different locations, both indoors and outdoors before (2009) and after (2011) the implementation of the tobacco law. During 2011, we also assessed smoke-free zone signage and indications of smoking in the outdoor areas of hospital campuses.

Results: The overall median $PM_{2.5}$ concentration fell from 12.22 µg/m^3 (7.80-19.76 µg/m^3) in 2009 to 7.80 µg/m^3 (4.68-11.96 µg/m^3) in 2011. The smoke-free zone signage within the campus was moderately implemented after the legislation in most hospitals, and 55% of hospitals exhibited no indications of tobacco consumption around the grounds.

Conclusions: After the law, $PM_{2.5}$ concentrations were much below the values obtained before the law and below the annual guideline value recommended by the World Health Organization for outdoor settings (10 µg/m^3). Our data showed the feasibility of implementing a smoke-free campus ban and its positive effects.

Keywords: second-hand smoke, particulate matter, smoke-free campuses, hospitals, tobacco smoke pollution.

Introduction

The implementation of smoke-free policies in hospitals and health care services became a challenge in the US when, in 1992, the Joint Commission on Accreditation established a compulsory requirement to ban smoking in indoor areas for hospital members. In 2000, the European Network of Smoke-free Hospitals (ENSH) also developed a guideline to establish smoke-free policies in hospitals (www.ensh.eu) (Martinez et al., 2009); however, that was a voluntary requirement in a strategy to become smoke-free and promote smoking prevention and cessation. There is evidence that indoor smoking bans alone promote slight decreases in tobacco consumption, are supported by employees, and elicit satisfaction among patients and visitors (Hopkins et al., 2010; IARC, 2009; Longo et al., 196; Longo et al., 2001; Martinez et al., 2008). However, some studies suggest that more restrictive smoke-free policies, including outdoor bans, would support employees in attempts to reduce or cease smoking (Fernandez and Martinez, 2010; Gadomski et al., 2010; Williams et al., 2009). Other benefits include the protection of non-smokers, the reduction of smoking opportunities, and the denormalization of smoking (IARC, 2009). Moreover, this policy are expected to promote a cleaner environment, reduce fire hazards, and increase productivity among staff (Fernández et al., 2010).

As a result, a new movement emerged to promote smoke-free hospital campuses, which extended smoking bans to outdoor areas (Fernández et al., 2010; Williams et al., 2009) following the recommendations based on Article 8 of the World Health Organization Framework Convention on Tobacco Control (FCTC)(World Health Organization, 2009). One objective of smoke-free hospital campuses is to set a clear example of good health-promoting practices, by providing a clear message to patients, visitors, and employees that tobacco consumption is a health risk, and therefore, it would not be allowed on the grounds of the institution. This message was expected to encourage patients, visitors, and employees to quit smoking and maintain a clean, neat environment (Fernández et al., 2010).

Recently, some countries, including the US, Japan, and Australia have implemented smoke-free campuses (Martinez et al., 2013; Nagle et al., 1996). In 2008, over 45% of US hospitals reported that they had extended tobacco-free policies to outdoor places(Williams et al., 2009). In Europe, among the 1,400 hospitals that belong to the ENSH, now called the Global Network for Tobacco Free Health Care Services, some have adopted smoke-free hospital campus policies, based on what is considered the GOLD standard for tobacco control in health care services (Fernández et al., 2010). In Spain, however, the implementation of smoke-free campuses became compulsory on January 2, 2011, when law 42/2010 was adopted to reinforce previous legislation (law 28/2005), which banned smoking in indoor places (including workplaces and public places, like hospitals). The new tobacco law prohibited smoking in all health care services, both indoors and outdoors, with the exception of medium- and long-stay psychiatric services and nursing homes, where designated smoking rooms are allowed (Ministerio de Sanidad y Consumo, 2005).

In Catalonia, Spain, in 2000, the Catalan Network of Smoke-free Hospitals (www.xchsf.com) was created, based on the ENSH model, with the objective of enforcing smoke-free hospitals and extending other tobacco control activities in the hospitals(Fernández et al., 2010). One of the activities included monitoring and evaluating tobacco control activities to assess the progress of smoke-free policies over the years (Martinez et al., 2009). With the implementation of the new smoke-free law 42/2010, the Catalan Network of Smoke-free Hospitals supported and assisted hospitals in implementing smoke-free campuses. The main aims of the present study were: (1) to describe SHS levels within the hospital after implementing the new tobacco law and, to compare the results obtained in 2009, before the implementation of the Law 42/2010; and (2) to evaluate the implementation of smoke-free campuses by measuring outdoor SHS levels, the presence of total smoke-free zone signage, and indications of tobacco consumption on the grounds of hospital campuses.

Methods

Study Design and Participants

This descriptive, repeated cross-sectional study, included all hospitals registered in the Catalan Network of Smoke-free Hospitals, in Catalonia (Spain). Data were collected before and after the implementation of smoke-free legislation using the same strategy. The pre-legislation data were obtained between February and September 2009 among the 53 hospitals affiliated to the Catalan Network of Smoke-free Hospitals at that time. Post-legislation data were obtained between March and October 2011 including a total of 60 hospitals of the Network by the year 2011. Data collections were performed after contacting the coordinator of the smoke-free hospital committee by telephone or e-mail to arrange an appointment.

Measurements and Variables

$PM_{2.5}$ concentrations. We measured $PM_{2.5}$, a selective airborne tobacco marker commonly used to evaluate SHS levels. We followed a common measurement protocol based on previous studies. We used a hand-held instrument to monitor particle size and mass concentration (TSI SidePak AM510 Personal Aerosol Monitor) (Fernandez et al., 2009; Sureda et al., 2010).The monitor was fitted with a 2.5 µm impactor to measure the concentration of particulate matter with a mass-median, aerodynamic diameter ≤2.5 µm. The sample flow rate through the TSI SidePak monitor was set at 1.7 l/min to ensure proper operation of the attached

2.5-μm impactor. We applied a K factor of 0.52 to all the measurements calculated with our specific instrument. The equipment was set to a one-second sampling interval and was zero-calibrated prior to each use with the attachment of a HEPA filter, according to the manufacturer's specifications. Every location was sampled for a period of 15 min, with the exception of the first location, which was measured for 20 min (the first 5 min were discarded). For each location, we recorded the start and finish times of measurements. All data were recorded with the TSI SidePak monitor and downloaded weekly onto a personal computer for management and statistical analysis. $PM_{2.5}$ concentrations are expressed in μg/m^3.

We measured $PM_{2.5}$ concentrations in eight standard locations within the hospital campus before and after the implementation of the law, including the hall, emergency department (waiting room), general medicine department, cafeteria, fire escape, dressing rooms (surgical and non-surgical), main building entrance (outdoor), and a background measurement performed at least 10 m from the campus main entrance. After the implementation of the smoke-free law, we included main campus entrance (outdoor) to evaluate the implementation of smoke-free campuses and, in some hospitals, we were also asked to measure an outdoor point suspected to be used for smoking ("conflicting points", according to the knowledge of the smoke-free committee coordinator). Measurements started in indoor locations and ended with outdoor locations.

Observational data. We recorded additional information for every $PM_{2.5}$ measurement, including the location area (m^2), location volume (m^3), temperature (ºC), relative humidity (%), and ventilation. We also recorded the presence of signage that stated smoking was prohibited and different indicators of the presence of tobacco smoking (number of hospital staff smoking, number of patients or visitors smoking, presence of ashtrays, presence of cigarette butts, and tobacco odor), based on the criteria used in previous observational studies(Fernandez et al., 2009; Sureda et al., 2010). When appropriate, we also recorded whether the location was completely outdoor or quasi-outdoor. Quasi-outdoor locations were defined as outdoor areas covered by a roof and/or protected with side walls, but not completely enclosed. Finally, we accounted for the traffic density (mean number of cars per min within a 15 min observation) near the hospital.

After the implementation of the new legislation, we selected some common locations around the grounds to evaluate the implementation of outdoor smoke-free zones, that included main building entrances, main campus entrances, other building entrances, gardens, cafeterias, kiosks, and other outdoor areas where smoking was suspected ("conflicting points"), based on information from the smoke-free hospital coordinators. For every outdoor location, we recorded the presence of tobacco-free zone signage; the message on the sign; the same indicators of tobacco consumption mentioned above; the physical characteristics of the area (garden, parking area, paved area); and the weather conditions (sunny, cloudy, or rainy). We established implementation criteria to assess compliance with the outdoor ban, depending on the signage of smoke-free zones and the presence of indicators of tobacco consumption.

We defined a smoke-free signage variable with three possible categories: (1) *fully implemented* was when 100% of the campus was well-delimited and all entrances to the campus and building had posted signs. The signs referred to the new law and/or they displayed the Catalan Network image; (2) *moderately implemented* was when there was poor signage across the campus, and only 50-75% of the entrances were signed. The signs displayed the Catalan Network image and/or mentioned the new law; and (3) *slightly implemented* was when there were no signs on the campus, and <50% of the entrances had posted signs.

We also defined a variable based on presence of indicators of tobacco consumption within the campus with three possible categories: (1) no indicators of tobacco consumption around the grounds of the hospital; (2) indicators of tobacco consumption in 1 or 2 outdoor locations; and (3) indicators of tobacco consumption in 3 or more outdoor locations.

Data analyses. We presented medians and interquartile ranges (IQRs) of $PM_{2.5}$ concentrations (and box-plot graphs) to describe the $PM_{2.5}$ concentrations in each location. We compared $PM_{2.5}$ medians with the non-parametric Wilcoxon test for paired samples by year of the measurements. For outdoor locations (main building entrances and main campus entrances), we described medians and corresponding IQRs of $PM_{2.5}$ concentrations in areas with distinct characteristics; for example, areas with different numbers of lit cigarettes (<10; ≥10); with an outdoor or quasi-outdoor location; with or without indicators of tobacco smoking (yes/no); with or without smoke-free zone signage (yes/no), and with high or low traffic density (≤10 cars/min; >10 cars/min). We used the non-parametric test to compare medians among groups. We calculated the proportion of hospitals with indicators of tobacco consumption and the percentages of outdoor locations signed. We performed all analyses with SPSS v. 15.00.

Results

Table 1 shows the median $PM_{2.5}$ concentrations and corresponding interquartile ranges of the 362 repeated measures in 53 hospitals before (2009) and after (2011) the implementation of the smoke-free law. The overall median $PM_{2.5}$ concentration fell from 12.22 $\mu g/m^3$ (7.80-19.76 $\mu g/m^3$) in 2009 to 7.80 $\mu g/m^3$ (4.68-11.96 $\mu g/m^3$) in 2011 ($p<0.001$). The reductions in median PM2.5 concentrations were statistically significant for hall, emergency department, cafeteria, fire escape, and main entrance. Before the implementation of the law, we observed indicators of tobacco smoking in 73 out of 362 locations, with a median $PM_{2.5}$ concentration of 15.08 $\mu g/m^3$ (IQR: 10.40-31.46 $\mu g/m^3$). After the legislation, 25 out of 362 locations had indicators of tobacco smoking with a median $PM_{2.5}$ concentration of 9.88 μg/m^3 (IQR: 5.98-16.90 μg/m^3).

[Table 1]

Among the 60 hospitals after the implementation of the smoke-free law, the highest median $PM_{2.5}$ concentrations were obtained in outdoor locations, including "conflicting points", with 10.40 μg/m^3 (IQR: 8.45-18.72 μg/m^3); main building entrances, with 9.88 μg/m^3 (IQR: 6.76-14.43 μg/m^3); and main campus entrances, with 9.62 μg/m^3 (IQR: 6.50-16.25 μg/m^3). The median $PM_{2.5}$ concentration obtained outside the building (background measurement) in those 60 hospitals was 9.10 μg/m^3 (IQR: 7.28–15.86 μg/m^3).

Table 2 shows $PM_{2.5}$ concentrations after the implementation of smoke-free campuses in outdoor main building entrances and main campus entrances. Median $PM_{2.5}$ concentrations were similar regardless the number of lit cigarettes, the type of enclosure, the presence of tobacco consumption indicators, the presence of tobacco signage, and traffic density outside the campus.

[Table 2]

We did not observe any indicators of tobacco consumption (people smoking, presence of ashtrays, presence of cigarette butts, and tobacco odor) around the grounds of 55% of hospital campuses in 2011. In 30% of hospital campuses, we observed indicators of tobacco consumption in 1 or 2 outdoor locations. In 3 out of 60 hospitals, we found indicators of tobacco consumption in 3 or more outdoor locations. In 12 out of 60 hospital campuses, smoke-free signage was fully implemented, with 100% of the campus delimited and all campus and building entrances signed. In most hospital campuses (n=45), smoke-free zone signage was moderately implemented, with 50-75% of entrances signed. Only 3 out of 60 hospitals had signage in less than half the entrances.

We evaluated 212 outdoor locations among the 60 hospital campuses in 2011, with most observations (87.7%) done in entrances. The other outdoor locations included gardens (n= 7), cafeterias (n= 6), fire escapes (n=5), parking areas (n=2), kiosks (n=1), and other "conflicting" points suggested by the smoke-free hospital committee (n=5). We did not observe any smokers in most of the locations (61.8%). Among the 60 hospital campuses, we found between 1 and 5 smokers in 63 locations (29.7%) and more than 5 smokers in 18 locations (8.5%). We recorded a total of 340 smokers, 63% were visitors or patients, and the remainder comprised hospital staff. We found indications of tobacco consumption in 95 out of the 212 outdoor locations evaluated, including tobacco odor, the presence of ashtrays combined with cigarette butts, and/or people smoking. Smoke-free zone signage was present in 77% of the observed outdoor locations.

Discussion

In our study, SHS levels, measured in terms of $PM_{2.5}$ concentrations, decreased in all locations after the implementation of the Law 42/2010 despite the already low concentrations due to the previous Spanish tobacco law (Law 28/2005) that had already prohibited indoor smoking in health care facilities. The Catalan Network evaluated the previous smoke-free policy before (2005) and after (2006) its implementation in January 2006. Second-hand smoke (SHS) exposure was assessed by measuring airborne nicotine concentrations in public hospitals of Catalonia (Fernandez et al., 2008). The results indicated that median nicotine concentrations had declined considerably after the law was implemented Another study conducted in Catalan hospitals in 2009 showed good compliance with the tobacco law, based on the low concentrations of small (≤2.5 μm in diameter), airborne particulate matter ($PM_{2.5}$) in most locations, except in outdoor designated smoking areas, cafeterias, and main entrances (outdoors) (Sureda et al., 2010). The results obtained in the present study could be explained by the reinforcement of the tobacco law to outdoor locations in the health care facilities and also by better implementation and development of the Catalan Network program over time(Martinez et al., 2009).

Moreover, $PM_{2.5}$ levels obtained after the implementation of the new Spanish smoke-free legislation were below the annual outdoor average (10 μg/m^3) recommended by the World Health Organization as the low end of the range associated with significant effects on health (Word Health Organization, 2006; World Health Organization, 2000). Only some “conflicting points” identified by the hospital smoke-free committee showed SHS levels slightly above the World Health Organization guideline value for long-term exposures. The highest $PM_{2.5}$ concentrations obtained in 2011 were found in outdoor locations (“conflicting points”, main building entrances, and main campus entrances). However, those levels were also below the 24 h outdoor average guideline value of 25μg/m^3 recommended by the same guidelines. After the implementation of the new law, we evaluated SHS levels in the main building and campus entrances and analyzed different variables that could modify those levels. $PM_{2.5}$ concentrations were slightly higher in the few places with 10 or more lit cigarettes compared to areas with less than 10 lit cigarettes, but the differences were not significant, possibly due to the low number of places with 10 or more lit cigarettes. Previous studies had shown that the number of smokers and/or lit cigarettes in an area were predictors of SHS levels in outdoor locations (Brennan et al., 2010; Cameron et al., 2010; CARB, 2005; Edwards and Wilson, 2011; Kaufman et al., 2010; Klepeis et al., 2007; Parry et al., 2011; Repace, 2005; St et al., 2011; Stafford et al., 2010;

Sureda et al., 2011; Wilson et al., 2011). While previous studies have considered the degree of enclosure as a factor for predicting outdoor SHS levels (Brennan et al., 2010; Cameron et al., 2010; Parry et al., 2011; Stafford et al., 2010; Sureda et al., 2011; Travers et al., 2007; Wilson et al., 2011), our data did not show any clear pattern

The presence of other indicators of tobacco smoking apart from lit cigarettes, was associated with a slight increase in $PM_{2.5}$ concentrations in main building entrances, but not in main campus entrances. Unlike tobacco odor and the presence of ashtrays and/or cigarette butts, which can be detected in the absence of people smoking, the $PM_{2.5}$ concentrations can immediately drop to background levels, depending on atmospheric conditions and the density and distribution of smokers (CARB, 2005; Klepeis et al., 2007; Repace, 2005). Finally, $PM_{2.5}$ concentrations, both in main building and campus entrances, moderately increased with higher traffic densities. However, the increase was not statistically significant. It is known that $PM_{2.5}$ derive from tobacco burning and other sources of combustion, like traffic-related air pollution (Gorini et al., 2005).

Smoke-free campuses were highly implemented in most of the hospitals affiliated with the Catalan Network of Smoke-free Hospitals. A majority (55%) of hospital campuses did not show any signs of tobacco consumption. These results suggested that outdoor smoke-free policies for hospitals were well accepted by the general public and hospital staff. A review on public attitudes towards smoke-free outdoor places showed that, in a number of jurisdictions, the majority of the public supported restricted smoking in various outdoor settings, including hospitals (Thomson et al., 2009). Another study conducted in Italy found that 79.9% of the population supported smoke-free policies in outdoor areas surrounding hospitals (Gallus et al., 2012). Nonetheless, 40% of outdoor locations showed people smoking within the grounds of the campus, including hospital staff. A previous study systematically observed smoking behavior in standard outdoor areas; with a reduction in the number of staff and visitors smoking on hospital grounds over a 2-year period (Poder et al., 2012).In the present study, we collected data between 3 and 10 months after the implementation of the smoke-free regulation for hospital campuses. Further monitoring would be needed to evaluate the long term compliance to the new law over time.

Smoke-free zone signage was moderately implemented, with 50-75% of the entrances well-signed. A previous study that evaluated the impact of introducing smoke-free zone signs in outdoor areas of the hospital grounds found that signage may be an effective strategy in reducing, but not eliminating smoking in those settings (Nagle et al., 1996). We recommend that other activities, beyond the implementation of smoke-free zone signage should be undertaken to achieve better compliance with the outdoor smoking ban. These activities might include improved communication, education, and training for hospital staff.

Study Limitations

The main limitation of the study is the absence of $PM_{2.5}$ measurements in main campus entrances and observational information around the grounds of the hospitals before the implementation of the law. However, we could compare $PM_{2.5}$ concentrations in most of the indoor locations before and after the law, including the main building entrances.

Another potential limitation of the study is that $PM_{2.5}$ is not a specific marker of SHS, because these particles can originate from other combustion sources, like cooking or traffic-related air pollution (Gorini et al., 2005). Those sources of combustion might explain the higher $PM_{2.5}$ concentrations found in kitchens and some outdoor locations near busy roads. For this reason, we considered traffic density a factor that might contribute to outdoor $PM_{2.5}$ levels. For indoor locations other than kitchens, tobacco smoke is considered the main contributor to $PM_{2.5}$. In fact, other studies used $PM_{2.5}$ to evaluate SHS in hospitals and found it was a feasible and sensible method for SHS assessments in those settings (Nardini et al., 2004; Sureda et al., 2010; Vardavas et al., 2007). Additionally, we measured background $PM_{2.5}$ levels to control for potentially day-to-day variability that could influence our results and we did not observed statistical significant differences in background levels before and after the implementation of the law suggesting that the differences observed in $PM_{2.5}$ levels within the hospital locations could not be explained by this day-to-day $PM_{2.5}$ levels variability.

Study Strengths

This was the first study to evaluate the implementation of the smoke-free hospital campus policy after the new Spanish tobacco law (Law 42/2010) that banned smoking in all hospital locations, both indoors and outdoors. Moreover, this was a real-life study conducted in real-time. Thus, unlike results from controlled experiments, we provided a realistic view of smoking behavior and the actual SHS exposure in different locations. We used an objective marker of SHS levels ($PM_{2.5}$), we compared those levels before (2009) and after (2011) the implementation of the law in the same hospitals and locations measured using the same standardized procedures, and we analyzed observational data from different locations around the hospital grounds after the new smoke-free law to evaluate the presence of smoke-free zone signage and indications of tobacco consumption. Finally, we included a large number of locations around the hospital grounds in this study. We observed nearly the entire grounds of hospitals, including nearly all the entrances to the buildings and campuses.

Conclusion

The present study suggests the effectiveness of the new Spanish tobacco law (Law 42/2010) in combination with the initiatives of the Catalan Network of Smoke-free Hospitals for implementing smoke-free campuses. We found lower SHS levels for all locations after the implementation of the law compared with the levels obtained in 2009. In addition, we found that nearly all the $PM_{2.5}$ concentrations were lower than the 10 µg/m^3 level recommended for outdoor settings by the WHO. Continuous evaluation of tobacco control policies can identify the strengths and weaknesses in each hospital and promote the development of new strategies for improving compliance. These results also show the feasibility of extending smoke-free legislation to outdoor settings and may encourage the full implementation of Article 8 of the WHO FCTC in other jurisdictions.

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Competing interest: none

Contributors: XS and EF designed the study to which all the authors contributed. XS, MB, MF, CM and EC collected the data in the participating hospitals. EC and CM performed quality-control procedures. XS prepared the database. XS analyzed the data and revised results with JMMS, MF, MB, CM, ES, and EF. All authors contributed to the interpretation of the results. XS drafted the manuscript, which was critically revised by all authors, who also approved the final version. EF is the guarantor.

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Table legend

Table 1. PM2.5 concentrations (µg/m3) in specific locations of 53 hospitals before (2009) and after (2011) the Spanish smoke-free legislation; Catalonia, Spain.

Table 2. PM2.5 concentrations in outdoor hospital campuses, Catalonia, Spain (2011)

Table 1. $PM_{2.5}$ concentrations (µg/m^3) in specific locations of 53 hospitals before (2009) and after (2011) the Spanish smoke-free legislation; Catalonia, Spain.

	n	Median (IQR) 2009 (µg/m^3)	Median (IQR) 2011 (µg/m^3)	p-value*
Location				
All	362	12.22 (7.80–19.76)	7.80 (4.68–11.96)	<0.001
Hall	50	13.26 (11.44–22.56)	6.24 (5.07- 11.05)	<0.001
Emergency department, waiting room	45	12.48 (7.02–21.32)	5.72 (3.90–9.10)	<0.001
General medicine	47	10.40 (8.32–13.52)	8.32 (4.68–11.96)	0.094
Cafeteria	47	14.56 (9.36–23.40)	9.36 (5.72–15.08)	0.013
Fire escape	39	13.00 (8.32–28.08)	7.28 (4.68–9.88)	0.007
Dressing room	46	6.50 (2.08–12.09)	6.76 (2.60–10.40)	0.472
Main entrance	47	14.04 (10.40–28.08)	9.88 (6.76–14.04)	0.005
Outside	41	11.44 (9.10–15.08)	8.84 (7.02–16.12)	0.134

* Wilcoxon test for paired samples
IQR: Interquartile ranges

Table 2. $PM_{2.5}$ concentrations in outdoor hospital campuses, Catalonia, Spain (2011)

	n	$PM_{2.5}$ main building entrances (µg/m^3) Median (IQR)	n	$PM_{2.5}$ main campus entrances (µg/m^3) Median (IQR)
Number of lit cigarettes				
< 10	54	9.88 (6.37 – 13.65)	31	8.84 (5.72 – 16.12)
≥ 10	2	23.66 (15.60 – 31.72)	7	11.44 (8.32 – 19.24)
p-value*		0.073		0.221
Enclosure				
quasi-outdoor	39	10.40 (5.20 – 17.16)	1	4.68
outdoor	17	9.36 (6.76 – 11.70)	34	10.40 (7.15 – 16.25)
p-value*		0.498		0.215
Indications of tobacco smoking				
yes	23	11.44 (7.80 – 17.68)	32	9.62 (6.76 – 16.51)
no	33	9.36 (5.20 – 13.00)	6	10.14 (4.29 – 15.73)
p-value*		0.125		0.770
Signage				
yes	48	9.88 (6.76 – 13.00)	28	9.10 (5.98 – 16.51)
no	10	11.96 (7.54 – 19.50)	10	10.40 (7.67 – 15.73)
p-value*		0.323		0.829
Traffic density				
≤ 10 cars/min	23	9.88 (5.20 – 14.04)	15	8.84 (4.68 – 15.08)
> 10 cars/min	21	11.44 (6.76 – 18.72)	14	9.10 (7.15 – 17.81)
p-value*		0.347		0.406

$PM_{2.5}$: Airborne particulate matter <2.5 µm in diameter; IQR: interquartile range; * Non-parametric test for comparing medians of independent samples.

Anexo 2. Artículo: Secondhand smoke levels in publi building main entrances: outdoor and indoor PM2.5 assessment

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Secondhand smoke levels in public building main entrances: outdoor and indoor $PM_{2.5}$ assessment

Xisca Sureda,[1,2,3] Jose M Martínez-Sánchez,[1,2,3] María José López,[4,5] Marcela Fu,[1,2,3] Fernando Agüero,[4,6] Esteve Saltó,[7,8] Manel Nebot,[4,5,9] Esteve Fernández[1,2,3]

[1]Tobacco Control Unit, Cancer Prevention and Control Programme, Institut Català d'Oncologia—ICO, L'Hospitalet de Llobregat, Barcelona, Spain
[2]Cancer Prevention and Control Group, Institut d'Investigació Biomèdica de Bellvitge—IDIBELL, L'Hospitalet de Llobregat, Barcelona, Spain
[3]Department of Clinical Sciences, Universitat de Barcelona, Barcelona, Spain
[4]Agència de Salut Pública de Barcelona, Barcelona, Spain
[5]CIBER de Epidemiología y Salud Pública, Barcelona, Spain
[6]Unitat Docent de Medicina Preventiva i Salut Pública IMAS-UPF-ASPB, Barcelona, Spain
[7]Department of Health, Generalitat de Catalunya, Barcelona, Spain
[8]Department of Public Health, School of Pharmacy, Universitat de Barcelona, Barcelona, Spain
[9]Department of Experimental Sciences and Health, Universitat Pompeu Fabra, Barcelona, Spain

Correspondence to
Dr Esteve Fernández, Tobacco Control Research Unit, Institut Català d'Oncologia, Av. Gran Via de l'Hospitalet, 199-203, 08908 L'Hospitalet de Llobregat, Barcelona, Spain; efernandez@iconcologia.net

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ABSTRACT

Background/Objectives To describe secondhand smoke (SHS) levels in halls and main entrances (outdoors) in different buildings by measurement of $PM_{2.5}$ and airborne nicotine.

Methods Cross-sectional study in a sample of 47 public buildings. The authors studied SHS levels derived from $PM_{2.5}$ (micrograms per cubic metre) using TSI SidePak Personal Aerosol Monitors. The authors tested four locations within buildings: hall, main entrance (outdoor), control (indoor) and control (outdoor). The authors also measured airborne nicotine concentration (micrograms per cubic metre) in main entrances (outdoor). The authors computed medians and IQRs to describe the data. Spearman correlation coefficient (rsp) was used to explore the association between $PM_{2.5}$ concentrations simultaneously measured in halls and main entrances as well as between $PM_{2.5}$ and nicotine concentrations.

Results The authors obtained an overall median $PM_{2.5}$ concentration of hall 18.20 $\mu g/m^3$ (IQR: 10.92−23.92 $\mu g/m^3$), main entrance (outdoor) 17.16 $\mu g/m^3$ (IQR: 10.92−24.96 $\mu g/m^3$), control (indoor) 10.40 $\mu g/m^3$ (IQR: 6.76−15.60 $\mu g/m^3$) and control (outdoor) 13.00 $\mu g/m^3$ (IQR: 8.32−18.72 $\mu g/m^3$). The $PM_{2.5}$ concentration in halls was more correlated with concentration in the main entrances (outdoors) (rsp=0.518, 95% CI 0.271 to 0.701) than with the control indoor (rsp=0.316, 95% CI 0.032 to 0.553). The Spearman correlation coefficient between nicotine and $PM_{2.5}$ concentration was 0.365 (95% CI −0.009 to 0.650).

Conclusions Indoor locations where smoking is banned are not completely free from SHS with levels similar to those obtained in the immediate entrances (outdoors) where smoking is allowed, indicating that SHS from outdoors settings drifts to adjacent indoors. These results warrant a revision of current smoke-free policies in particular outdoor settings.

INTRODUCTION

Exposure to secondhand smoke (SHS) has been associated with many adverse health effects, such as lung cancer, cardiovascular disease and respiratory tract diseases.[1] SHS is a complex mixture of >4.000 chemical substances defined as diluted and dispersed air pollutant emission generated from the consumption of tobacco products.[2] When occurring outdoors, SHS has been called outdoor tobacco smoke.[3]

Since the entry into force of the WHO Framework Convention on Tobacco Control in 2005, several countries have implemented smoke-free policies. The objective of these policies has been to protect people from SHS exposure, following the Article 8 guidelines recommendations.[4] In the beginning, these recommendations focused on providing universal protection from SHS in all indoor public places, workplaces and public transport. In 2007, the Article 8 guidelines development went further promoting quasi-outdoor and outdoor public places to be smoke-free under some circumstances, as a requirement to an effective protection.[5] They consider it is 'appropriate' to require protections in those areas, and they call on countries to 'adopt the most effective protection against exposure wherever the evidence shows that hazard exist'.[6 7]

There is no consensus about whether or not smoking should be prohibited in certain areas outdoors.[8−11] Opponents of the prohibition argue that it is ethically unsustainable because it does not respect the principle of freedom and autonomy of individuals, and there is insufficient evidence that SHS in these environments have an impact on health.[9 10] Contrary to the first objection to prohibit smoking outdoors, some research indicates that, in a number of jurisdictions, the majority of the public supports restricting smoking in various outdoors settings.[12] Otherwise, scientific evidence has firmly established that there is no safe level of exposure to SHS[13] and that exposure of non-smokers to levels of SHS is as high as or higher than that received in indoor spaces where smoking is unrestricted[8 14] Due to these new evidences, some governments have enacted smoking bans in outdoor areas such as parks, beaches, outdoor dining facilities and entrances to buildings in the recent years.[6] However, there are few data on actual levels of outdoor SHS exposure in those settings. Some recent articles show that levels of outdoor SHS can be comparable or even superior to indoor levels.[15−19] Moreover, it must be considered that levels of outdoor SHS are more susceptible to variations because they do not tend to accumulate and, because of their physicochemical characteristics, outdoor tobacco smoke can disperse influenced by environmental conditions such as temperature, humidity and ventilation. Studies of the California Air Resources Board[20] also demonstrates that the number of cigarettes being smoked, the position of smokers relative to the receptor and atmospheric conditions can lead to substantial variation in average exposures. Thus, although smoking is prohibited indoors, high levels of SHS can be detected in those settings due to smoke from the surroundings outside the building.[15 16 18]

As a consequence of workplace indoor tobacco regulations, many smokers have moved to the entrances of the buildings. However, objective assessments of the levels of SHS due to the placement of these smokers at the entrances are scarce. The main objective of our study was to assess the SHS levels in halls and main entrances (outdoors) in public buildings by measuring $PM_{2.5}$ and airborne nicotine.

MATERIALS AND METHODS

Study design

We conducted a cross-sectional study between April and July 2010 among a convenience sample of 47 public places in the city of Barcelona and its metropolitan area. Smoking was prohibited by a national ban (Law 28/2005) in these buildings since 1 January 2006.[21]

We classified the buildings into four different types: public administration (n=9), educational places (n=17), public transport stations (n=8) and healthcare centres (n=13).

The buildings were included in the study according to the following criteria: have an interior space adjacent to an outdoor area, separated by a doorway providing direct access; have at least one room physically separated from the hall; in case of having cooking facilities, they should be physically separated from the hall and from the other interior room. Moreover, there would be at least two lit cigarettes in main entrances (outdoor) during the time of the measurement.

The fieldwork took place on days when the weather conditions were favourable for the measurements (not rainy days, relative humidity <85%) and between 9:00 and 17:00, when most workers and visitors attend the building.

Measurements and variables

We measured respirable particles <2.5 μm in diameter ($PM_{2.5}$) as a well-established marker of tobacco[22] smoke with two precalibrated hand-held-operated monitors of particle size and mass concentration (TSI SidePak AM510 Personal Aerosol Monitor)[23] according to a common protocol based on previous studies.[24 25] The TSI SidePak uses a built-in sampling pump to draw air through the device, where the particulate matter in the air scatters the light from a laser. The two monitors were fitted with a 2.5 μm impactor to measure the concentration of particulate matter with a mass median aerodynamic diameter ≤2.5 μm. The sample flow rate through the TSI SidePak monitors was set at 1.7 l/min and logged $PM_{2.5}$ concentrations at 1 s intervals. The TSI SidePak monitors were calibrated in an experiment with a BAM-1020 instrument that measures and records airborne particulate concentration levels using the principle of β ray attenuation. The TSI SidePak measurements were made using a default K factor of 1.00 during the course of 4 h, and the experiment was repeated three times. The correlation between the TSI SidePak and BAM-1020 measurements was very high (r>0.98) in the three tests performed, and the K factor derived from the experiments was 0.52.[26] In addition to calibration with the gold standard, we tested whether both monitors provide similar measurements when used simultaneously in various environments (an indoor and an outdoor environment free of tobacco smoke and an outdoor environment with presence of tobacco smoke from active smokers). We found no differences in the median $PM_{2.5}$ concentrations between both monitors in these tests. $PM_{2.5}$ concentrations are expressed in μg/m^3. Both monitors were set to a 1 s sampling interval and zero-calibrated prior to use in each occasion by attachment of a high-efficiency particulate air filter according to the manufacturer's specifications.[23]

We defined four locations at each sample site to be tested as systematically represented in figure 1: hall (A, A'), defined as the interior space adjacent to an outdoor area; main entrances (outdoor) (B), as the area within a radius of 5 m over the door with direct access to public road and the most likely to be accessed by the public; control indoor (C), which was one room physically separated from the hall and placed at least 10 m of this and control outdoor (D), defined as the nearby outdoor spaces located >10 m from the main entrance (outdoor) where smoking was not present. We registered $PM_{2.5}$ concentrations simultaneously in the hall (A) and main entrance outdoors (B) during 30 consecutive minutes. The data collectors were situated 2 m of distance from the door, one in hall and the other in main entrance outdoors. We took another simultaneous measurement in the hall (A') and control indoor (C) during 10 min. Afterwards, we tested the control outdoor (D) during an additional 10 min period. All locations should not be potentially exposed to sources of $PM_{2.5}$ other than tobacco smoke during the measurements (mainly from combustion sources as those generated in kitchens or vehicles). All the measurements were collected as unobtrusive as possible hiding the TSI SidePack in a backpack.

For each location, we registered the time of measurement onset and completion. All data registered by the two TSI SidePak monitors were downloaded into a personal computer for management and statistical analysis.

We also sampled for airborne nicotine in main entrances outdoors at the same time as we recorded simultaneous $PM_{2.5}$ concentrations in the halls (indoor) and main entrances (outdoors). Because of operational reasons, we had to restrict our analysis to a subsample of buildings. We selected 28 of the 47 trying to maintain the proportionality of the types of building according to the full sample. We used nicotine sampler's devices connected through a tub to a pump (flow 3.02 ml/min) to take the measures. Nicotine samplers contained a filter that was 37 mm in diameter and treated with sodium bisulphate.[27 28] Nicotine was analysed in the Laboratory of the Public Health Agency of Barcelona by gas chromatography/mass spectrometry. The time-weighted average nicotine concentration (micrograms per cubic metre) was estimated by dividing the amount of nicotine extracted by the volume of sampled air multiplied by the total number of minutes the filter was exposed. Airborne nicotine concentrations are also expressed in micrograms per cubic metre, with a quantification limit of 5 ng per filter, equivalent to 0.06 μg/m^3 of nicotine per an exposure time of

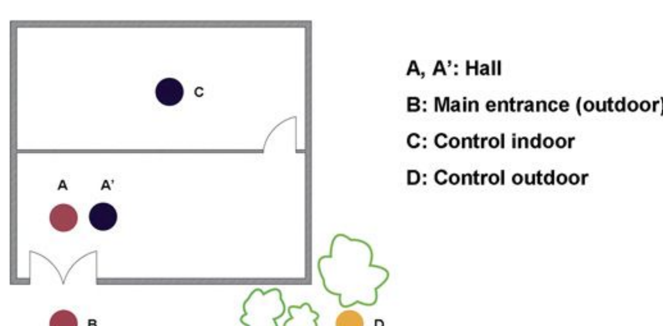

Figure 1 Outdoor and indoor locations of assessment of secondhand smoke levels in buildings. Repeated colours represent simultaneous measurements.

30 min. Samples with values below the quantification limit were assigned half of this value (limit of detection=0.03 μg/m^3).

We recorded additional information for every measurement sampling: location area (m^2), location volume (m^3), temperature (°C), relative humidity (%), outdoor or quasi-outdoor main entrance (outdoors) and distance to roadways. We considered quasi-outdoor main entrances (outdoors) when there were overhead cover and/or side walls. Overhead covers are defined as any permanent or temporary structure that impedes upward airflow. Walls are defined as any structure that impedes lateral airflow. We also registered different indicators of the presence of tobacco smoking such as the number of cigarettes lit in main entrance (outdoors) (counting continuously all cigarettes lit during the observation in a perimeter of 5 m), presence of ashtrays, presence of cigarette butts and tobacco smell as has been done in previous studies.[24 25] The same two investigators made all measurements and observations.

We did not require approval from the ethics committee because the study did not involve interventions or measurements in humans but rather environmental measures in public buildings.

Data analyses

To describe the data, we provide medians, geometric means, maximum values, IQRs and 95% CIs of the geometric means by building type and by location. We compared $PM_{2.5}$ medians with the non-parametric test for medians by location and the corresponding 95% CI, and we used the Spearman rank correlation coefficient (rsp). We describe medians and their corresponding IQR in hall and main entrance (outdoors) by selected characteristics: number of lit cigarettes in main entrances (<10, ≥10); outdoor or quasi-outdoor main entrance (outdoor); signs of tobacco smoking in hall (yes, no) and distance to roadways (<15 m, ≥15 m). We compared $PM_{2.5}$ medians in hall and in main entrances (outdoor) with the non-parametric test for medians. We studied the correlations between $PM_{2.5}$ concentrations for the simultaneous measurements (hall—main entrances (outdoors); hall—control indoor).

We also describe nicotine concentrations using medians and IQRs, and we evaluated correlations between $PM_{2.5}$ concentrations and nicotine concentrations using the Spearman rank correlation coefficient (rsp). For all analyses, we used SPSS V15.

RESULTS

Data were collected over 47 public buildings, with no statistically significant differences in the median $PM_{2.5}$ concentrations by type of building. As shown in table 1, the overall $PM_{2.5}$ median obtained in halls was 18.20 μg/m^3 (IQR: 10.92—23.92 μg/m^3), similar to the 17.16 μg/m^3 (IQR: 10.92—24.96 μg/m^3) $PM_{2.5}$ median concentration simultaneously obtained in main entrances (outdoor) (p=0.662). The $PM_{2.5}$ concentrations obtained in control locations were statistically significantly lower, 10.40 μg/m^3 (IQR: 6.76—15.60 μg/m^3) for indoors and 13.00 μg/m^3 (IQR: 8.32—18.72 μg/m^3) for outdoors. The same pattern was observed by building type. Hall and main entrances (outdoors) showed statistically significant higher $PM_{2.5}$ median concentration than controls (indoors and outdoors) in all cases. The $PM_{2.5}$ concentration in halls was more correlated with concentration in the main entrances (outdoors) (rsp=0.518, 95% CI 0.271—0.701) than with the control indoor (rsp=0.316, 95% CI 0.032—0.553).

Figure 2 presents real-time plots of $PM_{2.5}$ concentrations during a measurement session in a public building (educational place) using 10 s average values of $PM_{2.5}$ (micrograms per cubic metre). Panel A (top) represents the simultaneous measurements recorded in hall and main entrance (outdoor). The overall $PM_{2.5}$ median concentration in hall was 34.22 μg/m^3 (IQR: 31.06—38.95 μg/m^3) with a maximum value of 66.56 μg/m^3. The $PM_{2.5}$ concentration obtained in main entrances (outdoor) was 38.01 μg/m^3 (IQR: 34.23—48.22 μg/m^3) with a maximum value of 193.65 μg/m^3. Panel B (bottom) shows simultaneous measurements in hall and control indoors. $PM_{2.5}$ median concentration in hall was 82.71 μg/m^3 (IQR: 67.25—107.11 μg/m^3) with a maximum value of 196.35 μg/m^3. The $PM_{2.5}$ concentration obtained in control

Table 1 Medians, IQRs, geometric means and 95% CIs and maximum values of $PM_{2.5}$ by building type, raw data (1 s average) Barcelona Metropolitan Area, 2010

		Simultaneous measurements*		Simultaneous measurements†		
Building type	**n**	**Hall 1**	**Main entrance (outdoor)**	**Hall 2**	**Control (indoor)**	**Control (outdoor)†**
Overall	47					
Median (IQR) (μg/m^3)		18.20 (10.92—23.92)	17.16 (10.92—24.96)	18.20 (11.44—24.96)	10.40 (6.76—15.60)	13.00 (8.32—18.72)
Geometric mean (95% CI) (μg/m^3)		16.70 (16.21 to 17.19)	17.17 (16.65 to 17.69)	17.52 (16.99 to 18.05)	10.01 (9.49 to 10.53)	12.76 (12.32 to 13.20)
Maximum value (μg/m^3)		128.44	54.08	86.32	36.40	30.16
Public administration and libraries	9					
Median (IQR) (μg/m^3)		14.04 (12.22—21.84)	16.12 (8.32—23.14)	13.52 (9.88—24.44)	8.32 (5.46—12.22)	8.84 (7.80—18.98)
Geometric mean (95% CI) (μg/m^3)		15.33 (14.27 to 16.39)	14.33 (13.09 to 15.57)	15.36 (14.30 to 16.42)	7.71 (6.56 to 8.86)	11.70 (10.60 to 12.80)
Maximum value (μg/m^3)		34.32	42.64	36.40	15.60	30.16
Educational places	17					
Median (IQR) (μg/m^3)		18.20 (8.32—28.08)	17.68 (8.32—24.70)	19.24 (11.18—28.34)	10.40 (6.76—18.46)	9.10 (7.80—18.72)
Geometric mean (95% CI) (μg/m^3)		16.51 (15.70 to 17.32)	14.53 (13.63 to 15.43)	18.13 (17.25 to 19.01)	11.04 (10.20 to 11.88)	11.05 (10.29 to 11.81)
Maximum value (μg/m^3)		46.80	37.44	48.36	36.40	23.92
Public transport	8					
Median (IQR) (μg/m^3)		16.64 (9.62—20.80)	24.18 (14.95—37.96)	16.12 (9.49—22.49)	14.56 (9.88—15.99)	16.64 (14.30—20.28)
Geometric mean (95% CI) (μg/m^3)		13.69 (12.48 to 14.90)	24.44 (23.27 to 25.61)	14.19 (13.04 to 15.34)	11.50 (10.18 to 12.82)	17.11 (16.26 to 17.96)
Maximum value (μg/m^3)		21.84	54.08	27.04	19.24	23.40
Healthcare centres	13					
Median (IQR) (μg/m^3)		21.32 (12.74—28.34)	17.16 (15.08—28.86)	18.72 (12.87—27.82)	9.36 (5.98—16.38)	13.52 (10.14—18.85)
Geometric mean (95% CI) (μg/m^3)		20.33 (18.93 to 21.73)	19.48 (18.55 to 20.41)	20.87 (17.23 to 24.51)	9.69 (8.54 to 10.84)	13.68 (12.55 to 14.81)
Maximum value (μg/m^3)		128.44	46.28	86.32	21.32	22.36

*30 min measurements.
†10 min measurements.

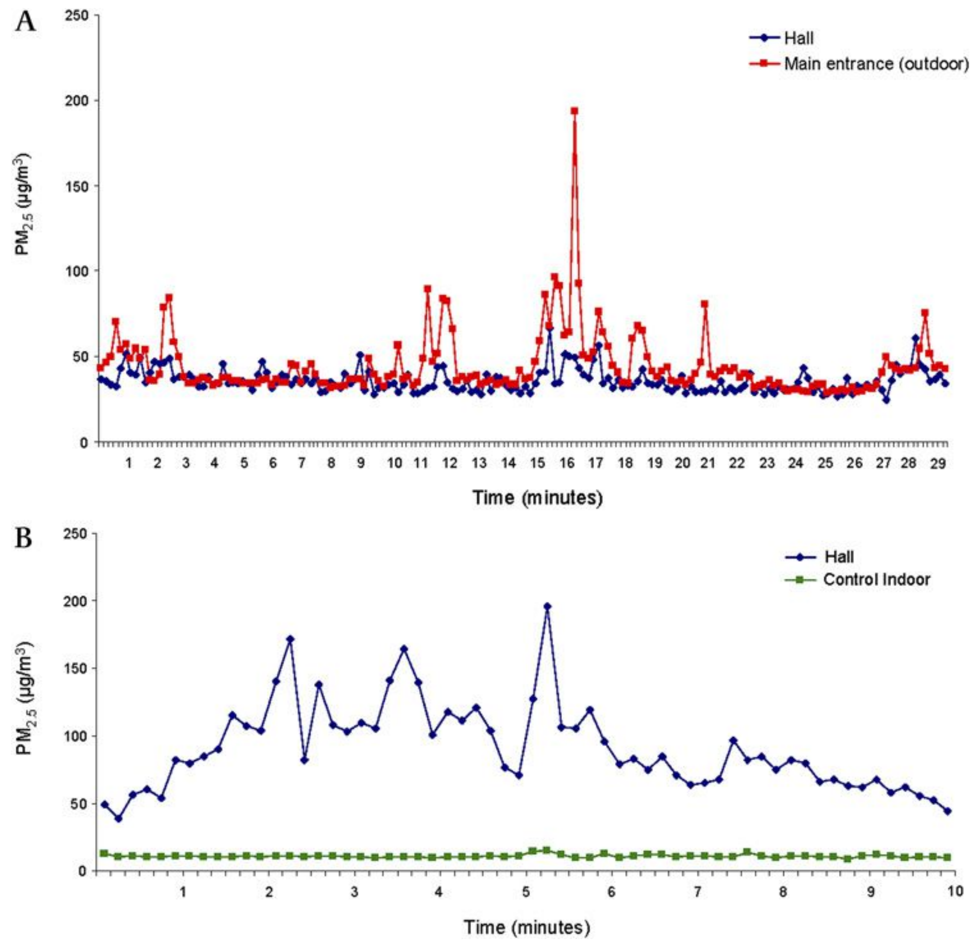

Figure 2 (A and B) Real-time plots of 10 s average values of $PM_{2.5}$ (micrograms per cubic metre) concentrations during a measurement session in a public building.

indoors was 10.74 μg/m^3 (IQR: 10.24–11.21 μg/m^3) with a maximum value of 15.08 μg/m^3.

Table 2 shows a descriptive analysis of $PM_{2.5}$ concentrations in halls and main entrances (outdoors) by different variables potentially related to tobacco smoke levels. Median $PM_{2.5}$ concentrations were higher but statistically non-significant in buildings with ≥10 lit cigarettes compared with <10 lit cigarettes both in halls (20.80 vs 16.38 μg/m^3, p=0.560) and main entrances outdoors (21.58 vs 15.86 μg/m^3, p=0.079). The same occurs when we compared outdoor and quasi-outdoor main entrances (outdoor) with higher $PM_{2.5}$ concentrations for quasi-outdoor areas both in halls and in main entrances (outdoor). The $PM_{2.5}$ levels in hall and main entrances (outdoor) did not substantially vary depending on signs of tobacco smoking in halls or the distance to the roadways. We did not find differences in concentrations obtained in halls and in main entrances (outdoors) according to the variables.

We studied nicotine concentrations in 28 of the 47 public buildings. The overall median nicotine concentration was 0.81 μg/m3 (IQR: 0.54–1.52 μg/m^3) with a maximum value of 3.74 μg/m^3. The Spearman correlation coefficient between nicotine and $PM_{2.5}$ concentration was 0.365 (95% CI −0.009 to 0.650).

DISCUSSION

Main findings and comparison with other studies

Our findings show that main entrances (outdoors) are a critical location to consider when promoting smoke-free environments for outdoors and for the adjacent areas indoors, such as halls. We did not find differences in $PM_{2.5}$ levels when comparing by building type. In all cases, $PM_{2.5}$ concentrations obtained in main entrances (outdoors) were very similar to those obtained in halls, and both of them were considerably higher than levels in indoors and outdoors control points.

A previous study conducted in 53 hospitals to evaluate SHS exposure found a correlation coefficient of 0.591 between $PM_{2.5}$ concentrations in hall and in main entrance (outdoor),[25] very similar to the correlation coefficient (rsp=0.518) in the present study. That correlation was higher than the one obtained between hall and control indoor. These results make sense with the real-time plots of $PM_{2.5}$ concentrations (figure 2). In general, there is an overlap of $PM_{2.5}$ concentrations in the case of hall and main entrance (outdoor) in contrast to what happens in hall and control indoor. All these results suggest that outdoor SHS drifts to immediate adjacent areas indoors where it can remain longer, as suggested in previous studies focused on outdoors levels of SHS.[3 15 18 19] Klepeis *et al*[3] studied SHS levels in outdoor public places (parks, side-walk café, restaurants and pubs), and they showed that outdoor SHS levels were comparable to indoor concentration under certain conditions. These studies also suggest that whereas the SHS levels indoors remained relatively high and slowly decayed for hours until the doors were opened to ventilate the venue, SHS outdoors concentrations dropped immediately to background levels when the cigarette source were extinguished.

There are some factors that can influence the levels of SHS outdoors as it has been suggested in other studies.[3 15–18] Although the difference was not statistically significant, we found slightly higher levels of SHS, both in hall and in main entrance (outdoor) when there were ≥10 lit cigarettes. This

Table 2 Medians, IQRs and maximum values of $PM_{2.5}$ measurements in halls and main entrances (outdoor) by selected characteristics, raw data (1 s average) Barcelona Metropolitan Area, 2010

	n	Hall Median (IQR)	Main entrance (outdoor) Median (IQR)	p Value*
Number of lit cigarettes in main entrance				
<10 lit cigarettes	32	16.38 (11.44—24.96)	15.86 (9.69—24.96)	0.285
≥10 lit cigarettes	15	20.80 (11.96—27.56)	21.58 (17.16—37.44)	0.495
Covered main entrance (outdoor)				
Quasi-outdoor	33	19.24 (11.44—26.00)	17.68 (13.00—27.56)	0.765
Outdoor	14	17.68 (11.31—22.62)	14.82 (7.67—21.65)	0.109
Signs of tobacco smoking in hall				
Yes	25	18.72 (9.88—24.44)	17.16 (10.14—23.92)	0.440
No	22	17.68 (11.44—26.78)	18.98 (10.85—35.88)	0.961
Distance to roadways				
<15 m	36	19.76 (12.03—26.91)	17.68 (12.48—28.34)	0.539
≥15 m	11	11.96 (10.92—19.24)	16.64 (9.36—20.28)	0.824

*Non-parametric test for medians for the comparison between hall and main entrance (outdoor).

finding is consistent with those of Kaufman *et al*, who showed that average levels of $PM_{2.5}$ in outdoor settings with ≥1 lit cigarettes present were two times higher than average levels of background air pollution.[17]

We found that SHS levels in quasi-outdoor main entrances were higher than those in hall and not covered main entrances. We concur with Klepeis *et al*[3] that highly enclosed outdoor areas may reduce the possibility of SHS naturally dissipating outdoors such as it is forced to drift into the adjacent indoor space. Moreover, we supposed that the more enclosed the outdoor area is, the more it allows the accumulation of cigarette emission indoors and outdoors.

Although our results were not averaged over 24 h, we found a high $PM_{2.5}$ median concentration with maximum values of 128.44 and 54.08 $\mu g/m^3$ in halls and main entrances (outdoor), respectively, higher than the 24 h outdoor average guideline value of 25 $\mu g/m^3$ recommended by the WHO Air Quality Guidelines.[29] Such levels of SHS and the recent evidence on effects of smoking in outdoor areas[6] has resulted in Framework Convention on Tobacco Control guidelines to require protection from SHS in outdoor and quasi-outdoor public places where it is 'appropriate'.[5]

Limitations of the study

One potential limitation of the study is that we did not control for wind conditions in our examination of outdoor $PM_{2.5}$ concentrations. SHS concentration outdoor are sensitive to wind speed and direction.[3 18] However, we performed the measurements in different hours and days during 4 months, and hence, potential bias due to the wind conditions might have occurred in a non-differential way. We recommend that future research include venue-specific wind measures to account for these effects. We did not take into account the distance between the monitor and lit cigarettes. A previous study controlled smoking activity at precise distances from monitored positions, and they observed a clear reduction in SHS levels outdoors as distance from a tobacco source increased.[18] While it would have been interesting to control for this variable, it is very difficult to calculate the proximity from every lit cigarette during the measurement in a non-controlled study since smokers may change their position during observation.

Finally, the number of buildings measured was limited for operational reasons. We included public buildings that followed the criteria established. In some cases, we selected the buildings because we knew it would be easy to find smokers in the main entrance (outdoor) (ie, some educational places and healthcare centres) and they were buildings of our interest. Other buildings were selected through an environmental scan. Anyway, our study includes a variety of public buildings that had not been studied so far.

Strengths of the study

To our knowledge, this is one of the few studies using simultaneous measurements of $PM_{2.5}$ levels in outdoor and indoor settings and the first one that includes both indoor and outdoor controls.

Moreover, this is real-life and real-time study. We are aware that we may have obtained some inconsistencies in the data as we did not control for some unpredictable variables. However, opposite to a controlled experiment, we got a realistic view of the behaviour of smokers and a real approach of the exposure to SHS in the building main entrances.

While $PM_{2.5}$ can originate from sources of combustion different to tobacco smoke, such as cooking or traffic-related air pollution, we took into account the traffic-related air pollution in the case of the outdoor measurements by registering each building's proximity to roadways. We observed that $PM_{2.5}$ concentrations did not substantially vary depending on the distance of the roadway. We also correlated $PM_{2.5}$ with airborne nicotine concentrations outdoors as also done in other studies with indoor measurements.[25 30] and we obtained a moderate correlation possibly due to the low SHS levels outdoors.

CONCLUSIONS

Our study shows that indoor locations where smoking is banned are not completely free from SHS with levels similar to those obtained in the immediate entrances (outdoors) where smoking

What this paper adds

- ► Indoor locations where smoking is banned show similar secondhand smoke levels to those obtained in the immediate entrances (outdoors), and both of them are considerably higher than levels in indoors and outdoors control points.
- ► Main entrances (outdoors) are a critical location to consider when promoting smoke-free environments for outdoors and for the adjacent areas indoors.

is allowed. This indicates that SHS from outdoors settings drifts to adjacent indoors. Scientific evidence has firmly established that there is no safe level of exposure to SHS. Consequently, these results warrant a revision of current smoke-free policies in outdoor building entrances to protect people from tobacco smoke exposure. Moreover, further studies should focus on SHS exposure in other outdoor or quasi-outdoor locations, such as terraces or patios, beaches, public parks, bus and train stops, and sports facilities to better evaluate the need of reinforcing smoke-free policies.

Acknowledgements We thank Francesc Centrich and Glòria Muñoz (Laboratory of Public Health, Agència de Salut Pública de Barcelona) for nicotine analysis.

Funding This study is partly funded by the Ministry of Science and Universities, Government of Catalonia (2009SGR192), and by Ministry of Health, Government of Spain (RTIC Cancer, RD06/0020/0089 and CIBERESP CB06/02/0032).

Competing interests None.

Contributors XS and EF designed the study to which all the authors contributed. XS and FA collected the data. XS, JMMS, MF and MJL prepared the database. XS analysed the data and JMMS, MF, ES and MN revised with her the results. All the authors contributed to the interpretation of results. XS drafted the manuscript, which was critically revised by all authors, who also approved the final version. EF is the guarantor.

Provenance and peer review Not commissioned; externally peer reviewed.

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Secondhand smoke levels in public building main entrances: outdoor and indoor $PM_{2.5}$ assessment

Xisca Sureda, Jose M Martínez-Sánchez, María José López, et al.

Tob Control published online September 28, 2011
doi: 10.1136/tobaccocontrol-2011-050040

Anexo 3. Carta de invitación y contacto

dCOT2
Estudi dels determinants de la cotinina
Estudio de los determinantes de la cotinina
Unitat de Control del Tabaquisme, ICO
Avda. Gran Via de L'Hospitalet, 199-203
08908 L'Hospitalet de Llobregat
Telèfon: 932607357

Estimado Sr., Estimada Sra.

El Institut Català d'Oncologia, en colaboración con el Departament de Salut de la Generalitat de Catalunya y el Institut Municipal d'Investigació Mèdica, ha iniciado el estudio *"Determinantes de la cotinina: Cambios en la exposición al humo ambiental del tabaco en la población adulta de Barcelona"*.

Usted ha sido seleccionado por sorteo entre todos los habitantes de la ciudad de Barcelona. Nos pondremos en contacto con usted durante las próximas semanas para hacerle una encuesta en su domicilio y recoger una pequeña muestra de saliva.

La participación en este estudio es voluntaria y en caso de desear más información puede contactar con nosotros por teléfono en horario de 9.00 a 17.00h.

Dra. Marcela Fu	93 260 73 57
Dra. Xisca Sureda	93 260 73 35
Sra. Olga López	93 260 71 86

o bien por e-mail: dcot2@iconcologia.net

Más información sobre el estudio en Internet: www.iconcologia.net/dcot2

Si usted prefiere ser visitado/da en una fecha y horario concretos (o en un lugar diferente a su domicilio) puede comunicarlo de la misma manera.

Su participación (tanto si fuma como si no) es muy importante y su colaboración es esencial para continuar avanzando en el conocimiento de los factores relacionados con el tabaquismo y así mejorar la salud de la población.

Muchas gracias por su participación.

Dr. Esteve Fernández Muñoz
Investigador Principal

El Institut Català d'Oncologia garantiza que toda la información que aporte será tratada de manera estrictamente confidencial y exclusivamente con el fin de alcanzar los objetivos del estudio.

ICO Institut Català d'Oncologia
Generalitat de Catalunya **Departament de Salut**
IMAS Institut Municipal d'Investigació Mèdica. IMIM

Anexo 4. Consentimiento informado

CONSENTIMIENTO PARA LA ENTREVISTA
Y LA OBTENCIÓN DE UNA MUESTRA DE SALIVA EN EL ESTUDIO
DETERMINANTES DE LA COTININA: CAMBIOS EN LA EXPOSICIÓN AL HUMO AMBIENTAL DEL TABACO EN LA POBLACIÓN ADULTA DE BARCELONA.

Yo, Sr./Sra.________________________________ de ______ de edad y con DNI ___________

DECLARO

Que he sido informado/da por el Sr./Sra. ____
colaborador/a del Estudio "Determinantes de la cotinina: Cambios en la exposición al humo ambiental del tabaco en la población adulta de Barcelona", que:

l'Institut Català d'Oncologia está llevando a cabo un estudio sobre el consumo de tabaco en la población de Barcelona,

se ha solicitado mi participación voluntaria en este estudio, que supone responder un cuestionario confidencial sobre consumo de tabaco y proporcionar 9 ml de mi saliva,

la información recogida en este estudio es confidencial y sólo los investigadores conocen la identidad de los participantes. La saliva se utilizará para la determinación de cotinina u otros marcadores de exposición al tabaco relacionados con la finalidad del estudio,

la saliva no utilizada en esta fase del estudio se congelará y podrá ser utilizada para futuras determinaciones relacionadas con las finalidades del estudio,

la publicación de los resultados no revelará en ningún caso la identidad de las personas participantes,

he sido informado/da de forma clara y comprensible de la finalidad, limitaciones y beneficios de este estudio, y que me han contestado a todas las preguntas que he hecho y dudas que he mostrado al respecto.

También he sido informado/da de que en cualquier momento puedo retirarme del estudio y anular mi consentimiento.

Por estas razones, **ACCEDO** a contestar el cuestionario, **AUTORIZO** la recogida de saliva y doy mi **CONSENTIMIENTO INFORMADO** para que esta información y la muestra de saliva sea utilizada por los investigadores en el estudio que están llevando a cabo con tal de mejorar y ampliar los conocimientos sobre el tabaquismo.

Firma del participante	Firma del entrevistador/a
Nombre y apellidos:	Nombre y apellidos:
DNI:	DNI:

Barcelona, a ___ / ____________ / ______

ICO Institut Català d'Oncologia — Generalitat de Catalunya Departament de Salut — IMAS Institut Municipal d'Investigació Mèdica, IMIM

Anexo 5. Aprobación del Comité Ético

Institut Català de la Salut
Ciutat Sanitària i Universitària
de Bellvitge

Comitè Ètic d'Investigació Clínica

INFORME DEL COMITÉ ÉTICO DE INVESTIGACIÓN CLÍNICA SOBRE PROYECTOS DE INVESTIGACIÓN

El Comité Ético de Investigación Clínica de la Ciudad Sanitaria y Universitaria de Bellvitge, en su reunión de fecha 7 de Mayo de 2002, tras examinar el proyecto de investigación ref. **56/02**, titulado:

"DETERMINANTES DE LOS NIVELES DE COTININA EN SALIVA EN UNA MUESTRA REPRESENTATIVA DE LA POBLACIÓN GENERAL"

presentado por el Dr. José Mª Borrás Andrés del Servicio de Prevención y Control delCáncer y Director del Instituto Catalán de Oncología como Investigador proncipal, así como los modelos propuestos de carta a los posibles participantes y de consentimiento informado, ha considerado que no existe inconveniente ético para su realización y ha acordado dar su aprobación definitiva al mencionado proyecto.

Institut Català de la Salut
Comitè Ètic d'Investigació Clínica

Dra. Ignacia Ferrer Salvans
Secretario del C.E.I.C.

L'Hospitalet de Llobregat, 10 de Mayo de 2002

14 722

Anexo 6. Proceso editorial del artículo publicado en el PLOS ONE

Impact of the Spanish smoke-free legislation on adult, non-smoker exposure to secondhand smoke: cross-sectional surveys before (2004) and after (2012) legislation

Carta de presentación del manuscrito a PLOS ONE

Prof. Damian Pattinson

Editors-in-Chief

PLOS ONE

Dear Prof. Pattinson:

Please find enclosed our manuscript "Impact of the Spanish smoke-free legislation on adult, non-smoker exposure to secondhand smoke: cross-sectional surveys before (2004) and after (2012) legislation" for your consideration in *PLOS ONE*.

On the 2nd of January, 2011, a new smoke-free legislation was established in Spain to amend the previous one. The new Spanish legislation extended the smoking ban to all kind of hospitality venues with no exceptions, and did extend the ban to some outdoors areas (hospital and educational campuses). While the new law has resulted in lower levels of exposure to secondhand smoke in bars and restaurants, its impact had not been assessed in the general population, as it has seldom been done in other jurisdictions with similar smoke-free laws.

In this investigation, we show that exposure to secondhand smoke in the adult non-smoking population has fallen in homes, workplaces, transportation vehicles, and during leisure time as derived from self-reports and, importantly, as derived from salivary cotinine concentrations assessment.

We first submitted the present manuscript to PLOS Medicine given the public health and medical interest it has in our opinion (PMEDICINE-D-13-03328), but they suggested we sent it to PLOS ONE. We believe that the results and implications of this study may be of the interest of the international audience of *PLOS ONE*. The objective assessment of the effectiveness of the Spanish smoke-free legislation at the population level (and not only in specific settings such as bars and restaurants) may hopefully trigger the development or enforcement of similar tobacco control policies in other countries.

Suggested Academic Editors to handle the manuscript: Erik von Elm

Suggested reviewers:

. Prof. Sally Haw, s.j.haw@stir.ac.uk, University of Stirling, Scotland, UK.

. Prof. Luke Clancy, lclancy@tri.ie, TobaccoFree Research Institute, Ireland.

. Prof. Stanton Glantz, glantz@medicine.ucsf.edu, University of California San Francisco, USA.

. Prof. John P. Pierce, jppierce@ucsd.edu, University of California San Diego, USA.

. Prof. José M. Martín-Moreno, jose.maria.martin@uv.es, University of Valencia, Spain.

All the authors carefully read the manuscript and fully approve of it. In their name I also declare that the manuscript is original and it is not submitted anywhere other than your journal. All the authors declare to have no conflict of interest. We would of course be ready to provide further information about our data and methods you so desire.

Correspondence about the manuscript should be addressed to me as indicated in the first page of the manuscript.

Thank you very much for your kind attention. With best regards,

Yours sincerely,

Esteve Fernandez, MD, PhD
Head, Tobacco Control Research Unit, Institut Català d'Oncologia
Associate Professor of Epidemiology & Public Health, Universitat de Barcelona
E-mail: efernandez@iconcologia.net

<u>Respuesta del editor y comentarios de los revisores de PLOS ONE</u>

PONE-D-13-43607
Impact of the Spanish smoke-free legislation on adult, non-smoker exposure to secondhand smoke: cross-sectional surveys before (2004) and after (2012) legislation
PLOS ONE

Dear Dr. Sureda,

Thank you for submitting your manuscript to PLOS ONE. After careful consideration, we feel that it has merit, but is not suitable for publication as it currently stands. Therefore, my decision is "Major Revision."

We invite you to submit a revised version of the manuscript that addresses the points raised by our reviewers below.

We encourage you to submit your revision within forty-five days of the date of this decision.

When your files are ready, please submit your revision by logging on to http://pone.edmgr.com/ and following the Submissions Needing Revision link. Do not submit a revised manuscript as a new submission. Before uploading, you should proofread your manuscript very closely for mistakes and grammatical errors. Should your manuscript be accepted for publication, you may not have another chance to make corrections as we do not offer pre-publication proofs.

If you would like to make changes to your financial disclosure, please include your updated statement in your cover letter.

Please also include a rebuttal letter that responds to each point brought up by the academic editor and reviewer(s). This letter should be uploaded as a Response to Reviewers file.

In addition, please provide a marked-up copy of the changes made from the previous article file as a Manuscript with Tracked Changes file. This can be done using 'track changes' in programs such as MS Word and/or highlighting any changes in the new document.

If you choose not to submit a revision, please notify us.

Yours sincerely,

Thomas Behrens
Academic Editor
PLOS ONE

Journal requirements:

When submitting your revision, we need you to address these additional requirements.

1) Thank you for including your ethics statement on the online submission form: "Participants were asked to sign an informed consent form before proceeding with the face-to-face interview.In case of subjects aged 16 an 17, parental written consent was obtained. "

To help ensure that the wording of your manuscript is suitable for publication, would you please also add this statement to the Methods section of your manuscript file.

<u>Reviewers' comments</u>:

Reviewer's Responses to Questions

Comments to the Author

1. Is the manuscript technically sound, and do the data support the conclusions?

The manuscript must describe a technically sound piece of scientific research with data that supports the conclusions. Experiments must have been conducted rigorously, with appropriate controls, replication, and sample sizes. The conclusions must be drawn appropriately based on the data presented.

Reviewer #1: Yes
Reviewer #2: Partly
Reviewer #3: Yes

Please explain (optional).

Reviewer #1: Were there other interventions such as increase in taxation, restriction of sales, smoking cessation programmes etc in Barecelona in the same time period?
How they would have contributed to the decline in smoking? Are the observed changes due to a decline in overall smoking in Barcelona or only smoking restrictions in the settings mentioned.
Can the decline in public and private transport be given separately?
Also can the decline in workplaces other than hospitality industry be presented? (Since the law didi not cover them initially)

Reviewer #2: The study is based on pre-policy data from 2004-2005 and post-policy data from 2011-2012. This means that the study analyses the effects of both Spanish smoking laws, although the authors state that they only study the effects of the latest version of the law. I have a few comments in relation to this:

1) If the focus should be on the effects of the second version of the smoking law, then the authors should include the results of studies of the effects of the first law in their discussion.

2) In the conclusion (line 378-380) the authors write "The strategy of strengthening the law (28/2005) to extend to hospitality venues without exception was clearly effective". Although this statement is not wrong, I find that it should be highlighted that what they actually study is the effect of both laws.

Reviewer #3: This paper presents the results of two cross-sectional surveys, one before there were any legal restrictions on where one could smoke and one after comprehensive legislation was in place in Spain. The authors collected data on self-reported exposure and also an objective biomarker of exposure (cotinine). Both dropped following implementation of the legislation, with much larger drops in cotinine than self-report.

The fact that the cotinine dropped by so much (88%) is very important and deserves more prominence in the results. The fact that the cotinine dropped so much suggests that, while people are still getting some (albiet much less) exposure in the various venues the authors studied, the intensity of exposure in these venues is much less. (The authors only assessed WHETHER people were exposed in the venues, not HOW MUCH.)

The finding that there were big increases in (voluntary) smokefree homes is a very important finding that deserves more emphasis and which should be presented in more positive terms. Right now they authors just mention the substantial increase in smokefree homes as evidence that there was not displacement of smoking into homes when smoking was restricted in workplaces and public places. This is no doubt in response to such predictions (made by the tobacco companies and politicians sympathetic to the tobacco companies), but there was never any meaningful data to support these assertions. Rather than repeating these (groundless) assertions and saying that they are wrong, the authors should affirmatively present their results as demonstrating the positive side effect of the law as stimulating voluntary smokefree home policies.

Two related papers that deal with this point (which ought to be integrated into this paper) are:

Association between smokefree laws and voluntary smokefree-home rules.
Cheng KW, Glantz SA, Lightwood JM.
Am J Prev Med. 2011 Dec;41(6):566-72. doi: 10.1016/j.amepre.2011.08.014

Association between clean indoor air laws and voluntary smokefree rules in homes and cars.
Cheng KW, Okechukwu CA, McMillen R, Glantz SA.
Tob Control. 2013 Oct 10. doi: 10.1136/tobaccocontrol-2013-051121. [Epub ahead of print]

Specific comments:

Line 139: What is the power associated with these calculations? 80%?

Line 261: Here the authors say that there was no significant change in workplace exposure, but later on the same page (line 271) they say there was. This inconsistency needs to be resolved (and the abstract revised accordingly).

Line 264: If is not clear what these percentages are percentages of.

Line 381: Replace "there was no displacement of SHS exposure due to increased smoking in this setting" with "the social norm changes reflected in the law lead to increases in voluntary smokefree policies, further reducing exposure to SHS."

Table 1 (and associated discussion): Was the fact that exposure in several venues was already low before the law took effect the reason that there were not bigger relative drops in self-reported exposure? (Also see earlier point about the fact that cotinine dropped much more than the self-reported exposures in Table 1.) Revise the text and abstract accordingly.

Table 2: Suggest changing "percentage change" to "percentage reduction" in the table and also in the discussion of this table in the text and abstract. These large across-the-board reductions are impressive and should be stressed.

----

2. Has the statistical analysis been performed appropriately and rigorously?

Reviewer #1: Yes
Reviewer #2: Yes
Reviewer #3: Yes

Please explain (optional).

Reviewer #1: In addition, adult smoking prevalence in Barcelona over the period from 2005 to 2012 can be presented. This will help to know the trend in tobacco use prevalence. Is there any correlation between change in adult smoking prevalence and exposure to SHS?

Reviewer #2: The analyses seem to be appropriate; adjusting for common confounders and accounting for the skewed distribution of cotinine concentrations.

Reviewer #3: (No Response)

----

3. Does the manuscript adhere to standards in this field for data availability?

Authors must follow field-specific standards for data deposition in publicly available resources and should include accession numbers in the manuscript when relevant. The manuscript should explain what steps have been taken to make data available, particularly in cases where the data cannot be publicly deposited.

Reviewer #1: Yes

Reviewer #2: No

Reviewer #3: Yes

Please explain (optional).

Reviewer #1: (No Response)

Reviewer #2: The data does not seem to be publicly available

Reviewer #3: (No Response)

----

4. Is the manuscript presented in an intelligible fashion and written in standard English?

PLOS ONE does not copyedit accepted manuscripts, so the language in submitted articles must be clear, correct, and unambiguous. Any typographical or grammatical errors should be corrected at revision, so please note any specific errors below.

Reviewer #1: No

Reviewer #2: Yes

Reviewer #3: Yes

Please explain (optional).

Reviewer #1: it will be useful to show a schematic diagramme of the process with two time periods, number of subjects interviewed etc for the reader to get a complete picture.

If space permits, the summary of the legislation and key elements for implementation can be presented.

Reviewer #2: (No Response)
Reviewer #3: (No Response)

----

5. Additional Comments to the Author (optional)

Please offer any additional comments here, including concerns about dual publication or research or publication ethics.

Reviewer #1: Overall a very useful paper which will strengthen tobacco control policies.

Can other countries with limited resources do this study without salivary cotinine estimation? What would have been the difference in this study if cotinine values were not available?

Reviewer #2: I find that this is a well-written paper on an interesting topic. The methodology is not new or very advanced, but the study seems to be soundly performed; especially it is good that self-reported data is supplement by objective biomarkers. Evaluations of smoking laws are very relevant from a policy perspective. If the comments made below and in section #1 are taken into consideration I would recommend the paper for publications.

The authors are aware of the potential problems involved with using self-reported data and discuss this (line 344-353). However, it would be good to also discuss the appropriateness of the questions used from the questionnaire; I find that the level of detail varies quite a bit between the questions (only some include exposure time or dose), but they are all included in the same way in the analysis.

Individuals aged 16 years and older were included in the study. It would be good if the authors could briefly inform what the legal minimum age for smoking is in Spain – or whether there is no such minimum age.

Reviewer #3: (No Response)

----

6. If you would like your identity to be revealed to the authors, please include your name here (optional).

Your name and review will not be published with the manuscript.

Reviewer #1: (No Response)
Reviewer #2: (No Response)
Reviewer #3: (No Response)

Respuesta a los revisores de PLOS ONE

Journal requirements

When submitting your revision, we need you to address these additional requirements.
1) Thank you for including your ethics statement on the online submission form: "Participants were asked to sign an informed consent form before proceeding with the face-to-face interview. In case of subjects aged 16 an 17, parental written consent was obtained. "
To help ensure that the wording of your manuscript is suitable for publication, would you please also add this statement to the Methods section of your manuscript file.
This statement was already included in the Methods section in the last manuscript file sent to the journal.

Response Reviewers' comments

We thank the reviewers for the useful comments and include them below with our answers, indicating when necessary any changes made to the manuscript.

1. Is the manuscript technically sounds, and do the data support the conclusions?
Reviewer #1: Yes
Reviewer #2: Partly
Reviewer #3: Yes

Reviewer #1

Were there other interventions such as increase in taxation, restriction of sales, smoking cessation programmes etc in Barcelona in the same time period?

How they would have contributed to the decline in smoking? Are the observed changes due to a decline in overall smoking in Barcelona or only smoking restrictions in the settings mentioned.

In the present manuscript we are referring to second-hand smoke exposure and not to smoking itself. The hypothesis that changes in smoking prevalence may affect the prevalence of exposure to SHS is appealing. However, we know from previous studies in Barcelona and Spain, and also from the international literature, that the changes occurred in smoking prevalence during the last two decades (decreasing trend in males and leveled off in women) did not affect the prevalence of exposure to SHS. Moreover, the slight decline in smoking observed in Barcelona during the same period follows the already present trend, as also observed for Catalonia and Spain. This is, the smoke-free legislation has not influenced the prevalence of smoking. During the last years, there have been some increases in taxation but not strengthen of other public tobacco control policies, such as cessation programs, limitation of publicity or media campaigns. Regarding taxation, a recent paper from Lopez-Nicolas et al. (Nicotine & Tob Res. 2013) showed that the changes in the structure of the taxes in Spain did not influence tobacco consumption. Hence, we believe that no changes regarding this point should be introduced in the manuscript.

Can the decline in public and private transport be given separately?

We appreciate the reviewer's comment. In fact, we were dubitative about including the exposure to SHS separately for public and private transportation because the smoke-free law did not affect very much transportation. Smoking in public transportation (inside buses, trains and enclosed stations) was already banned before the 28/2005 Law by local ordinances, and no regulation did exist on smoking in private vehicles. The 42/2010 law banned smoking in taxis (already banned in the Metropolitan area of Barcelona) and in commercial vehicles (private vehicles considered workplaces).

We have analyzed it in separate and we are including them in the Table 1 and the Results section. In brief, we observed a decline in public transportation but not in private transportation, and the findings are commented in the Discussion section.

Also can the decline in workplaces other than hospitality industry be presented? (Since the law did not cover them initially)

The previous law prohibited smoking in all public places, including workplaces but had some important exceptions in hospitality venues that the present tobacco smoke-free law covers. It would have been interesting to separate results according to the specific workplace but this information was not registered in the questionnaire. Moreover, this approach would be highly inefficient, since the proportion of people employed in the hospitality sector among our sample of the general population would be very low. Finally, the effect of the 42/2010 Law in the exposure to SHS in hospitality places among the population can partly be observed in the reduction in exposure to SHS during leisure time.

Reviewer #2

The study is based on pre-policy data from 2004-205 and post-policy data from 2011-2012. This means that the study analyses the effects of both Spanish smoking laws, although the authors state that they only study the effects of the latest version of the law. I have a few comments in relation to this:

1) If the focus should be on the effects of the second version of the smoking law, then the authors should include the results of studies of the effects of the first law in their discussion.

We appreciate and agree with the reviewer's comment. To clarify this point and make clear that we are *de facto* studying the impact of both laws, we have introduced changes across the manuscript: in the Introduction including the objective, in the Results section, and also in the Discussion, as suggested by the reviewer.

2) In the conclusion (line 378-380) the authors write "The strategy of strengthening the law (28/2005) to extend to hospitality venues without exception was clearly effective". Although this statement is not wrong, I find that it should be highlighted that what they actually study is the effect of both laws.

According to the reviewer's advice, we now stress in the conclusion that we studied both laws in the first sentence. Once this first sentence is highlighted, we are inclined to maintain the second sentence.

Reviewer #3

This paper presents the results of two cross-sectional surveys, one before there were any legal restrictions on where one could smoke and one after comprehensive legislation was in place in Spain. The authors collected data on self-reported exposure and also an objective biomarker of exposure (cotinine). Both dropped following implementation of the legislation, with much larger drops in cotinine than self-report.

The fact that the cotinine dropped by so much (88%) is very important and deserves more prominence in the results. The fact that the cotinine dropped so much suggests that, while people are still getting some (albiet much less) exposure in the various venues the authors

studied, the intensity of exposure in these venues is much less. (The authors only assessed WHETHER people were exposed in the venues, not HOW MUCH.)

The finding that there were big increases in (voluntary) smokefree homes is a very important finding that deserves more emphasis and which should be presented in more positive terms. Right now they authors just mention the substantial increase in smokefree homes as evidence that there was not displacement of smoking into homes when smoking was restricted in workplaces and public places. This is no doubt in response to such predictions (made by the tobacco companies and politicians sympathetic to the tobacco companies), but there was never any meaningful data to support these assertions. Rather than repeating these (groundless) assertions and saying that they are wrong, the authors should affirmatively present their results as demonstrating the positive side effect of the law as stimulating voluntary smokefree home policies.

Two related papers that deal with this point (which ought to be integrated into this paper) are:

Association between smokefree laws and voluntary smokefree-home rules. Cheng KW, Glantz SA, Lightwood JM. Am J Prev Med. 2011 Dec;41(6):566-72. doi: 10.1016/j.amepre.2011.08.014

Association between clean indoor air laws and voluntary smokefree rules in homes and cars. Cheng KW, Okechukwu CA, McMillen R, Glantz SA. Tob Control. 2013 Oct 10. doi: 10.1136/tobaccocontrol-2013-051121. [Epub ahead of print]

We appreciate the reviewer's comment and have stressed it in the Discussion section as well as in the Conclusion.

Specific comments:

Line 139: What is the power associated with these calculations? 80%?

As already mentioned in the Methods section, the beta error (type II error) was 20%, and statistical power is 1-beta (this is 80% in this study).

Line 261: Here the authors say that there was no significant change in workplace exposure, but later on the same page (line 271) they say there was. This inconsistency needs to be resolved (and the abstract revised accordingly).

We consider the results are correct. We observed a decline in SHS exposure in workplaces. In line 261, the results are not adjusted for sex, age and educational level and in that case the decrease in SHS was not significant. In line 271 we explained that after controlling for those variables the decline was significant.

Line 264: If is not clear what these percentages are percentages of.

These percentages follow the scheme used in the precedent line when beginning to report the prevalence of exposure to SHS in 2004-05, in 2011-12, and the corresponding relative reduction. In order to be not repetitive, we do not include by each percentage all the information.

Line 381: Replace "there was no displacement of SHS exposure due to increased smoking in this setting" with "the social norm changes reflected in the law lead to increases in voluntary smokefree policies, further reducing exposure to SHS."

We changed the sentence according to the previous comment.

Table 1 (and associated discussion): Was the fact that exposure in several venues was already low before the law took effect the reason that there were not bigger relative drops in self-reported exposure? (Also see earlier point about the fact that cotinine dropped much more than the self-reported exposures in Table 1.) Revise the text and abstract accordingly.

Although we concur with the reviewer that some prevalence of exposure to SHS before the legislation could be considered low in some of the settings (because smoking was already regulated totally or partly in those settings, such as workplaces and transportation), we do not agree with the interpretation. All relative reductions ranged between 12% and 40%, which cannot be considered low. We believe that in this case it is more informative to use the relative reduction rather than the absolute reduction (ie, at home the prevalence of exposure to SHS decreases from 32.5% to 27.6%, "just" 4.9 points of prevalence, but a relative reduction of 15.1%).

Table 2: Suggest changing "percentage change" to "percentage reduction" in the table and also in the discussion of this table in the text and abstract. These large across-the-board reductions are impressive and should be stressed.

We prefer "change" because it is a more neutral term and we did not know *a priori* whether a change would occur and in which direction --although our hypothesis was a reduction. Thus, we are inclined to maintain "percentage of change".

----

2. Has the statistical analysis been performed appropriately and rigorously?

Reviewer #1: Yes

Reviewer #2: Yes

Reviewer #3: Yes

Reviewer #1

In addition, adult smoking prevalence in Barcelona over the period from 2005 to 2012 can be presented. This will help to know the trend in tobacco use prevalence. Is there any correlation between change in adult smoking prevalence and exposure to SHS?

As previously commented, higher smoking prevalence rates do not correlate with the proportion of people exposed to SHS. We prefer not to include data on smoking prevalence in Barcelona since the focus of the study is SHS.

Reviewer #2

The analyses seem to be appropriate; adjusting for common confounders and accounting for the skewed distribution of cotinine concentrations.

Reviewer #3

No Response

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3. Does the manuscript adhere to standards in this field for data availability?

Reviewer #1: Yes

Reviewer #2: No

Reviewer #3: Yes

Reviewer #1

No Response

Reviewer #2

The data does not seem to be publicly available.

Reviewer #3

No Response

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4. Is the manuscript presented in an intelligible fashion and written in standard English?

Reviewer #1: No

Reviewer #2: Yes

Reviewer #3: Yes

Reviewer #1

It will be useful to show a schematic diagramme of the process with two time periods, number of subjects interviewed etc for the reader to get a complete picture.

As suggested by the reviewer, we have included a diagramme (new Figure 1) with the figures of participants in both surveys.

If space permits, the summary of the legislation and key elements for implementation can be presented.

We explain the main characteristics of the new tobacco smoke-free law and the changes from the previous law in the paragraph 3 in the Introduction Section, and have expanded with a sentence on penalties and enforcement.

Reviewer #2

No Response

Reviewer #3

No Response

5. Additional Comments to the Author (optional)

Reviewer #1

Overall a very useful paper which will strengthen tobacco control policies.

Can other countries with limited resources do this study without salivary cotinine stimation? What would have been the difference in this study if cotinine values were not available?

The use of an objective, specific biomarker of SHS exposure was to reduce the information bias derived from the use of a questionnaire. The high reduction in cotinine levels corroborates the self-reported reduction in SHS by non-smokers. Similar cross-sectional studies not including cotinine are also of value and have been used in other jurisdictions, although the validity of the study is higher when cotinine is available.

Reviewer #2

I find that this is a well-written paper on an interesting topic. The methodology is not new or very advanced, but the study seems to be soundly performed; especially it is good that self-reported data is supplement by objective biomarkers. Evaluations of smoking laws are very relevant from a policy perspective. If the comments made below and in section #1 are taken into consideration I would recommend the paper for publications.

The authors are aware of the potential problems involved with using self-reported data and discuss this (line 344-353). However, it would be good to also discuss the appropriateness of the questions used from the questionnaire; I find that the level of detail varies quite a bit between the questions (only some include exposure time or dose), but they are all included in the same way in the analysis.

We agree with the reviewer that the questions to assess SHS exposure were different in some cases depending on the setting. But in this manuscript we did not analyze how much non-smokers were exposed but if they were exposed or not. At the end, all the questions used were valid to derive a dichotomous variable of exposure to SHS at different settings studied: (1) non-exposed individuals, which included those with no exposure according to answers to both questions, and (2) exposed individuals, which included all others.

Individuals aged 16 years and older were included in the study. It would be good if the authors could briefly inform what the legal minimum age for smoking is in Spain – or whether there is no such minimum age.

The law prohibits sales of tobacco to age 18. We restricted the age of participant to obtain reliable and direct information on both tobacco consumption and exposure to SHS. Usually, information from minors is obtained from proxies, but we excluded people <16 years old.

Reviewer #3

No Response)

6. If you would like your identity to be revealed to the authors, please include your name here (optional).

Reviewer #1: (No Response)

Reviewer #2: (No Response)

Reviewer #3: (No Response)

Carta de aceptación del manuscrito en PLOS ONE

PONE-D-13-43607R1

Impact of the Spanish smoke-free legislation on adult, non-smoker exposure to secondhand smoke: cross-sectional surveys before (2004) and after (2012) legislation

Dear Dr. Sureda,

I am pleased to inform you that your manuscript has been deemed suitable for publication in PLOS ONE. Congratulations! Your manuscript will now be passed on to our Production staff, who will check your files for correct formatting and completeness. During this process, you may be contacted to make necessary alterations to your manuscript, though not all manuscripts require this.

Please check the accepted PDF of your manuscript very closely. THERE IS NO AUTHOR PROOFING. You should consider the accepted PDF or any corrected files you upload during the production process as equivalent to a production proof. If you would like to make any corrections to your manuscript, please email our Production team (one_production@plos.org) as soon as possible with your request. The text you supply will be faithfully represented in your published manuscript exactly as you supply it. This is your last opportunity to correct any errors that are present in your manuscript files.

Now that your manuscript has been accepted, please log into Editorial Manager at http://www.editorialmanager.com/pone, click the "Update My Information" link at the top of the page, and update your user information to ensure an efficient production and billing process. If you have any questions about billing, please contact authorbilling@plos.org.

If you or your institution will be preparing press materials for this manuscript, you must inform our press team in advance. We no longer routinely supply publication dates to authors; if you need to know your paper's publication date for media purposes, you must coordinate with our press team. Your manuscript will remain under a strict press embargo until the publication date and time. For more information please contact onepress@plos.org.

Please contact one_production@plos.org if you have any other questions or concerns. Thank you for submitting your work to PLOS ONE.

With kind regards,

Thomas Behrens

Academic Editor

PLOS ONE

Anexo 7. Proceso editorial del artículo publicado en Environmental Health Perspectives

Second-hand tobacco smoke exposure in open and semi-open settings: a systematic review

<u>Carta de presentación del manuscrito a Environmental Health Perspectives</u>

Prof. Hugh A. Tilson

Editor-in-Chief

Environmental Health Perspectives

Dear Prof. Tilson:

Please find enclosed our manuscript “Second-Hand Tobacco Smoke Exposure in Open and Semi-Open Settings: A Review” for your consideration in Environmental Health Perspectives as a Review paper.

As a consequence of workplace indoors tobacco regulations, many smokers have moved to particular outdoor settings and some controversy exists regarding whether smoking should be prohibited in those settings. Secondhand smoke exposure has been commonly studied in different indoor locations; however, outdoor secondhand has been scarcely evaluated. The objective of the present study is to review research on secondhand smoke exposure in outdoor settings. The reviewed evidence identifies high SHS levels at some outdoor smoking areas, especially those that are semi-enclosed, and also in the adjacent smoke-free indoor areas.

To the best of our knowledge, this is the first review of secondhand smoke exposure in outdoor settings; we believe its results and implications may be of the interest of the international audience of EHP.

Suggested reviewers:

James Repace, Repace Assoc., repace@comcast.net

Luke Clancy, TobaccoFree Institute Ireland, lclancy@tri.ie

Sean Semple, University of Aaberdeen, sean.semple@abdn.ac.uk

John P. Pierce, Unversity of California, San Diego jppierce@ucsd.edu

All the authors carefully read the manuscript and fully approve of it. In their name I also declare that the manuscript is original and it is not submitted anywhere other than your journal. All the authors declare to have no conflict of interest. We would of course be ready to provide further information about our data and methods you so desire.

Correspondence about the manuscript should be addressed to me as indicated in the first page of the manuscript.

Thank you very much for your kind attention. With best regards, Yours sincerely,

Esteve Fernandez, MD, PhD
Head, Tobacco Control Research Unit, Institut Català d'Oncologia
Associate Professor of Epidemiology & Biostatistics, Universitat de Barcelona
E-mail: efernandez@iconcologia.net

Respuesta del editor y comentarios de los revisores de Environmental Health Perspectives

11 September 12

Dear Mrs. Sureda:

Manuscript ID 12-05806-REV titled "Second-Hand Tobacco Smoke Exposure in Open and Semi-Open Settings: A Review" which you submitted to Environmental Health Perspectives, has been reviewed. The comments are included at the bottom of this letter.

The reviewer(s) have recommended some major revisions to your manuscript. Therefore, I invite you to respond to the comments and revise your manuscript. You have six weeks from the date of this letter to complete your revisions. If you require additional time, you must contact us by e-mail [EHPManuscripts@niehs.nih.gov] PRIOR TO THE DUE DATE to request an extension, otherwise your paper will not be available for revision.

Note: Papers for which major revisions are recommended have a low to moderate overall rating that the Associate Editor believes might be improved with significant revisions. Significant revisions may include substantial or extensive changes in the text, figures, or tables. Additional experiments, data collection, analyses, or new information may also be required. It is possible that the paper may not be accepted even if additional material is provided since the new information may not support the original conclusions or may uncover other serious problems that would warrant rejection. Manuscripts that are resubmitted after major revisions will be sent back to reviewers for reevaluation.

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EHP word limits (including the title page, keywords, abstract, main text, references and tables, plus 250 additional words for each figure):

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- Reviews, Substantive Reviews, Quantitative Reviews or Meta-Analyses: 10,000 words
- Emerging Issues Reviews: 5,000 words
- Commentaries: 5,000 words

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Select "Manuscripts Awaiting Revision." Under "Actions," click on "create a revision." The manuscript will appear under "Revised Manuscripts in Draft" with the original manuscript number appended to denote the revision. [Note: you may also see an option to "Click here to submit a revision" when you log into your Author Center. If that option is available you can select it, and it will automatically create the revision for you.]

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- In order to expedite the processing of your revised manuscript, please be as specific as possible in your response to the reviewer(s). We recommend that you copy the editors' and/or reviewers' comments into your response letter and respond to each comment individually, including the specific changes made in response to each comment (if any) and where the changes are located in the revised draft. Adding line numbers to your documents will make it easier to indicate the location of specific text or changes. (In Word, go to Format → Document → Layout → Line Numbers to add line numbers to your document).

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If you have added new coauthors to the paper you must enter their information here. You may also edit coauthor information or delete coauthors if needed.

- NOTE: You must submit a revised competing financial interest (CFI) form if you have added new coauthors to your paper.

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You may enter the text of your cover letter into the space provided or upload your cover letter as a separate file here.

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Please answer all of the questions on the Details & Comments page, even if they are also addressed elsewhere (e.g., in your cover letter).

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9. Review & Submit
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Once again, thank you for submitting your manuscript to Environmental Health Perspectives. I look forward to receiving your revision.

Sincerely,

Dr. Manolis Kogevinas
Associate Editor, Environmental Health Perspectives
ehpmanuscripts@niehs.nih.gov

<u>Editor's Comments:</u>

This is an interesting paper addressing an important topic. The paper could be considerably improved and the authors should respond to the comments by the reviewers. They should particularly take care to:

1. Review the papers suggested by the reviewers and if appropriate include them
2. Follow in the reporting the guidelines proposed by international groups such as PRISMA (Moher et al 2009, PlosMed) or MOOSE (JAMA 2000). EHP does not recommend specific guidelines for reviews but the authors should have tried to adapt their review, analysis and reporting following published guidelines. Full reporting of the search process is absolutely

necessary and inclusion of a flowchart would be helpful (see PRISMA). Basic information on the search process should also be included in the abstract.

3. Results and discussion of the results should try to adapt to some of these guidelines. For example, although publication bias is probably not an issue in this area, we actually do not know this. If possible, this should be evaluated. If not, indicate why you could not evaluate publication bias.

4. It would be clearly helpful to follow the recommendation of Rev2 to distinguish between the hospitality industry and other venues.

5. A minor but rather preoccupying point is that the authors mistook the location of the 2 studies conducted in Athens, Georgia (USA), for the ex-Soviet Republic Georgia. Such mistakes may happen but this could also be a sign of non-careful reading of the full paper. There are no other obvious mistakes to my understanding; however, I would strongly recommend that the authors reviewed again the full papers.

6. Try and suggest one or 2 Figures summarizing the results. I understand that it is probably impossible to do a meta-analysis, but this type of narrative reviews are very hard to follow. Readers would be helped if they could see a summary of the most important results.

7. In the discussion the authors suggest that more and better studies are needed. Suggest which are the main areas where an improvement in methods could be addressed in new studies. This does not have to be long, something short and concise.

8. The aim of the paper as described in lines 135-136 is incomplete. Complete the objectives by moving to the introduction probably the section described in lines 190-196.

9. Introduction. The second and first sentence say the same thing

10. Line 190. “Disparities”, is not the appropriate word here; you probably mean differences, different methodologies

<u>Reviewer(s)' Comments</u>:

Reviewer: 1

Sureda et al. in their review paper, Second-Hand Tobacco Smoke Exposure in Open and Semi-Open Settings: A Review, note that some countries have recently extended smoke-free policies to certain outdoor settings; and note that there is controversy regarding whether this is scientifically and ethically justifiable. They conclude that the available evidence identifies high SHS levels at some outdoor smoking areas, as well as the adjacent smoke-free indoor areas, but that further research and standardization of methodology are needed to better understand the results, and to evaluate the need to extend smoke-free legislation to outdoor settings.

Their review includes 16 articles and reports. This reviewer suggests adding two more published papers:

Outdoor air pollution in close proximity to a continuous point source
Neil E. Klepeis*, Etienne B. Gabel, Wayne R. Ott, Paul Switzer. Atmospheric Environment 43 (2009) 3155–3167.
Repace JL. Benefits of smoke-free regulations in outdoor settings: beaches, golf courses, parks, patios, and in motor vehicles. William Mitchell Law Review 34(4):1621-1638 (2008), online at http://www.repace.com/reports.html.

And possibly two more academic reports presented at conferences and available on the internet:

Smoke infiltration in apartments, 2011 (pdf file 2.1MB), pages 19 & 20 only.
Indoor and outdoor carcinogen pollution on a cruise ship, 2004. At:
http://www.repace.com/reports.html.

The paper is well-written, and one cannot disagree with the conclusions. It is clear from the research this reviewer has conducted, however, that secondhand smoke can travel over significant distances outdoors, can present a health hazard to workers in outdoor cafes, and a nuisance to many nonsmokers in public settings such as sidewalks, parks, and beaches, and the authors may wish to note that some cities in California and New York have banned smoking in parks and beaches.

Reviewer: 2

This non-systematic review addresses a topic of importance; however a few rough edges remain, while the presentation of the results should focus on seperating the venues by type which is of interest to legislators and scientists

Major comments

- My initial comment is on the study methodology, as the research performed seems like it was not done the way a systematic review is usually performed. I.e. specific combinations of terms, two researchers, a flow chart, etc. While some of the above are noted, and thus it is possible that this is a systematic review, this should be clarified and thus should conform to the guidelines for a systematic review. If not, please state that this is not a systematic review

- Due to the use of many different settings in the studies, I strongly recommend grouping the same venue types together. The authors mention parks, streets, airports, campus, bars etc. From a policy and exposure perspective it would be of more interest to group bars and restaurants (i.e hospitality industry) together as this would be the area of potential legislation in the future. Based on the above point, the results should be re-structured.

Minor comments

- Page 4, line 79, "mixture of thousands of gases", I recommend replacing "gases" with "compounds"
- Page 4, Lines 88, 92, the authors mention a number of short term effects of SHS exposure, however they do not note the most severe or the most recent. Acute SHS exposure may also impair arterial stiffness, heart rate variability, hormone production etc. (flouris et al. 2010, Pope et al., 2001; frey 2012 etc.)
- Page 5, lines121-122, the authors mention that "outdoor smoking bans might also support smokers…..consumption" while plausible, this would need a supporting reference at least.
- Page 7, line 176. The authors mention "Georgia". This actually refers to Georgia in the USA, not Georgia the country. Please correct.
- Page 8, line 180,181. The authors mention one study that used a personal biological marker. Recently in EHP another article was published with NNAL measured (a tobacco specific carcinogen). During a small review within Pubmed the following recently published article appeared. Please include it in your review St Helen G, Bernert JT, Hall DB, Sosnoff CS, Xia Y, Balmes JR, Vena JE, Wang JS, Holland NT, Naeher LP. Exposure to secondhand smoke outside of a bar and a restaurant and tobacco exposure biomarkers in nonsmokers. Environ Health Perspect. 2012 Jul;120(7):1010-6. Epub 2012 Apr 6.
- Page 8 line 194-196. The authors mention that their 4th structuring in the results was to "comply with air quality standards established by the WHO". We should keep in mind, that while $PM_{2.5}$ is a common regulatory marker, SHS does not contain only $PM_{2.5}$ but numerous other compounds that air pollution may not contain. Caution is needed in comparing SHS studies with WHO guidelines.
- Page 10, line 242. This sentence "Boffi….indoors" seems out of place, does it belong to the paragraph above?
- Page 12, line 299. Within the Wilson study the high levels of SHS in the smoke free venue were attributable to "SHS drift" i.e. SHS entering a smoke free venue. Please state this clearly in that section.
- Page 13, line 324. The authors note the large differences in exposure, please separate this by source.
- I am not sure of the relevance of the SHS levels and air quality standards section in the discussion. While interesting I am not sure if its needed.

- Within the limitations section the authors note that "further research should either record the presence of other sources of combustion etc.. this is correct, however I would note that usually in most studies background levels are removed from the total $PM_{2.5}$ concentrations during the analysis.
- In the table I would transform the CARD results into μg/m^3 from mg/m^3. so that the results are comparable with the other studies.

Respuesta a los revisores de Environmental Health Perspectives

Response to Editor and Reviewers' comments

We thank the editor and reviewers for the useful comments and include them below with their respective answers, indicating when necessary any changes made to the manuscript.

Editor's Comments:

Thank you very much for the opportunity to revise and resubmit the manuscript according to the useful comments.

1. Review the papers suggested by the reviewers and if appropriate include them.
As the editor suggest, we have included two more articles that fit with the inclusion criteria, one suggested by reviewer #2 (St Hellen et al. 2012) and another just published (López et al. 2012). Both articles were published after the submission of the present review to EHP. We have updated the search up to September 2012, and have introduced the corresponding changes in the Results section (and the new flow chart).

- **Lopez MJ, Fernandez E, Gorini G, Moshammer H, Polanska K, Clancy L, Dautzenberg B, Delrieu A, Invernizzi G, Munoz G, Precioso J, Ruprecht A, Stansty P, Hanke W, Nebot M.** 2012. Exposure to secondhand smoke in terraces and other outdoor areas of hospitality venues in eight European countries. PLoS ONE 7:e42130.
- **St HG, Bernert JT, Hall DB, Sosnoff CS, Xia Y, Balmes JR, Vena JE, Wang JS, Holland NT, Naeher LP.** 2012. Exposure to secondhand smoke outside of a bar and a restaurant and tobacco exposure biomarkers in nonsmokers. Environ Health Perspect 120:1010-1016.

2. Follow in the reporting the guidelines proposed by international groups such as PRISMA (Moher et al 2009, PlosMed) or MOOSE (JAMA 2000). EHP does not

recommend specific guidelines for reviews but the authors should have tried to adapt their review, analysis and reporting following published guidelines. Full reporting of the search process is absolutely necessary and inclusion of a flowchart would be helpful (see PRISMA). Basic information on the search process should also be included in the abstract.

As also commented by Reviewer #2, we want to clarify about the nature of this review. In fact, when we designed and planned this study we wanted to perform a systematic review and, if possible, with a meta-analysis. Thus, we used the methods for systematic reviews but after retrieving the papers, it seemed more appropriate to us not to label our work as systematic review because of the heterogeneity of the results (and also this prevented us to perform a meta-analysis to obtain a summary measure of the concentration of $PM_{2.5}$ or nicotine in the studies reviewed). However, we have reconsidered it in light of the comments received, acknowledging that perhaps our criteria was so strict. Therefore, we are inclined now to label the work as a systematic review and hence we have introduced all the elements in our report according to the PRISMA Statement that were lacking in the previous version. Please see the rewritten Abstract, Methods and Results sections of the manuscript (Abstract now including: Data sources and study selection; Methods now including: PubMed search syntaxis, study selection, data collection procedures; Results section now including: flow chart of studies considered, separate tables, and a new figure to graphically present the main results –without summary measure because we do not perform a meta-analysis).

3. Results and discussion of the results should try to adapt to some of these guidelines. For example, although publication bias is probably not an issue in this area, we actually do not know this. If possible, this should be evaluated. If not, indicate why you could not evaluate publication bias.

Please see our response to the previous comment. In addition, we have included in the Discussion the topic of publication bias. We are not able to assess it using the typical funnel plot used in meta-analysis but have done some considerations:

> Publication bias is a potential source of error in systematic reviews. In ours, we searched the available literature in PubMed, the main biomedical database, in addition we searched in Google Scholar and check for cross-references. Thus, we were able to identify documents not published in academic journals. However, the possibility of non-including non-published manuscripts or other documents addressing the topic of interest is low. This field of research is a new and emerging one with most research devoted to describe the levels of SHS outdoors. Thus, no "negative" nor "positive" results are expected, but the accurate description of the exposures. This should prevent, al least theoretically, publication bias.

4. It would be clearly helpful to follow the recommandation of Rev2 to distinguish between the hospitality industry and other venues.

We appreciate the comment and accordingly we have distinguished between hospitality industry and other venues. We have split **Table 1** into two tables: Table 1 presents the description of the studies concerning to hospitality venues and Table 2 presents the description of the studies including the other venues. In the case that one article refers to both settings, we have included that article in both tables (with the relevant information to the specific setting).

Accordingly, we have rewritten the third paragraph in results section as follows:

> "The studies included between 5 and 127 locations. Depending on the specific study objectives, different locations were tested. Most of the studies were conducted in hospitality venues such as pubs, restaurants, bars, cafés and outdoor dining areas. Table 1 shows a description of the studies including hospitality venues. In Table 2 we have included the information of studies in other locations such as entrances to buildings and the adjacent indoor area, transportation settings, parks, streets, university campuses, and one junior college campus."

Other changes regarding this comment --we have rewritten the paragraph in the Results section under "***Indoor and outdoor SHS levels"*** heading*:*

> The most common topic identified was describing SHS levels both indoors and outdoors in different settings in the presence or absence of smoking. $PM_{2.5}$ mean concentrations outdoors across the studies carried out in hospitality venues ranged between 8.32 µg/m^3 (Stafford, Daube, & Franklin, 2010) and 182 µg/m^3 (Hall et al., 2009) when smokers were presence. In non-hospitality venues, $PM_{2.5}$ concentrations in outdoor settings range between 4.60 µg/m^3 (Boffi, Ruprecht, Mazza, Ketzel, & Invernizzi, 2006) and 17.80 µg/m^3 (Boffi et al., 2006). In one experimental study, SHS levels were provided for hospitality venues and other settings combined and they obtained an overall $PM_{2.5}$ mean of 30 µg/m^3 (Klepeis, Ott, & Switzer, 2007). In the same experimental study $PM_{2.5}$ concentrations reached values of 200 µg/m^3 and 500 µg/m^3 depending of other external conditions, apart from tobacco (Klepeis et al., 2007). SHS in indoor settings where smoking was banned but near outdoor smoking areas varied from 4 µg/m^3 (Kaufman, Zhang, Bondy, Klepeis, & Ferrence, 2010) to 120.51 µg/m^3.(Lopez et al., 2012) both studies carried out in hospitality venues. Indoor SHS levels far away from outdoor tobacco sources were lower (Sureda et al., 2011; Wilson, Edwards, & Parry, 2011).

Other changes regarding this comment --we have rewritten the paragraph in the Discussion section under '***SHS levels and Air Quality Standards'*** heading:

> In general, the outdoor SHS levels obtained in the different studies were high, particularly in hospitality venues where $PM_{2.5}$ concetrations range between 8.32 μg/m^3 (Stafford et al., 2010) and 182 μg/m^3 (Hall et al., 2009) when smokers were presence. Indoor areas adjacent to outdoor smoking areas also showed considerable SHS levels. Hall et al. (2009) and St Helen et al. (2012) demonstrated that people had higher saliva cotinine concentrations following exposure to terraces outside bars and restaurants when smoking was allowed, than after exposure to smoke-free terraces. These results suggest that especially hospitality workers and also patrons can be exposed to high SHS levels under certain conditions. Although these outdoor SHS levels are more transient than indoor levels and can immediately drop to background levels they merit consideration and its health effects under these conditions be further studied

5. A minor but rather preoccupying point is that the authors mistook the location of the 2 studies conducted in Athens, Georgia (USA), for the ex-Soviet Republic Georgia. Such mistakes may happen but this could also be a sign of non-careful reading of the full paper. There are no other obvious mistakes to my understanding; however, I would strongly recommend that the authors reviewed again the full papers.

We thank the comment. We read this and all the other papers carefully and know that the useful papers from St Helen, Hall and colleagues come from the USA. Unfortunately we committed this error in the final process of composing the tables and it was transferred to the Results section. Accordingly, we have clarified it in the tables and in the second paragraph of the results section:

> "Table 1 and table 2 present descriptions of the included studies and their main findings. The papers were published between 2005 and 2011, and the studies were conducted in Australia (*n* = 3), Canada (*n* = 2), New Zealand (*n* = 4), the United States (*n* = 6), Denmark (n=1), Spain (n=1) and a multicenter study in 8 European countries (n=1)."

6. Try and suggest one or 2 Figures summarizing the results. I understand that it is probably impossible to do a meta-analysis, but this type of narrative reviews are very hard to follow. Readers would be helped if they could see a summary of the most important results.

We agree with the editor that a figure makes easier to follow the review. While a figure including all the results is hard itself to be drawn, we believe that the most important results can be summarized in a figure. We have plotted in a figure those studies measuring $PM_{2.5}$ in outdoor settings splitting the results by hospitality/non-hospitality and presence/absence of smokers in the nearby. Unfortunately, we are not able to include 95% confidence intervals of the point estimates of the studies because this information was lacking in the papers reviewed. In some cases, we have computed the summary statistics for a study from the range of concentrations presented in the paper or from the individual data presented. Finally, we have decided not to compute an overall summary measure given the disparity of statistics used in the papers (medians, arithmetic and geometric means).

7. In the discussion the authors suggest that more and better studies are needed. Suggest which are the main areas where an improvement in methods could be addressed in new studies. This does not have to be long, something short and concise.

We appreciate the editor's comment. We consider that improvement in methods has been suggested through Discussion section but we agree it seems diffusely and inconsistently explained. Therefore, we have added a paragraph at the end of the conclusion section as follows:

> "New studies should face improvements in the methodology used and in the presentation of results: it is time to conduct studies using representative samples of the locations; the standardization of statistical analysis using the same measures of central tendency (or systematically including different statistics such as medians and means) and including measures of variability (standard errors, confidence intervals or quartiles); to consider potential modifiers of SHS levels that include necessarily smoker density and degree of enclosurement of the outdoor locations and, secondary, wind speed and direction and proximity to smokers. Finally, further research is necessary to determine which would be the most appropriate SHS marker. Although, $PM_{2.5}$ is the most commonly used it could be useful to combine $PM_{2.5}$ measures with other specific SHS environmental markers (such as airborne nicotine) or even combining them with a specific personal biological marker (ie, cotinine in saliva)."

8. The aim of the paper as described in lines 135-136 is incomplete. Complete the objectives by moving to the introduction probably the section described in lines 190-196.

We thank the editor for this specific comment. As the editor mention we have completed the objectives by moving to the last paragraph of the Introduction the fourth paragraph of the Results section as follows:

> "The aim of the present study is to review research on objectively assessed SHS levels in outdoor settings. The specific questions to be addressed are: a) What are the indoor and outdoor SHS concentrations when smoking occurs and when it does not? How can a ban influence indoor and outdoor SHS levels? b) What is the relation between outdoor and indoor SHS levels? Can outdoor tobacco levels modify indoor air quality? c) What variables can influence both outdoor and indoor SHS concentrations? d) Do the SHS levels obtained in the studies comply with the Air Quality Standards established by the World Health Organization?".

9. Introduction. The second and first sentence says the same thing.

We also agree with this comment and we have removed the second sentence in the Introduction section: "SHS contains over 4,500 compounds found both in vapor and particle phases".

10. Line 190. "Disparities", is not the appropriate word here; you probably mean differences, different methodologies.

We need not to do the change suggested by the editor because we have removed the sentence containing this word from the manuscript (see response to question 8).

<u>Reviewer(s)' Comments</u>:

We thank the reviewers for their positive and thoughtful comments that help us to improve the manuscript.

<u>Reviewer: 1</u>

Sureda et al. in their review paper, Second-Hand Tobacco Smoke Exposure in Open and Semi-Open Settings: A Review, note that some countries have recently extended smoke-free policies to certain outdoor settings; and note that there is controversy regarding whether this is scientifically and ethically justifiable. They conclude that the available evidence identifies high SHS levels at some outdoor smoking areas, as well as the adjacent smoke-free indoor areas, but that further research and standardization of methodology are needed to better understand the results, and to evaluate the need to extend smoke-free legislation to outdoor settings.

Their review includes 16 articles and reports. This reviewer suggests adding two more published papers:

Outdoor air pollution in close proximity to a continuous point source
Neil E. Klepeis*, Etienne B. Gabel, Wayne R. Ott, Paul Switzer. Atmospheric Environment 43 (2009) 3155–3167.

Repace JL. Benefits of smoke-free regulations in outdoor settings: beaches, golf courses, parks, patios, and in motor vehicles. William Mitchell Law Review 34(4):1621-1638 (2008), online at http://www.repace.com/reports.html

And possibly two more academic reports presented at conferences and available on the internet:

Smoke infiltration in apartments, 2011 (pdf file 2.1MB), pages 19 & 20 only.

Indoor and outdoor carcinogen pollution on a cruise ship, 2004. At: http://www.repace.com/reports.html.

The paper is well-written, and one cannot disagree with the conclusions. It is clear from the research this reviewer has conducted, however, that secondhand smoke can travel over significant distances outdoors, can present a health hazard to workers in outdoor cafes, and a nuisance to many nonsmokers in public settings such as sidewalks, parks, and beaches, and the authors may wish to note that some cities in California and New York have banned smoking in parks and beaches.

We agree with the reviewer's comments about the hazard to workers in outdoor cafes. According to the editor and the reviewer #2 comments we have stressed this issue in the Results section and with have split **Table 1** into two tables, one focused on hospitality venues (see response to editor's question 4). We also have commented in the Introduction that one of the reasons in favor of banning smoking in some outdoor location is the nuisance from SHS to many nonsmokers and that some countries have just extended smoking bans to some outdoor locations, as suggested by the reviewer.
Regarding to the papers suggested by the reviewer, after carefully reviewing them we consider they do not fit with the inclusion criteria of our systematic review. Anyway we have included the second paper recommended to support some statements given in the Introduction. The reasons not to include the other papers are given below:

Outdoor air pollution in close proximity to a continuous point source. Atmospheric Environment 43 (2009) 3155–3167.→ One of the inclusion criteria was that the paper studied air pollution outdoors specifically derived from SHS. This article is not specific of SHS but air pollution in general.

Benefits of smoke-free regulations in outdoor settings: beaches, golf courses, parks, patios, and in motor vehicles. William Mitchell Law Review 34(4):1621-1638 (2008), online at http://www.repace.com/reports.html → This report does not only study SHS exposure in outdoor settings but also it explains benefits of smoke-free regulations and smoke-free outdoor policies just implemented. One of its chapters mentions other studies of outdoor tobacco smoke concentrations already included in the present review (when they fit the inclusion criteria).

Finally we have only included published articles and reports or pieces of work available on the internet but not academic reports presented at conferences. Anyway, during the submission of the present review to EHP we found two more articles that fit the inclusion criteria and we have included them (please see response to editor's question 1).

Reviewer: 2

This non-systematic review addresses a topic of importance; however a few rough edges remain, while the presentation of the results should focus on seperating the venues by type which is of interest to legislators and scientists

Major comments

• My initial comment is on the study methodology, as the research performed seems like it was not done the way a systematic review is usually performed. I.e. specific combinations of terms, two researchers, a flow chart, etc. While some of the above are noted, and thus it is possible that this is a systematic review, this should be clarified and thus should conform to the guidelines for a systematic review. If not, please state that this is not a systematic review.

We thank the reviewer for this comment. Accordingly, we have followed his/her advice, as also recommended by the editor. Please, see detailed response to the editor's comment above (question 2).

• Due to the use of many different settings in the studies, I strongly recommend grouping the same venue types together. The authors mention parks, streets, airports, campus, bars etc. From a policy and exposure perspective it would be of more interest to group bars and restaurants (i.e hospitality industry) together as this would be the area of potential legislation in the future. Based on the above point, the results should be re-structured.

We do agree with the reviewer and have split the table into two tables, one for hospitality settings and another one for the other settings, and have referenced it at the beginning of the Results section. Within the Results section, we have maintained the former structure which fits the specific questions to be addressed by the review, as also requested by the editor. Please, see detailed response to the editor's comment above (question 4).

Minor comments

• Page 4, line 79, "mixture of thousands of gases", I recommend replacing "gases" with "compounds".

Done.

• Page 4, Lines 88, 92, the authors mention a number of short term effects of SHS exposure, however they do not note the most severe or the most recent. Acute SHS exposure may also impair arterial stiffness, heart rate variability, hormone production etc. (flouris et al. 2010, Pope et al., 2001; frey 2012 etc.)

We have included more recent references about short-term effects of SHS exposure as suggested by the reviewer (Junker et al., 2001; Flouris and Koutedakis 2011; Pope et al., 2001).

• Page 5, lines121-122, the authors mention that "outdoor smoking bans might also support smokers…..consumption" while plausible, this would need a supporting reference at least.

We have added a reference (Williams et al., 2009) supporting the statement.

• Page 7, line 176. The authors mention "Georgia". This actually refers to Georgia in the USA, not Georgia the country. Please correct.

Done. Please see response to Editor's comment #5.

•Page 8, line 180,181. The authors mention one study that used a personal biological marker. Recently in EHP another article was published with NNAL measured (a tobacco specific carcinogen). During a small review within Pubmed the following recently published article appeared. Please include it in your review. St Helen G, Bernert JT, Hall

DB, Sosnoff CS, Xia Y, Balmes JR, Vena JE, Wang JS, Holland NT, Naeher LP. Exposure to secondhand smoke outside of a bar and a restaurant and tobacco exposure biomarkers in nonsmokers. Environ Health Perspect. 2012 Jul;120(7):1010-6. Epub 2012 Apr 6.

Done. Please see response to Editor's comment #1.

- **Page 8 line 194-196. The authors mention that their 4th structuring in the results was to "comply with air quality standards established by the WHO". We should keep in mind, that while $PM_{2.5}$ is a common regulatory marker, SHS does not contain only $PM_{2.5}$ but numerous other compounds that air pollution may not contain. Caution is needed in comparing SHS studies with WHO guidelines.**

It is clear that Air Quality Standards refer to $PM_{2.5}$ derived from any source of combustion. In any case, $PM_{2.5}$ are harmful by themselves, and SHS contains other toxics and carcinogens not in particulate form (ie, nicotine present in SHS smoke is mostly in vapor-phase form). We have used this standard because it has been used in previous studies of SHS measured throw $PM_{2.5}$. Thus, we are inclined to maintain these paragraphs in their present form.

- **Page 10, line 242. This sentence "Boffi….indoors" seems out of place, does it belong to the paragraph above?**

We agree with the reviewer and we have removed this sentence to the preceding paragraph.

- **Page 12, line 299. Within the Wilson study the high levels of SHS in the smoke free venue were attributable to "SHS drift" i.e. SHS entering a smoke free venue. Please state this clearly in that section.**

We have clarified this point as suggested:

> "However, an Australian study (Edwards & Wilson, 2011) showed higher indoor concentrations associated with the door being open for more time and allowing the drift of tobacco smoke from outside smokers to the indoors"

- **Page 13, line 324. The authors note the large differences in exposure, please separate this by source.**

We do not fully understand the reviewer's comment. All the papers included in this paragraph assessed SHS exposure from cigarette combustion as the source of $PM_{2.5}$. Our intention was to show the variability and high concentrations of $PM_{2.5}$ at certain times comparing them to background levels in outdoor settings in the absence of smokers. We believe it is not necessary to introduce changes in the paragraph.

• **I am not sure of the relevance of the SHS levels and air quality standards section in the discussion. While interesting I am not sure if its needed.**

In our opinion, it is necessary to mention Air Quality Standards in the Discussion sections since several studies have used them and it is a good reference to compare SHS levels across studies.

• **Within the limitations section the authors note that "further research should either record the presence of other sources of combustion etc.. this is correct, however I would note that usually in most studies background levels are removed from the total $PM_{2.5}$ concentrations during the analysis.**

As the reviewer notes, several studies (but not all the studies) assess background levels and a few of them "correct" the recorded levels indoors or outdoors with the background levels. We agree that background levels are useful to evaluate if $PM_{2.5}$ concentrations are influenced by other sources of combustion. However, the statistical handling of these background levels is not clear, since the mere "discounting" of this concentration from the total seems too simplistic. Thus, we now suggest incorporating in the studies; firstly the systematic assessment of background SHS levels, and secondly, to incorporate the corresponding figures into the tables, in order the readers can figure out by themselves their influence. We have rewritten the sentence as follows:

> "Further research should either record the presence of other sources of combustion—such as cooking facilities, proximity to roadways, or traffic density, measure background levels of SHS and show them in the results' tables and use specific SHS markers such as airborne nicotine".

• **In the table I would transform the CARB results into µg/m^3 from mg/m^3. so that the results are comparable with the other studies.**

Done. We have changed this concentration and all the other concentrations to the same units (µg/m^3).

<u>**Segunda respuesta del editor asociado de Environmental Health Perspectives**</u>

4 January 2013

Dear Mrs. Sureda:

Manuscript ID 12-05806-REV.R1 titled "Second-Hand Tobacco Smoke Exposure in Open and Semi-Open Settings: A sYSTEMATIC Review" which you submitted to Environmental Health Perspectives, has been reviewed. The comments are included at the bottom of this letter.

The editor(s) have recommended some minor revisions to your manuscript. Papers for which minor revisions are recommended have a moderate to high overall rating that the Associate Editor believes may be improved with appropriate revisions. Acceptance is not guaranteed, but is considered likely if you thoroughly respond to reviewer requests. Therefore, I invite you to respond to the comments and revise your manuscript. You have six weeks from the date of this letter to complete your revisions. If you require additional time, you must contact us by e-mail [EHPManuscripts@niehs.nih.gov] PRIOR TO THE DUE DATE to request an extension, otherwise your paper will not be available for revision.

Please refer to your original revision checklist (attached) for formatting guidelines. Please observe EHP length limitations when revising your manuscript. Revised manuscripts that substantially exceed length limitations may be returned for shortening before being sent out for review.

EHP word limits (including the title page, keywords, abstract, main text, references and tables, plus 250 additional words for each figure):

- Research articles: 7,000 words
- Reviews, Substantive Reviews, Quantitative Reviews or Meta-Analyses: 10,000 words
- Emerging Issues Reviews: 5,000 words
- Commentaries: 5,000 words

To revise your manuscript, log into http://mc.manuscriptcentral.com/ehp, enter your Author Center, and follow the instructions below.

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Once again, thank you for submitting your manuscript to Environmental Health Perspectives. I look forward to receiving your revision.

Sincerely,

Dr. Manolis Kogevinas
Associate Editor, Environmental Health Perspectives
ehpmanuscripts@niehs.nih.gov

<u>Editor's Comments:</u>

1. The authors have done a very good job in reviewing the paper. It is an important issue and has clear public health implications. It is still a descriptive review but I believe the authors are right I that they cannot do a proper meta-analysis. The figure summarising the findings is good and probably the best we can get in little space all the main results. The paper needs still editing. I indicate a few editorial type suggestions particularly for the abstract.
2. The abstract should be edited. Parts of the abstract could be shortened so as to leave more space for results. Results are now very short.
3. Abstract. Line 59 (of clean manuscript); PubMed not PudMed
4. Abstract: Data sources should just mention the data sources ie PubMed and reference lists. The remaining information should go to "Study Selection"
5. Abstract. Study Selection. The exact search string is not needed in the abstract, though it is needed in the main text. Delete and gain space to add results. This part can be shorter without loss of information.
6. Abstract, Results. Add results, for example from lines 235-239 reporting levels.
7. Based on Figure 1, the number of articles which were discarded reviewing the title were 196. The information provided in the text (line 63, abstract) does not say the same and mentions that you reviewed the abstracts of 196 papers. Also, it would be preferable to have in the text the same numbers as in the abstract. I am aware that you do mention them in the Figure but please include the information in lines 63 of the abstract also in the corresponding part of the main text.
8. Line 250, "One study" rather than "One manuscript"
9. Line 312. Perhaps subtitle should be "Factors influencing outdoor SHS levels" rather than "Other factors influence outdoor SHS levels"

<u>Segunda respuesta al editor asociado de Environmental Health Perspectives</u>

Response to Editors' comments

1. The authors have done a very good job in reviewing the paper. It is an important issue and has clear public health implications. It is still a descriptive review but I believe the authors are right I that they cannot do a proper meta-analysis. The figure summarising the findings is good

and probably the best we can get in little space all the main results. The paper needs still editing. I indicate a few editorial type suggestions particularly for the abstract.

Thank you very much for the opportunity to resubmit the manuscript according to these useful comments.

2. The abstract should be edited. Parts of the abstract could be shortened so as to leave more space for results. Results are now very short.

As the Editor suggests, we have rewritten some parts of the abstract and extended the results it contains (see new version).

3. Abstract. Line 59 (of clean manuscript); PubMed not PudMed

Done.

4. Abstract: Data sources should just mention the data sources ie PubMed and reference lists. The remaining information should go to "Study Selection".

Done.

5. Abstract. Study Selection. The exact search string is not needed in the abstract, though it is needed in the main text. Delete and gain space to add results. This part can be shorter without loss of information.

Done.

6. Abstract, Results. Add results, for example from lines 235-239 reporting levels.

Done

7. Based on Figure 1, the number of articles which were discarded reviewing the title were 196. The information provided in the text (line 63, abstract) does not say the same and mentions that you reviewed the abstracts of 196 papers. Also, it would be preferable to have in the text the same numbers as in the abstract. I am aware that you do mention them in the Figure but please include the information in lines 63 of the abstract also in the corresponding part of the main text.

Thank you for the comment. We did a mistake in the abstract because we did not reviewed 196 abstracts but 67. 196 abstracts were discharged after reading the abstract. We have corrected the mistake and also included the information in the main text.

8. Line 250, "One study" rather than "One manuscript".

Done.

9. Line 312. Perhaps subtitle should be “Factors influencing outdoor SHS levels” rather than “Other factors influence outdoor SHS levels”.
Done.

Carta de aceptación del manuscrito en EnvironmentaHealth Perpectives

01-May-2013

Dear Mrs. Sureda:

The revised paper "Second-Hand Tobacco Smoke Exposure in Open and Semi-Open Settings: A Systematic Review" has been accepted for publication in Environmental Health Perspectives.

The Advance Publication version of your paper will be published online by the end of next week. The Advance Publication version will be assigned a stable citation (DOI number) that will remain with the paper when it is published in a monthly online issue of EHP. After your manuscript is copyedited we will replace the Advance Publication version with the copyedited version. You may not make changes to the final version of the paper. However, you will have an opportunity to review page proofs of the final copyedited paper before it is published. You will receive your page proofs in approximately 8 to 12 weeks.

I hope that you will continue to consider EHP as a source for potential publication of your research in the future.

Thank you for your interest in EHP.

Dr. Hugh Tilson
Editor in Chief
Environmental Health Perspectives
ehpmanuscripts@niehs.nih.gov

nts of disease are

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