Evaluation of the impact of Spanish smoking legislation on tobacco consumption and passive exposure

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EVALUATION OF THE IMPACT OF SPANISH SMOKING LEGISLATION ON TOBACCO CONSUMPTION AND PASSIVE EXPOSURE

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Abbreviations

International Agency for Research on Cancer (IARC)

Environmental Tobacco Smoke (ETS)

Secondhand Smoke (SHS)

United Kingdom (UK)

United States of America (USA)

World Health Organization Framework Convention on Tobacco Control (WHO FCTC)

Tobacco Control Scale (TCS)

'Hospital del Mar' Medical Research Institute (IMIM)

Determinants of Cotinine phase 3 project (dCOT3)

Gas Chromatography followed by Mass Spectrometry detection (GC/MS)

Liquid Chromatography coupled with Tandem Mass Spectrometry (LC/MS/MS)

Roll Your Own cigarette (RYO)

Electronic cigarettes (e-cigarettes)

Smoke-Free Home (SFH)

Abstract

In Spain, two smoke-free laws have been passed after the approval of the FCTC. In 2005, it came into effect a smoke-free legislation (Law 28/2005). This law was a great advance for public health in Spain; however, it was not complete in terms of health protection to secondhand smoke (SHS) exposure because it allowed smoking in hospitality sectors according to size of venues. The scientific evaluation of this law showed the need to promote a total ban and motivate the modification of the law in 2010 (Law 42/2010), extending the smoke-free regulation to all hospitality venues without exception and to some outdoors areas, including hospital premises, educational campuses, and playgrounds.

The objectives of this doctoral thesis were: To assess the impact of the Spanish smoking legislations (Law 28/2005 and Law 42/2010) on tobacco epidemic (changes in consumption, dependence, motivation to quit and smoking cessation) among smokers of a general population cohort through self-reported information and biomarkers. To evaluate the impact of the Spanish tobacco control legislation on exposure to environmental tobacco smoke (self-reported and according to levels of cotinine in saliva) on non-smokers in a cohort population. To analyze the changes in the pattern of passive smoking of the non-smokers (displacement of exposure at workplace and leisure time to home) according to age, sex, and socioeconomic level. To analyze the correlation between the implementation of tobacco control policies and tobacco consumption, particularly rolling tobacco, electronic cigarettes (e-cigarettes) users and the intent to quit smoking in 27 countries of the European Union. To describe the acceptability of the recently implemented tobacco products regulations and to explore their relation with tobacco control legislation levels in Europe.

The results of this doctoral thesis has been conducted through seven scientific articles, four of them published in journals indexed in Web of Science and three of them in peer review in journals indexed in Web of Science (please see the Section Scientific Articles of this thesis). Moreover, during my training in this doctoral thesis I got involved in other two articles one published and the other in peer review, both in journals indexed in Web of Science.

In conclusion, the implementation of the two smoke-free legislations in Spain is related to a reduction in smoking prevalence and SHS exposure (either using salivary cotinine concentrations or information on self-reported exposure). However, the consumption of other tobacco products, particularly hand-rolled tobacco, has increased specially among young population. A significant increase was found in the salivary cotinine concentration among adult continuing smokers after both Spanish legislations. After the implementation of the two Spanish smoke-free bans, the main setting of SHS is in the leisure time and in work, where most of the exposed ones declared expending most of the time outdoor and not having specific areas for smokers. However, cotinine concentrations in non-smokers were significantly higher only among those declaring exposure to SHS at home after both legislations. The implementation of the two smoke-free legislations in Spain is related to an increasing of voluntary adoption of smoke-free homes (SFH) rules, in particular with an increase in complete SFH rules. In addition, we observed an association between complete indoor SFH adoption and the perceived risk of SHS exposure. In addition, great support for the studied tobacco products regulations was found which were positively related with European tobacco control levels of implementation at both ecological and individual levels.

1. Introduction

1.1 Active and passive smoking: a known health risk

Tobacco is one of the biggest threats to the public health the world has ever faced, yet it continues to be the single leading cause of preventable death in the world and the second risk factor of death globally (1). In this sense, the Institute for Health Metrics estimated that about 18% of worldwide population smoked in 2012 causing 11.5% of the global deaths in 2015 attributable to active smoking and 1.6% to passive smoking (1). In Spain, the latest data reported showed that 23.6% of Spanish population were tobacco users (2012) (2), causing 60,456 deaths attributable to active smoking (2).

Moreover, active smoking has been causally linked to diseases of nearly all organs of the body, being related to more than 25 diseases and being responsible for 30% of all cancers, respiratory diseases and cardiovascular diseases (3). Cancers that are considered by the International Agency for Research on Cancer (IARC) to be causally related to active smoking are lung, oral cavity, nasal cavity and paranasal sinuses, nasopharynx, oropharynx, hypopharynx, larynx, oesophagus (adenocarcinoma and squamous cell carcinoma), upper aerodigestive tract combined, stomach, pancreas, liver, kidney (body and pelvis), ureter, urinary bladder, cervix and myeloid leukaemia (4). A recent meta-analysis shows that smoking is also associated with head, neck, higher colorectal gastric and breast cancer (5). Furthermore, smoking during pregnancy is associated with placental abruption, placenta previa, premature rupture of membranes, premature birth, spontaneous miscarriage, ectopic pregnancy and harmful effects on fetuses, infants and children such as stunted gestational development, stillbirth, sudden infant death syndrome, reduced lung function and impaired lung development, asthma and bronchitis exacerbation, acute lower respiratory infection,

respiratory irritation, childhood cancers, orofacial cleft, possible increased risk of allergic diseases and possible increased risk of learning disability and attention deficit (6).

Taking into account the harmful effects associated with active smoking, it is important to try to define the tobacco epidemic in order to be able to control it. For this, a four stage descriptive model (7) is commonly used allowing us to categorize a given country into a specific stage of a defined process. According to this model, the beginning of the epidemic in a given population would be defined as the first stage in which the prevalence of smoking in men is relatively low (<15%), whereas in women it will rarely exceed 10% and may be less than 5% in many cases. Death and illnesses caused by tobacco use are not yet evident. This first stage may be relatively rapid, in one or two decades. During the second stage, which can last between two to three decades, the prevalence of tobacco use in men continues to increase rapidly, reaching a maximum of 50-80%. This prevalence in women, which normally follows the pattern of that of men with a time span of one to two decades, also increases rapidly. At this stage the proportion of former smokers is still relatively low. At the end of this stage tobacco consumption causes about 10% of deaths in men but relatively few in women. The third stage is characterized by a decrease in the prevalence of consumption in men, quite possibly after exceeding 60% for an extended period, to about 40% at the end of this stage, which can last for three decades or more. The prevalence of tobacco use tends to be lower in middle or advanced age men, many of whom have become former smokers. The end of this stage is characterized by the beginning of the decrease in women prevalence, in whom the maximum reached generally is considered inferior to the one of the men. But the main characteristic of this stage is the rapid increase in mortality attributable to tobacco, which in the case of men reaches 25-30%, but in the case of women still does not exceed 5%. Finally, in the fourth stage, prevalence in both sexes continues to decrease, reaching in women around 30% and 33-35% in men. The increase in mortality reaches its maximum in men, possibly between 30-35%, while

in women it continues to rise to reach its maximum of 20-25%. Finally, the mortality attributable to tobacco in both sexes will decrease progressively.

Data of 2009 about tobacco epidemic worldwide stages (8) suggested that, among men, trends in smoking prevalence and in the proportion of all smoking attributed deaths at ages 35-69 had generally been stable or decreasing in developed countries. This smoking-attributed proportion is not yet decreasing much in Spain, Portugal, Greece, Bulgaria, Romania, Hungary, Norway and Japan; and the most extreme decreases are in Finland (from 38% in 1970 to 15% in 2009) and United Kingdom (UK) (from 47% in 1970 to 22% in 2009). Among women, in many developed countries smoking prevalence also decreased, although more slowly than in men. Nonetheless, the female proportion of all smoking attributed deaths at ages 35-69 had not yet decreased much in any developed country, and in some it continues to increase rapidly. This smoking-attributed proportion is currently higher (26% to 30%) in The Netherlands, Denmark, Hungary and Canada; and is also high (18% to 20%) in the United States of America (USA), UK, Norway, Sweden, Poland and New Zealand. Regarding Spain, the Institute for Health Metrics (1) estimated the age-standardizes smoking prevalence between 1980 and 2012 and the smoking attributed deaths prevalence between 1990 and 2016 (1). According to these trends, smoking prevalence has clearly decreased among men, in which smoking attributed deaths prevalence begins to decrease in the last decades. However, smoking prevalence among women reminds more stable, showing a slightly increase in smoking attributed deaths prevalence.

Moreover, tobacco smoke is also known to be harmful for non-smokers. During the 1970s, a growing body of evidence about the dangers of environmental tobacco smoke (ETS), or secondhand smoke (SHS), made evident that tobacco smoke can harm non-smokers who inhale it passively (9). The smoke that cigarette smokers draw into their lungs is "mainstream"

smoke, while the smoke that comes off the burning tip of a cigarette is "sidestream" smoke which actually contains higher concentrations of many toxic chemicals than mainstream smoke (10), because sidestream smoke is not filtered and because cigarettes burn at a lower temperature when they are smoldering, leading to a less complete, dirtier combustion. The air pollution resulting from sidestream and extracted mainstream smoke is called SHS or ETS, and people who breathe this smoke are known as passive smokers or involuntary smokers.

Furthermore, SHS exposure has been classified as a type I carcinogen by the International Agency for Research on Cancer (11) and has been associated with larynx, pharynx (4) and lung cancer, coronary artery disease, stroke, reproductive effects in women, nasal irritation and harmful effects on children such as sudden infant death syndrome, low birth weight, impaired lung function, lower respiratory illness, respiratory symptoms and middle ear disease (6). According to the Tobacco Atlas, globally, about 40% of children and a third of non-smoking adults were exposed to SHS in 2004 (12). What is more, SHS exposure is responsible of 1% of the global mortality (more than 600.000 deaths) (13) and 1,028 to passive smoking at home and work (2011) (14).

1.2 Monitoring the tobacco epidemic

High-quality representative data are needed in order to regularly have available updated information about the extent of the epidemic in a country. In this sense, the monitoring of the tobacco epidemic informs the leaders of governments and civil society about the tobacco epidemic damages on their countries, and helps them allocate tobacco control resources where they are most needed and will be most effective (15). At present, more than a quarter

of countries, with 40% of the world's population, regularly monitor tobacco use among adults and youth using nationally representative surveys (16). This highlights the need to urge other countries to implement regular monitoring programs of tobacco epidemic and SHS exposure as WHO recommend (17).

In general, monitoring and measurement of tobacco epidemic and SHS exposure can be performed by direct and indirect methods. Among the direct methods, environmental markers (e.g. airborne nicotine and benzene) (18,19) and/or human biomarkers such as cotinine in biological samples (the main ones being saliva, urine, plasma, and hair) (20,21) can be measured. Although direct methods are the most reliable to measure SHS exposure, indirect methods –such as questionnaires- are the most commonly used in the scientific literature (4,22) because they are low cost and simple to implement.

Cotinine, the major proximate metabolite of nicotine, has been widely used as a biomarker of tobacco smoke absorption as a direct method (23). Cotinine concentration in biological fluids (blood, urine or oral fluid, widely referred to as saliva) (24) indicate tobacco exposure over the previous 1-2 days (25) and are strongly correlated with the number of cigarettes smoked daily (26). Furthermore, biomarkers allow to objectively ascertaining smoking status by consistent salivary concentration. For instance, when using salivary cotinine, a concentration inferior to 10 ng/ml (27) would define a non-smoker and otherwise a smoker would be defined. By doing this, self-reported data can be validated potentially minimizing limitations related to survey based studies.

Among indirect methods, questionnaires are the most commonly used method to measure the tobacco epidemic. According with WHO suggestions, such surveys should gather information on tobacco use prevalence and consumption levels by age group, sex, income and other

demographic subdivisions, carried out both nationally and by province or region (15). These surveys should also be repeated at regular intervals using the same questions, sampling, data analysis and reporting techniques. Only taking these requirements into account can comparable data across different survey periods be obtained to accurately monitor tobacco epidemic and additionally evaluate the impact of tobacco control interventions over time. Moreover, standardized questions about tobacco use can be embedded in existing population-based surveys or censuses (28).

1.3 Framework Convention on tobacco Control

Whit the aim to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke, the WHO Framework Convention on Tobacco Control (WHO FCTC) emerged (29). This international treaty was adopted by WHO member countries in 2003 and entered into force in 2005, after it had been ratified, accepted, or approved by 40 States. International efforts led by WHO resulted in rapid entry into force of the WHO FTCT which in 2015 already covered about 90% of the world's population (6).

The core suggestions of demand reduction in the WHO FCTC include price and tax measures to reduce the tobacco consumption, and non-price measures to reduce the demand for tobacco. Article 8 of the treaty also addresses SHS exposure as a health risk and identifies interventions, such as smoke-free bans, to protect citizens from its hazardous exposure. Fundamentally, the treaty requires parties to implement clear indoor air laws. Smoke-free legislations can be implemented in a variety of sectors and facilities to protect the population from the harmful

effects of SHS. Other measures included in the WHO FCTC are regulation of tobacco product disclosures; packaging and labelling of tobacco products; education, communication, training and public awareness; tobacco advertising, promotion and sponsorship; and demand reduction measures concerning tobacco dependence and cessation (30). Further suggestions refer to illicit trade in tobacco products sales to and by minors; and provision of support for economically viable alternative activities (30).

With these suggestions, WHO FTCT provides the basis for countries to implement and manage tobacco control interventions. To help make this a reality, in 2008 WHO introduced the MPOWER measures which correspond to one or more articles of the Framework Convention that have been proven to reduce smoking prevalence, in order to assist in reducing the demand for tobacco products at country-level (17). MPOWER policy package requires implementation of proven tobacco policies and interventions, with a high level of coverage, gather information to target and refine their implementation, and rigorous monitoring to evaluate their impact (17).

To implement MPOWER policy package, countries need to (17): **M**onitor tobacco use, in order to obtain nationally representative and population based periodic data on key indicators of tobacco use and tobacco policies and interventions impacts. **P**rotect people from tobacco smoke by enacting and enforcing completely smoke-free environments in health-care and educational facilities and in all indoor public places including workplaces, bars and restaurants. **O**ffer help to quit tobacco use, strengthening health systems so they can make tobacco cessation advice available as part of primary health care and supporting quit lines and other community initiatives in conjunction with easily accessible, low cost pharmacological treatment where appropriate. **W**arn about the dangers of tobacco through effective packaging warning labels Intervention, application of counter-tobacco advertising interventions and free

media coverage of anti-tobacco activities. **E**nforce bans on tobacco advertising and promotion by enacting and enforcing effective legislations that comprehensively ban any form of direct tobacco advertising, promotion and sponsorship Intervention and legislations that ban indirect tobacco advertising, promotion and sponsorship. **R**aise taxes on tobacco products and ensure that they are adjusted periodically to keep pace with inflation and rise faster than consumer purchasing power in addition to strengthen tax administration to reduce the illicit trade in tobacco products.

1.4 Tobacco control measures

In 2003, the World Bank proposed in the fact sheet tobacco control at a glance (31) the six most cost effective tobacco control interventions based in the evidenced. These measures are higher taxes on cigarettes and other tobacco products; bans/restrictions on smoking in public and workplaces (schools, health facilities, public transport, restaurants, cinemas, etc.); comprehensive bans on advertising and promotion of all tobacco products, logos and brand names; better consumer information (counter-advertising, media coverage, research findings, etc.); large, direct warning labels on cigarette boxes and other tobacco products; help for smokers who wish to quit, including increased access to nicotine replacement and other cessation therapies. Price increase has been proven to be the most effective and cost-effective intervention in reducing smoking consumption, however, the best results are achieved when a comprehensive set of measures are implemented (31).

A few years later, in 2005, Joosseens and Raw proposed a scale to quantify the implementation of tobacco control policies nationwide in European countries, namely the Tobacco Control Scale 'TCS' (32) that takes values from 0 to 100. The TCS is based on the six

policies described by 'The World Bank'. These policies are punctuated in the TCS with the following values: increase in prices by raising taxes in cigarettes and other tobacco products, which takes values from 0 to 30; prohibitions and restrictions on smoking in public places and work environments, which takes values from 0 to 22; better consumer information through public information campaigns, media and publication of research findings, which takes values from 0 to 15; prohibitions on advertising and promotion of all tobacco products, which takes values from 0 to 13; large and direct health warning labels on tobacco packets and on all tobacco products, which takes values from 0 to 10, and finally, treatments to help dependent smokers quit smoking, including increased smoking access to medicines, which takes values from 0 to 10. Through the sum of the measurement of these policies the TCS is obtained. This scale makes it possible to quantify tobacco control policies in the different countries of the European Union and thus to be able to assess the impact of these policies (i.e. on tobacco consumption or exposure to SHS).

1.5 Tobacco control measures in Spain

Although in Spain the smoking consumption in public places was regulated since the end of the 1980s through law 192/1988 (33), more than half of the places breached this law (34). It wasn't until 2005 when it came into effect a more comprehensive legislation (Law 28/2005 (35)). This law was a great advance for public health in Spain being a compendium of public health measures against smoking and including regulations on publicity, sale, supply, and consumption of tobacco products (35). The law provided that retail sales and supply of tobacco products may solely be made through tobacco and stamps outlet networks, or through vending machines that had received the relevant administrative authorizations. All other places or means were expressly banned. It were further prohibited to sell or deliver tobacco

products to minors, same as any other product simulating them and leading them smoke. The law also regulated the prohibition of free or promotional distribution of products, goods or services, or any other action which has the direct or indirect purpose or effect of promoting a tobacco product, same as any form of advertising, promotion and sponsorship of tobacco products in all media. Measures for the prevention of tobacco use were also incorporated in the law, fostering actions for health education and information and addressing the promotion of programs for overcoming tobacco addiction in the assistance network of the National Health System.

Moreover, smoking was banned in all indoor workplaces, public places, public transport facilities including enclosed stations, hospitals and other health care facilities, schools and universities as well as in retail stores and shopping centres. However, hospitality venues were subject to only a partial ban. In bars and restaurants of less than 100 m^2, the proprietor could choose between permitting or prohibiting smoking. Bars and restaurants larger than 100 m^2 were defined as smoke-free, but the law allowed the proprietor to provide a physically separated and independently ventilated smoking area comprising less than 30% of the total floor area. For this exception the Spanish smoking law was known as the “Spanish model” (36).

The scientific evaluation of this law showed the need to promote a total ban (37-39) and motivate the modification of the law in 2010 (Law 42/2010 (40)), that extended the smoke-free regulation to all hospitality venues (41) without exception and extended the ban to some outdoors areas, including hospital premises, educational campuses, and outdoor children’s playgrounds. However, designated smoking rooms were permitted in psychiatric services, nursing homes, prisons and up to 30% of hotel rooms. Smoking is also allowed in outdoors areas in universities and adult educational centers. However, this new regulation made the Spanish legislation as one of the most stringent smoke-free National laws in Europe (42).

The introduction of both tobacco control laws was a great advance indeed, however, there are still points to improve (43).

Regarding help smokers to quit, although Law 28/2005 encouraged the development of various initiatives to quit smoking, the assistance intervention in smoking, especially in primary care, has been also included in various strategies, both state and by regions. However, its application continues to be deficient. Pharmacological treatment for cessation, despite having proved its efficacy, is not financed by the National Health System on a global basis, although there are experiences in some Spanish regions that have offered it in specific population groups or periods.

Moreover, in Spain, two prevention campaigns have been coordinated, one in July 2006 with the motto "Thank you for not smoking" and another in April 2007 with the motto "This girl smokes a daily package", aimed at raising awareness among adults on the harmful effects of ETS on children's health. In addition, some Spanish regions developed their own campaigns. In the year 2009, Catalonia launched a media campaign with the slogan "Smoke is fatal" which has also widely disseminated a telephone service to help quit smoking (061). However, it is evident that the number of media actions has been much lower than the Law 28/2005 itself established.

However, in the period from 2004 to 2013 have notably improved measures regulating the sale, supply and consumption of products, and their advertising, promotion and sponsorship. The direct and indirect advertising is limited, but tobacco industry dodges the restriction through covert advertising on television and the media writing. In relation to labeling, new actions have been proposed in the recent years, such as increasing the percentage of warnings

or implementing generic or neutral packaging. However, such proposals are still pending development.

Finally, fiscal policies are among the most cost-effective smoking control interventions. However, only 10% of the world's population lives in countries with sufficiently high taxes, making it the least applied measure. In Spain, the government has strengthened regulations on tobacco taxes since 2005. The implementation of Law 28/2005 was followed by several tax reforms. However, it should be noted that these changes have mainly affected to manufactured cigarettes, while other types of tobacco products have been less affected by tax increases and becoming cheaper and more affordable alternatives for smokers.

1.6 New challenges in tobacco control

Tobacco control policies in Spain have made a great advance in the last 10 years. However, there are still some points to improve in order to end the tobacco epidemic and taking into account that policymakers must use existing strategies that have been proven effective in reducing tobacco prevalence, and must explore innovative tactics to achieve the endgame for tobacco use. As follows, some important challenges that future Spanish tobacco control legislations need to introduce are going to be detailed.

Tobacco control policies, particularly increasing of prices, are generally focused on conventional cigarettes, whereas other tobacco products receive relatively little attention, increasing the gap between their prices. In Spain, several tax reforms have accompanied the implementation of more restrictive tobacco regulations, but they have been mainly applied to manufactured cigarettes not including other tobacco products as hand-rolled cigarette (also

known as roll your own cigarette or RYO). In recent years, the prices of these products have been remarkably different in Spain, with RYO costing about 50% less than manufactured cigarettes until 2009, when a small tax was introduced. In addition, there is a widespread belief of minimal hazardous RYO health effects even though it has been proven that it is not so (44). All this has led in Spain, as well as in other countries, to a shift in smoking pattern of consumption from manufactured to RYO cigarettes, especially among younger smokers (45). In fact, one study showed that daily consumption per capita of RYO cigarettes increased on average by 14.1% per year between 1991 and 2012 in Spain while the consumption of manufactured cigarettes decreased by 3% on average (45).

Other form of tobacco use to take into account is electronic cigarettes (e-cigarettes). The potential risks and benefits of e-cigarette in the medium and long term are still unknown, which has generated intense debate in scientific journals and in the media. Some researchers (46) and citizens, in particular e-cigarette users and the tobacco industry which have economic interests in e-cigarettes, defend these devices as a useful tool to quit smoking or reduce consumption and as a harm reduction strategy for smokers. A recent meta-analysis (47) based on 13 studies (two randomized controlled trials and 11 controlled cohort studies) has shown that e-cigarettes could help prevent relapse among former smokers or that could promote smoking cessation among smokers but has failed to demonstrate that e-cigarettes help smoker quit in the long term compared to placebo e-cigarettes. However, a later longitudinal study (48) showed that dropout depends on the type of e-cigarettes used and their frequency of use. On the other hand, other researchers and tobacco control activists show e-cigarettes as a threat to smoking-free legislation, normalizing again smoking in public, as well as favoring new nicotine addicts (and potential tobacco smokers), especially among the younger population (49-51), and promoting their dual use with other tobacco products, as shown by some studies

(51-53). In a previous study carried out in Barcelona (Spain) it was observed a prevalence of e-cigarette use of 6,5% in 2013-2014 (51).

However, e-cigarettes are regulated in Spain as a whole since 2014 by Law 3/2014 (54). This regulation prohibits the sale of e-cigarettes to minors and their use in certain public spaces, including hospitals, educational centers and buildings of the Administration, public transport and children's playgrounds, and limits their advertising in the media according to their broadcasting schedules with the goal of protecting minors. Moreover, some Spanish autonomous communities, such as Andalusia, Aragon, Catalonia and the Canary Islands, went ahead of the ban on e-cigarettes in playgrounds, Public Administration units as well as health and education centers.

Other important challenge for the future of tobacco control regards to plain packaging, which involves the removal of all branding and advertising from packs, such that packs are relatively indistinguishable from one another, other than the brand name in mandated text, size and style (55). Moreover, available evidence suggests that plain packaging may reduce smoking prevalence (56). In 2012, Australia implemented laws requiring plain (standardized) packaging of tobacco products. Scientific evaluation shows support for plain packaging increased significantly among Australian smokers after implementation of the law (being 28.2% after the implementation and 49% before) (57). Moreover, support for plain packaging is associated with higher levels of quitting activity while opposition mainly comes from those who smoke heavily and those who underestimate the risk of future smoking related harms (57). In addition, a recent systematic review shows plain packaging is associated with a reduction in package attractiveness and smoking appeal, and that it will make the legally required health warnings to be more salient (58). Since then, France, Ireland and UK have passed laws to implement plain packaging and several other countries have initiated legislative processes with the same goal (55). Furthermore, evidence to support the implementation of plain packaging

was obtained in Australia, New Zealand, Canada, UK, Norway, Belgium, France, Italy, Brazil and India (59).

Other action to consider would be implement further smoke-free policies as nowadays they are mainly focused on closed public spaces. As commented before, Spanish tobacco control legislation includes ban on smoking in specific outdoor spaces such as playground enclosures, school enclosures and hospital enclosures. However, in some cases as schools, hospitals and terraces of bars and restaurants some clarifications need to be done as some controversy can be found (43).

Moreover, the Spanish smoke-free legislation should consider to include some restrictions in specific private areas, such as private transport, as it has been already done in other countries (42). In this regard, there is at present an open debate on whether smoke-free legislation should be extended to private settings, with some suggesting that this could further reduce the social acceptability of public tobacco use, thereby promoting smoking cessation efforts and positively benefitting the health of the entire population (60).

Other area to consider in future smoke-free legislations may be households, as they are usually the main source of exposure to SHS in children (61). A study carried out in 21 countries showed that almost 50% of children had been exposed to SHS in their home between 2009 and 2013 (62). In addition, children are especially vulnerable to SHS exposure due to they breathe more rapidly, inhaling more pollutants per pound of body weight than adults (63). What is more, passive smoking includes exposure to smoking behavioral models which implies that living with smokers doubles the risk that children become regular smokers (64). However, currently smoke-free multiunit housing are still uncommon in Europe although are gaining popularity in the USA where multiunit housing operators reported having complete or partial

smoke-free building policies for at least some of their properties (65). On the other hand, voluntary adoption of smoke-free homes (SFH) rules is growing. In Europe (66), 61% of households had some kind of SFH rules in 2009. The highest prevalence of SFH was observed in Finland (95%) and the lowest in Macedonia (30%), whereas 44% of the Spanish households had SFH rules. Nonetheless, SHS in private venues remains a challenge and further research on the topic is needed.

Finally, some municipal jurisdictions, both in our country and in others, have approved smoking restrictions on beaches, sports venues, campuses, municipal swimming pools and, in general, places where there are minors (67). This type of normative not only protects from SHS, but also favors denormalisation of tobacco and reduces or delays the initialization of consumption among young people. In addition, some Spanish regions have made progress in developing their own regulatory framework, such as Basque Country, which in April 2016 reformed its drug addiction law to prevent tobacco use in some open and semi-open places, as sports fields, and which regulates the use of the electronic cigarette equating it with tobacco.

2. Hypothesis and objectives

Hypothesis

- The Spanish comprehensive smoke-free legislations (Law 28/2005 and Law 42/2010) have led to a decrease in tobacco consumption and nicotine dependence among smokers, along with an increase in motivation to quit smoking.

- The Spanish comprehensive smoke-free legislations (Law 28/2005 and Law 42/2010) have also led to a reduction in the exposure to environmental tobacco smoke among non-smoking adult population.

- The expected decrease in SHS exposure will mainly be due to a reduction in exposure in workplaces and leisure places, essentially in the hospitality sector.

- Exposure to SHS in households has not increased by displacement of exposure in workplaces and recreational settings to private environments.

- There exists an inverse correlation between the levels of tobacco control policies implemented across European countries and the consumption of conventional cigarettes and SHS exposure at the ecological level.

- Support for tobacco products regulations is positively related with European tobacco control levels of implementation.

Objectives

- To assess the impact of the Spanish smoking legislations (Law 28/2005 and Law 42/2010) on tobacco epidemic (changes in consumption, dependence, motivation to quit and smoking cessation) among smokers of a general population cohort through self-reported information and biomarkers.

- To evaluate the impact of the Spanish tobacco control legislations on SHS exposure (self-reported and according to levels of cotinine in saliva) in non-smokers in a cohort population.

- To analyze the changes in the pattern of passive smoking of the non-smokers (displacement of exposure at workplace and leisure time to home) according to age, sex, and socioeconomic level.

- To analyze the correlation between the implementation of tobacco control policies and tobacco consumption, particularly rolling tobacco, electronic cigarettes users and the intent to quit smoking in 27 countries of the European Union.

- To describe the acceptability of the recently implemented tobacco products regulations and to explore their relation with tobacco control legislation levels in Europe.

3. Methods

In order to achieve the objectives of this doctoral thesis, different sources of information were used regarding tobacco consumption, passive exposure, and attitudes towards tobacco policies. Moreover, diverse epidemiological studies were used including cross-sectional, cohort, multilevel and ecological study; please see the methodology of the papers of the doctoral thesis. A brief description on the sources used in this doctoral thesis can be found as follows.

3.1 Questionnaire information

Self-reported information was obtained through a longitudinal study of a representative sample of the adult (≥ 16 years old) non-institutionalized population of Barcelona (Spain; n=1245, 694 women and 551 men) called 'Determinants of Cotinine phase 3' project (dCOT3, website: http://bioinfo.iconcologia.net/es/content/estudio-dcot3). The baseline survey was conducted between 2004 and 2005, before both Spanish smoking legislations, and it is detailed elsewhere (68,69). We followed up adult participants who responded to a face-to-face questionnaire in 2004-2005 and agreed to take part in future studies. At the beginning of 2013, we updated the vital status and contact information (addresses and telephone numbers) of all participants teaming with Insured Central Registry of Catalonia. We restricted the follow-up to the participants who were alive in 2013 and still lived in the province of Barcelona.

We traced 1010 participants out of the 1245 from the baseline study (101 died, 49 migrated out of the province of Barcelona, and 85 did not give consent to be followed or were <18 years old in 2004-2005). The follow-up survey was conducted between May 2013 and February 2014, after both Spanish smoking legislations. In total, 72.9% of the eligible sample agreed to

participate and answered the questionnaire, 18.5% refused to participate, 7.2% moved elsewhere and 1.3% died. The final sample analyzed was 736 individuals (400 women and 336 men). We administered the same questionnaire that gathered information on the smoking status, tobacco consumption and exposure to SHS before and after Spanish smoking legislations. In addition, although there were no statistically significant differences between the followed-up sample and the participants lost according to age, sex, level of education and smoking status, the final sample was skewed as slightly older in comparison with the population of Barcelona. Therefore, we weighted our data according to age distribution of the city of Barcelona to maintain its representativeness of the sample.

3.2 Biomarker information (cotinine)

Biomarker information about tobacco exposure and consumption was obtained through salivary cotinine. We collected 9 ml of saliva sample (i.e. oral fluid) for cotinine analysis, following the same protocol, before and after the Spanish smoking legislations. Participants were asked to rinse their mouths and then suck a lemon candy (Smint) to stimulate saliva production. Saliva samples were frozen and sent to the 'Hospital del Mar' Medical Research Institute (IMIM) in Barcelona. Salivary samples from baseline survey (2004-2005) were analyzed 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 follow-up survey (2013-14) were analyzed with liquid chromatography coupled with tandem mass spectrometry (LC/MS/MS) (70) with multiple reaction monitoring. The limit of quantification was 0.1 ng/mL and the limit of detection was 0.03 ng/mL (quantification error <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 baseline survey (2004-2005)

were reanalyzed with the LC/MS/MS method. For cotinine concentrations below the limit of quantification a value of half the level of quantification (0.05 ng/mL) was assigned.

3.3 Eurobarometer and tobacco control information

The Eurobarometer is a series of multi-topic, pan-European surveys undertaken for the European Commission since 1970 on attitudes towards European integration, institutions, policies, social conditions, health, culture, the economy, citizenship, security, information technology, the environment and other topics. The European Commission maintains the Eurobarometer overview page were all available data obtained though the series of surveys can be found. Standard and Special Eurobarometer surveys consist of regular face-to-face interviews at the participants' homes in their native languages with approximately 1,000 subjects in each EU member state.

In some of the articles of this doctoral thesis, we used information obtained through different Eurobarometer. We used data on tobacco, SHS and attitudes towards tobacco control activities in 2009 (71), 2012 (72) and 2014 (73). The Eurobarometers used were the Special Eurobarometers conducted by 'TNS Opinion & Social'. The fieldwork of each Eurobarometer was performed in October 2009, between February and March of 2012, and between November and December of 2014, respectively. The final sample was 80,831 (Eurobarometer' sample of 2009: 27,288; Eurobarometer' sample of 2012: 26,751; and Eurobarometer' sample of 2014: 26,792). The surveys were only conducted on adult (older than 15 years old) population.

In addition, we used data on tobacco control activities in 27 European countries in 2005 (74), 2007 (74), 2010 (75) and 2013 (76) measured by TCS.

4. Objectives and results of the thesis articles

The present doctoral thesis is composed of seven scientific articles four of them published in journals indexed in Web of Science and three of them in peer review in journals indexed in Web of Science. The correspondence with the journal of the accepted paper of the present thesis can be found from the Annex III to the Annex VI. Moreover, during my training in this doctoral thesis I got involved in other two articles, one of them published in a journal indexed in Web of Science (see Annex I and Annex II). The articles included in this thesis are the following ones.

1. Cristina Lidón-Moyano, Marcela Fu, Montse Ballbè, Juan Carlos Martín-Sánchez, Nuria Matilla-Santander, Cristina Martínez, Esteve Fernández, and José M. Martínez-Sánchez. Impact of the Spanish smoking laws on tobacco consumption and secondhand smoke exposure: a longitudinal population study. Addictive Behaviors 2017; 75:30-35. Addictive Behaviors is included in the Journal Citation Report of ISI-Web of Science with and impact factor in 2016 of 2.944 (position 5/18 in the category Substance abuse).

2. Cristina Lidón-Moyano, Marcela Fu, Raúl Perez-Ortuño, Montse Ballbè, Juan Carlos Martín-Sánchez, Nuria Matilla-Santander, José A. Pascual, Esteve Fernández, and Jose M. Martínez-Sánchez. Assessment of the Spanish smoking legislations among smokers: A longitudinal study with biomarkers in Barcelona (Spain). This manuscript is in peer review in a journal index in Web of Science.

3. Cristina Lidón-Moyano, Marcela Fu, Raúl Pérez-Ortuño, Montse Ballbè, Marc Sampedro-Vida, Juan Carlos Martín-Sánchez, José A. Pascual, Esteve Fernández, and José M. Martínez-Sánchez. Assessment of salivary cotinine concentration among general non-smokers

population: before and after Spanish smoking legislations. This manuscript is in peer review in a journal index in Web of Science.

4. Cristina Lidón-Moyano, Marcela Fu, Montse Ballbè, Juan Carlos Martín-Sánchez, Cristina Martínez, Esteve Saltó, Esteve Fernández, and José M. Martínez-Sánchez. Impact of the Spanish smoking legislations in the adoption of smoke-free rules at home: a longitudinal study in Barcelona (Spain). Tobacco Control 2016 (in press). Doi:10.1136/tobaccocontrol-2016-053114. Tobacco Control is included in the Journal Citation Report of ISI-Web of Science with and impact factor in 2016 of 5.469 (position 11/172 in the category Public, Environmental and Public Health).

5. Cristina Lidón-Moyano, José M. Martínez-Sánchez, Marcela Fu, Montse Ballbè, Juan Carlos Martín-Sánchez, Cristina Martínez, Esteve Saltó, and Esteve Fernández. Secondhand smoke risk perception and smoke-free rules in homes: a cross-sectional study in Barcelona (Spain). BMJ Open 2017; 7: e014207. BMJ Open is included in the Journal Citation Report of ISI-Web of Science with and impact factor in 2016 of 2.369 (position 38/154 in the category Medicine General and International).

6. Cristina Lidón-Moyano, Juan Carlos Martín-Sánchez, Patrick Saliba, Jan Graffelman, José M. Martínez-Sánchez. Correlation between tobacco control policies and consumption of rolled tobacco and e-cigarettes, and intention to quit conventional tobacco, in Europe. Tobacco Control 2016 (in press). Doi: 10.1136/tobaccocontrol-2015-052482. Tobacco Control is included in the Journal Citation Report of ISI-Web of Science with and impact factor in 2016 of 5.469 (position 11/172 in the category Public, Environmental and Public Health).

7. Cristina Lidón-Moyano, Marc Sampedro-Vida, Nuria Matilla-Santander, Juan Carlos Martín-Sánchez, Adrián González-Marrón, Kailey Bunch, and Jose M. Martínez-Sánchez. Attitudes towards policies of the tobacco product directive implemented in Europe in 2016 and the relationship with the tobacco control policies. This manuscript is in peer review in a journal index in Web of Science.

The main objective and results of the articles of the thesis are:

1. Cristina Lidón-Moyano, Marcela Fu, Montse Ballbè, Juan Carlos Martín-Sánchez, Nuria Matilla-Santander, Cristina Martínez, Esteve Fernández, and José M. Martínez-Sánchez. Impact of the Spanish smoking laws on tobacco consumption and secondhand smoke exposure: a longitudinal population study. Addictive Behaviors 2017; 75:30-35.

Objective: To assess the impact of the Spanish smoking legislations on the active and passive smoking through a population cohort in Barcelona (Spain).

Results: After the implementation of the two Spanish smoke-free bans, it was observed a significantly decrease in the smoking prevalence (from 34.5% to 26.1%, PR=0.76,$p<0.001$), in the average of conventional cigarette daily consumption (median from 15.2 cigarettes per day to 10.0,$p<0.001$), in the percentage of conventional tobacco consumption (from 92.6% to 74.4%, PR=0.80,$p<0.001$) and in the self-reported SHS exposure in all the assessed settings (home, work, transport, and leisure time); as well as a significant increase in the percentage of hand-rolled tobacco (from 6.1% to 30.9%, PR=5.07,$p<0.001$) and other tobacco products (from 17.1% to 32.8%, PR=1.92,$p<0.001$).

2. Cristina Lidón-Moyano, Marcela Fu, Raúl Perez-Ortuño, Montse Ballbè, Ariadna Feliu, Juan Carlos Martín-Sánchez, Nuria Matilla-Santander, José A. Pascual, Esteve Fernández, and Jose M. Martínez-Sánchez. Assessment of the Spanish smoking legislations among smokers: A longitudinal study with biomarkers in Barcelona (Spain) (in revision).

Objective: To evaluate the impact of both Spanish smoking legislations in the tobacco consumption and the displacement to other tobacco products by using a cohort study of adult smokers in Barcelona (Spain) along with biomarker information (salivary cotinine concentration).

Results: The salivary cotinine concentration significantly increase 28.7% (GM from 91.7 ng/ml to 117.3 ng/ml, p=0.015) after the implementation of the two Spanish smoke-free bans. Statistical significant decrease was found in the proportion of individuals classified as medium FTCD (from 23.3% to 9.1%, p=0.017) when comparing pre and post legislation. Nonetheless, there was no pattern of change observed in the number of cigarettes smoked daily. Even though, an increase in the number of cigarettes smoked daily can be observed in those who switch from conventional to dual use consumption (conventional and hand-rolling cigarettes, RYO) when differentiating between kinds of tobacco smoked.

3. Cristina Lidón-Moyano, Marcela Fu, Raúl Pérez-Ortuño, Montse Ballbè, Marc Sampedro-Vida, Juan Carlos Martín-Sánchez, José A. Pascual, Esteve Fernández, and José M. Martínez-Sánchez. Assessment of salivary cotinine concentration among general non-smokers population: before and after Spanish smoking legislations (in revision).

Objective: To assess the impact of the impact of the Spanish smoking legislations on the SHS exposure in an adult non-smoking population cohort in Barcelona (Spain) using salivary cotinine concentrations and information on self-reported exposure.

Results: The geometric mean of salivary cotinine concentration significantly decreased 88% (from 0.98 ng/mL to 0.12 ng/mL, p<0.001) and salivary cotinine concentration was significantly higher only among those declaring exposure to second-hand smoke at home (exposed=0.33 ng/mL vs non-exposed=0.11 ng/mL, p<0.001); after the implementation of the two Spanish smoke-free legislations.

4. Cristina Lidón-Moyano, Marcela Fu, Montse Ballbè, Juan Carlos Martín-Sánchez, Cristina Martínez, Esteve Saltó, Esteve Fernández, and José M. Martínez-Sánchez. Impact of the Spanish smoking legislations in the adoption of smoke-free rules at home: a longitudinal study in Barcelona (Spain). Tobacco Control 2016 (in press). Doi:10.1136/tobaccocontrol-2016-053114.

Objective: To assess the impact of two Spanish smoking legislations in the adoption of voluntary smoke-free homes rules in Spain.

Results: The households with voluntary smoke-free rules (complete or partial) relatively increased 31% after Spanish smoking bans (from 55.6% to 72.6%, p<0.001). The houses with complete rules relatively increased 57% (from 23.9% to 37.6%, p<0.001) whereas the houses with partial rules increased 11% (from 31.7% to 35.0%, p=0.148). The increase of any type of rules (complete and partial) was statistically significantly independent of sex (PR between 1.29 and 1.33), age (PR between 1.24 and 1.33), educational level (PR between 1.19 and 1.47), and

minimum age in house (PR between 1.12 and 1.40). However, the increasing was statistically and significantly higher only among never smokers (PR=1.46) at baseline.

5. Cristina Lidón-Moyano, José M. Martínez-Sánchez, Marcela Fu, Montse Ballbè, Juan Carlos Martín-Sánchez, Cristina Martínez, Esteve Saltó, and Esteve Fernández. Secondhand smoke risk perception and smoke-free rules in homes: a cross-sectional study in Barcelona. BMJ Open 2017; 7: e014207.

Objective: To describe the voluntary adoption of smoke-free homes in Spain among general population and to identify variables associated with its voluntary adoption.

Results: 57.4% of households had complete indoor smoke-free rules. The prevalence of households with complete indoor rules was higher among women (PRa: 1.15; 95% CI: 1.00 - 1.33), married (PRa: 1.18; 95% CI: 1.01 - 1.38), never-smokers (PRa: 2.68; 95% CI: 2.06 – 3.50), and in households where a minor lived (PRa: 1.40; 95% CI: 1.20 - 1.65) (table 1). Believe that breathing tobacco smoke from smokers is dangerous for non-smokers (PRa: 1.77; 95% CI: 1.06-2.97) is associated with the voluntary adoption of complete indoor smoke-free home.

6. Cristina Lidón-Moyano, Juan Carlos Martín-Sánchez, Patrick Saliba, Jan Graffelman, José M. Martínez-Sánchez. Correlation between tobacco control policies and consumption of rolled tobacco and e-cigarettes, and intention to quit conventional tobacco, in Europe. Tobacco Control 2016 (in press). Doi: 10.1136/tobaccocontrol-2015-052482.

Objective: To analyze the correlation between the implementation of tobacco control policies and tobacco consumption, particularly rolling tobacco, electronic cigarettes (e-cigarettes) users, and the intent to quit smoking in 27 countries of the European Union.

Results: There was a negative correlation between TCS and prevalence of smoking (r_{sp}=-0.41; 95%CI: -0.67 - 0.07). We also found a negative correlation (r_{sp}=-0.31) between TCS and the prevalence of ever e-cigarette users, but not statistically significant. Among former smokers, there was a positive and statistically significant correlation between TCS and the consumption of hand-rolled tobacco (r_{sp}=0.46; 95%CI: 0.06 - 0.70). A similar correlation was observed between TCS and other tobacco products (cigars and pipe) among former smokers. There was a significant positive correlation between TCS and intent to quit smoking in the last 12 months (r_{sp}=0.66; 95%CI: 0.36 - 0.87).

7. Cristina Lidón-Moyano, Marc Sampedro-Vida, Nuria Matilla-Santander, Juan Carlos Martín-Sánchez, Adrián González-Marrón, Kailey Bunch, and Jose M. Martínez-Sánchez. Attitudes towards policies of the tobacco product directive implemented in Europe in 2016 and the relationship with the tobacco control policies (in revision).

Objective: To describe the acceptability of the recently implemented tobacco products regulations and to explore their relation with tobacco control legislation levels in Europe.

Results: Great support for the studied tobacco products regulations, which modestly increased over time, was observed. The highest support was seen for health warnings (80.8% in 2012) while the lowest was found in increasing taxes (58.6% in 2012). Moreover, a positive relation

was generally observed between TCS and support for the studied tobacco products regulations at both ecological and individual level.

5. Scientific articles of the doctoral thesis

5.1 Impact of the Spanish smoking laws on tobacco consumption and secondhand smoke exposure: a longitudinal population study

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Impact of the Spanish smoking laws on tobacco consumption and secondhand smoke exposure: A longitudinal population study

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HIGHLIGHTS

- Smoke-free regulations in Spain were associated with a reduction in smoking prevalence and SHS exposure.
- There was a change on the smoking pattern in consuming cheaper tobacco products, such as hand rolled cigarettes.
- The main settings of SHS exposure after Spanish bans were leisure time and in work.

ARTICLE INFO

Keywords:
Smoke-free legislation
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ABSTRACT

Background: In Spain, two smoke-free laws have been passed after the approval of the WHO-FCTC. This study assesses the impact of these Spanish smoking legislations on the active and passive smoking through a population cohort in Barcelona (Spain).

Methods: This is a longitudinal study before and after the implementation of two national smoking bans in Spain in a representative sample ($n = 1245$) of adults (≥ 16 years old) from Barcelona (Spain) surveyed in 2004–2005 and followed-up in 2013–2014. The final sample analyzed was 736 individuals. Both questionnaires (before and after the two laws) included the same variables about active and passive smoking. We calculated the prevalence and the prevalence ratio (PR, with their 95% confidence intervals, 95% CI) of smoking cigarettes and hand-rolled tobacco and also the prevalence of exposure to secondhand smoke (SHS) at home, work, public transport, leisure time and at any setting after *vs.* before Spanish legislations.

Results: After the implementation of the two Spanish smoke-free bans, a significant decrease was observed in the smoking prevalence (from 34.5% to 26.1%, PR = 0.76, $p < 0.001$), in the average cigarettes per day (median from 15.2 to 10.0, $p < 0.001$), and in the percentage of conventional tobacco consumption (from 92.6% to 74.4%, PR = 0.80, $p < 0.001$). Furthermore, a significant increase in the use of hand-rolled tobacco (from 6.1% to 30.9%, PR = 5.07, $p < 0.001$) and other tobacco products (from 17.1% to 32.8%, PR = 1.92, $p < 0.001$) was observed. In addition, a significant decrease in the self-reported SHS exposure was observed in all the assessed settings (home, work, transport, and leisure time).

Conclusions: The implementation of the two smoke-free legislations in Spain is related to a reduction in smoking prevalence and SHS exposure. However, the smoking of other tobacco products, particularly hand-rolled tobacco, has increased among young population.

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1. Introduction

Tobacco smoking has been causally linked to diseases of nearly all organs of the body and to diminish health status, including such common diseases as diabetes mellitus, rheumatoid arthritis, and colorectal cancer (U.S. Department of Health and Human Services, 2014). Similarly, exposure to secondhand tobacco smoke (SHS) has been associated with cancer, respiratory and cardiovascular diseases among adults, and with adverse effects on the health of infants and children (U.S. Department of Health and Human Services, 2014).

The World Health Organization (WHO) estimated that about 22.1% of worldwide population smoked in 2010 (World Health Organization, n.d.) and that tobacco use is responsible for about six million deaths across the world each year, which includes about 600,000 deaths from the effects of exposure to SHS (World Health Organization, n.d.). In Spain, the latest data available shows that 23.6% of Spanish population are tobacco users in 2012 (Gutiérrez-Abejón, Rejas-Gutiérrez, Criado-Espegel, et al., 2015), and 60,456 deaths are annually attributable to active smoking (Gutiérrez-Abejón et al., 2015) and 1,028 to passive smoking at home and work (López, Pérez-Ríos, Schiaffino, et al., 2016).

To take action against this tobacco epidemic, several countries have implemented smoke-free legislations, as suggested by the WHO Framework Convention on Tobacco Control (FCTC) (World Health Organization, 2015). Smoke-free legislations has already been associated with a reduction in the SHS exposure, a decrease in the incidence of acute coronary events, a reduction of respiratory symptoms, and an improvement of perinatal and child health, along with a moderate decrease in tobacco use (Gupta, Ray, & Singh, n.d.; International Agency for Research on Cancer World Health Organization, 2009).

In Spain, two smoke-free laws have been passed after the approval of the WHO-FCTC. In 2006, a smoke-free legislation came into effect banning smoking in public and workplaces (Law 28/2005). This law was not complete in terms of full health protection from SHS exposure, because it included some exceptions, as allowing smoking in the hospitality sector under some conditions (Fernández, 2006), leading to identification of the Spanish smoking law as the "Spanish model" (Schneider, Sebrie, & Fernandez, 2011). The scientific evaluation of this law evidenced the need to promote a total ban (Fernández, Fu, Pascual, et al., 2009; Grupo de Trabajo sobre Tabaquismo de la Sociedad Española de Epidemiología, 2009; Grupo de Trabajo sobre Tabaquismo de la Sociedad Española de Epidemiología, 2017; Nebot, López, Ariza, et al., 2009), which came into force in 2011 (Law 42/2010). That law extended smoke-free regulation to all hospitality venues without exception and to some outdoor areas, including hospital premises, educational campuses, and playgrounds (Fernández & Nebot, 2011).

Currently, there are scarce studies that have evaluated the impact of smoking legislation using a general population cohort, which increases the internal validity of the results (International Agency for Research on Cancer World Health Organization, 2009). in Spain, there are few studies that have assessed the impact of both Spanish legislations (Law 28/2005 and Law 42/2010) on smoking and SHS exposure (Jiménez-Ruiz, Riesco-Miranda, Altet-Gómez, et al., 2014; Lidón-Moyano, Martínez-Sánchez, Fu, et al., 2016; López, Fernández, Pérez-Ríos, et al., 2013; Sureda, Ballbè, Martínez, et al., 2014; Sureda, Martínez-Sánchez, Fu, et al., 2014; Tarrazo, Pérez-Ríos, Santiago-Perez, et al., 2016). Therefore, the objective of this study is to carry out a comprehensive assessment of the impact of these two smoke-free laws in active and passive smoking among a population-based cohort sample in Barcelona (Spain).

2. Methods

This is a longitudinal study of a representative sample of non-institutionalized population (≥ 16 years old) of Barcelona (Spain; n = 1245, 694 women and 551 men) ("Determinants of Cotinine phase 3" project, dCOT3; website: http://bioinfo.iconcologia.net/es/content/estudio-dcot3). The baseline characteristics are detailed elsewhere (Fu, Fernández, Martínez-Sánchez, et al., 2009; Martínez-Sánchez, Fernández, Fu, et al., 2009). In brief, we followed-up participants who responded to a face-to-face questionnaire in 2004–2005 and agreed to take part in future studies. At the beginning of 2013, we updated the vital status and contact information (addresses and telephone numbers) of all participants using the Insured Central Registry of Catalonia. We restricted the follow-up to the participants who were alive in 2013 and still lived in the province of Barcelona.

We traced 1,010 participants out of the 1,245 from the baseline study (101 died, 49 migrated out of the province of Barcelona, and 85 did not give consent to be followed or were minors (< 18 years old) in 2004–2005 as their parents were not asked to provide informed consent to re-contact). The percentage of follow-up in this first stage was 81.1%. The follow-up survey was conducted between May 2013 and February 2014. In total, 72.9% of the eligible sample agreed to participate and answered the questionnaire (736 out of 1,010 traced, second stage of follow-up), and 18.5% refused to participate, 7.2% moved elsewhere and 1.3% had died. The final sample analyzed were 736 individuals (400 women and 336 men). 51.9% (736 out of 1,245) of the cohort subjects participated in both surveys. There were no statistically significant differences between the participants followed-up (n = 736) and those lost in the second stage (n = 274) according to age, sex, level of education, district, and smoking status. However, there were statistically significant differences according to age, level of education, and smoking status between the follow-up sample (n = 736) and the participants lost in both stages of the follow-up (n = 509) (data not shown). For this reason, the final sample was skewed as older in comparison with the population of Barcelona. Therefore, we used inverse probability weights to balance our data according to age distribution of the city of Barcelona to maintain the representativeness of the sample. The research and Ethics Committee of the Bellvitge University Hospital provided ethical approval for the study. This study meets the code of the Declaration of Helsinki.

2.1. Variables

Both questionnaires (baseline and follow-up, before and after the two laws) included the same following variables:

Smoking status, was obtained from the question: "Which of the following statements better describes your smoking status?" with the possible answers: "Nowadays I smoke everyday (at least one cigarette per day)", these are current daily smokers; "Nowadays I smoke occasionally (less than one cigarette per day)", these are current occasionally smokers; "I don't smoke now, but I smoked before every day", these are former daily smokers; "I don't smoke now, but I smoked before occasionally", these are former occasionally smokers; and "I have never smoked", these are never smokers. We also aggregate these categories when appropriate as "smokers" (current daily and occasionally smokers) and "non-smokers" (former daily and occasionally smokers plus never-smokers).

Number of cigarettes smoked per day, obtained from the question: "On average, how many cigarettes per day do you usually smoke?". This question was only available for daily smokers.

Fagerström Test for Cigarette Dependence (FTCD) is a standard instrument for assessing the intensity of physical addiction to nicotine, it includes 6 items/questions and the score ranges from 0 to 10. The six items are: time to first cigarette (0–3 points), difficulty to refrain (0–1 points), hardest cigarette to give up (0–1 points), cigarettes smoked per day (0–3 points), smoking more in the morning than during the rest of the day (0–1 points), and smoking when ill (0–1 points). The FTCD was developed to decide whether or not nicotine replacement therapy is needed to treat withdrawal syndrome. A previous study has demonstrated the reliability of the test (0.66) (Becona & Vazquez, 1998). In our study, these questions were only addressed to daily smokers as recommended by guidelines (Guideline Update Panel, 2008).

Type of tobacco product used, obtained through the question: "What type of tobacco product do you usually smoke?" with the possible answers: "cigarettes", "hand-rolled tobacco", "cigars", "little cigars", "pipes", "hookah" and "e-cigarettes". The answers to this question were aggregated as 'cigarettes', 'hand-rolled tobacco' and 'other products' including cigars and little cigars. This question was gathered from daily and occasional smokers.

Exposure to SHS at home was determined through two questions: "Currently, how many individuals usually smoke inside your home per day?" and "During the last 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. These questions were only provided for non-smokers (former and never smokers). Based on these two questions, we derived a dichotomous variable: non-exposed at all (responses = 0 to both questions) and exposed (responses ≥ 1 to any of the questions).

Exposure to SHS at work, only provided for non-smokers, was determined through 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 work?". We also derived a dichotomous variable of exposure to SHS at the workplace: non-exposed at all (responses = 0 to both questions) and exposed (responses ≥ 1 to any of the questions).

Exposure to SHS at public transport, only provided for non-smokers, was obtained through the questions: "During the last week, were you in a public transport vehicle while someone was smoking?" We defined a dichotomous variable of exposure to SHS in public transport: non-exposed at all (responses = 0 to both questions) and exposed (responses ≥ 1 to any of the questions).

Exposure to SHS at leisure time, only provided for non-smokers, was determined through the question "How much time have you spent in any place with tobacco smoke that was not at home or at work?". The answers were gathered for typical working and non-working days. We derived a dichotomous variable of exposure to SHS during leisure time: non-exposed at all (responses = 0 to both questions) and exposed (responses ≥ 1 to any of the questions). Exposure to SHS in any setting was defined as exposure in at least one of the above mentioned settings.

2.2. Statistical analysis

We calculated the prevalence and the prevalence ratio (PR) after *vs.* before both smoke-free legislations with their 95% confidence intervals (95% CIs) of smoking status, type of tobacco product smoked, and exposure to SHS in the different settings. We used Generalized Estimating Equation (GEE) models with individuals as random effects and using Poisson family with log link to calculate the prevalence ratio adjusted for sex, age and educational level (aPR). We also calculated the median number of cigarettes smoked daily and the FTCD score. We assessed median differences through Wilcoxon test for paired samples. The results were stratified by sex, age and educational level, categorized as low (unschooled, elementary school completed or uncompleted and special education); intermediate (high school and training cycles) and high (university education). The statistical programs used were R-3.0.2 and STATA v.14.

3. Results

3.1. Tobacco consumption

Overall, it was observed a significant decrease in smoker's prevalence from 34.5% to 26.1% (PR = 0.76, *p*-value = 0.006) along with a significant increase in former smoker's prevalence from 25.6% to 34.1% (PR = 1.33, *p*-value = 0.004) (Fig. 1).

Moreover, 22.6% (95% CI: 19.7–25.8) are smokers and 62.0% (95% CI: 58.4–65.5) are non-smokers (never and former smokers) at baseline and at follow-up. 11.9% (95% CI: 9.7–14.5) of smokers in the baseline quit smoking at the follow-up and 3.5% (95% CI: 2.3–5.2) of non-smokers in the baseline initiated or relapsed tobacco use at the follow-up (0.2% were never smokers at baseline and 3.3% were former smokers).

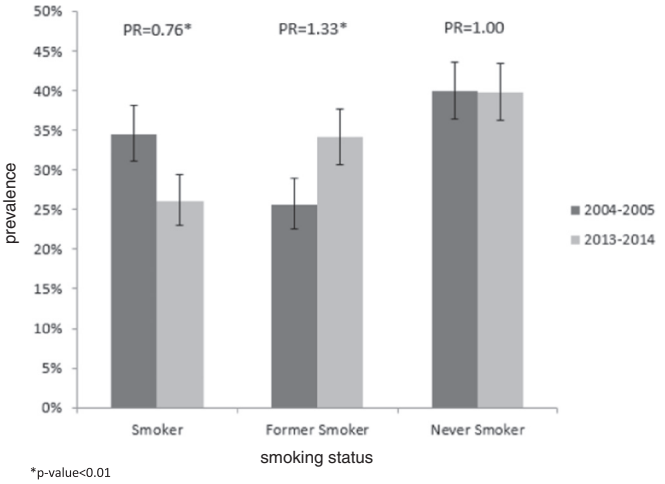

Fig. 1. Prevalence and prevalence ratio (PR) of smoking status before and after the implementation of both Spanish smoke-free bans.

The smoking prevalence significantly decreased, from 34.5% to 26.1%, after the implementation of the two Spanish smoke-free bans (Table 1). In particular, a higher decrease was observed in women (aPR in men = 0.77 *vs.* aPR in women = 0.74), as well as among older people (> 65 years old) (aPR = 0.63), and in those with intermediate (aPR = 0.70) or high education (aPR = 0.71). We obtained similar unadjusted PRs.

A significant decrease in the average cigarettes smoked per day was observed (median from 15.2 to 10.0 cigarettes per day, *p*-value < 0.001; Table 1). A higher decrease was observed among men (median differences between both surveys were 8.6 and 2.9 cigarettes per day among men and women respectively; both *p*-values < 0.05), as well as among people aged 45–64 years old (median difference = 6.6 cigarettes per day, *p*-value < 0.001), and in those with high education (median difference = 6.6, *p*-value = 0.003). Moreover, there was not any significant change in the cigarette dependence (Table 1).

Regarding type of tobacco used, a significant decrease in the prevalence of conventional cigarettes was observed (from 92.6% to 74.4%, PR = 0.80, *p*-value = 0.001), as well as in the prevalence of hand-rolled tobacco (from 6.1% to 30.9%, PR = 5.07, *p*-value < 0.001) and other tobacco products (from 17.1% to 32.8%, PR = 1.92, *p*-value < 0.001; Table 2). These changes were higher among young population (< 44 years), men and intermediate or high educational level.

3.2. Exposure to secondhand smoke

We observed a statistically significant decrease in the self-reported SHS exposure in all the assessed settings (Table 3). The highest prevalence of self-reported exposure to SHS, before and after the two Spanish smoke-free laws, as well as the lower reduction, was obtained during the leisure time, from 71.7% to 52.2% (aPR = 0.75, *p*-value < 0.001) and at work, from 36.1% to 29.8% (aPR = 0.82, *p*-value = 0.045; Table 3).

4. Discussion

Our results show a reduction in smoking prevalence after both smoke-free bans legislations: however, the use of other tobacco products, particularly hand-rolled tobacco, has increased among young population (< 44 years). Moreover, we also observed an important reduction in the self-reported exposure to SHS in all settings.

Table 1
Changes in the smoking status, number of cigarettes smoked per day and FTCD before and after both Spanish smoke-free laws.

	n	Current Smokers					Cigarettes per day[a]			Cigarette dependence[b]		
		PRE %	POST %	PR	aPR	*p*-value[c]	PRE median	POST median	*p*-value[d]	PRE median	POST median	*p*-value[d]
Overall	736	34.5	26.1	0.76 (0.68–0.84)	0.75 (0.68–0.84)	< 0.001	15.2	10.0	< 0.001	3.0	3.3	0.462
Sex												
Men	341	39.9	30.9	0.77 (0.68–0.88)	0.77 (0.68–0.88)	< 0.001	18.6	10.0	< 0.001	4.0	4.0	0.801
Women	395	29.8	22.1	0.74 (0.62–0.88)	0.74 (0.62–0.88)	< 0.001	12.9	10.0	0.028	2.7	3.0	0.441
Age												
26–44	420	42.9	34.0	0.79 (0.69–0.91)	0.79 (0.69–0.91)	< 0.001	15.0	10.0	0.010	3.0	3.5	0.074
45–64	203	31.0	20.9	0.67 (0.57–0.80)	0.67 (0.57–0.80)	< 0.001	16.6	10.0	< 0.001	4.0	3.0	0.245
≥ 65	113	9.6	6.1	0.63 (0.39–1.03)	0.63 (0.39–1.03)	0.210	6.1	5.0	0.727	0.5	0.0	0.699
Educational level												
Low	241	27.1	24.5	0.90 (0.77–1.07)	0.91 (0.77–1.07)	0.306	16.0	10.0	0.048	3.0	4.0	0.975
Intermediate	206	45.8	32.2	0.70 (0.58–0.86)	0.70 (0.58–0.86)	< 0.001	15.4	10.5	0.016	4.0	4.0	0.178
High	289	32.6	23.1	0.71 (0.59, 0.85)	0.71 (0.59–0.85)	< 0.001	14.3	7.7	0.003	2.7	3.0	0.802

PR: Prevalence Ratio, PRa: Prevalence Ratio adjusted for sex, age and educational level.
[a] Daily smokers PRE: (n = 199); Daily smokers POST: (n = 160).
[b] As measured with the Fagerström Test for Cigarette Dependence.
[c] *p*-value: Adjusted Generalized Estimating Equation (GEE) model.
[d] *p*-value: Paired samples Wilcoxon test.

Our results on smoking consumption trends are consistent with a recent evidence report published which shows a decline of prevalence before the Spanish smoke-free laws, that became more striking after their implementation mainly among women but not among men (Grupo de Trabajo sobre Tabaquismo de la Sociedad Española de Epidemiología, 2017). In regards to the increase of hand-rolled cigarettes the economic crisis that took place in Spain in 2008 could have affected the shift on tobacco products as also reported (Grupo de Trabajo sobre Tabaquismo de la Sociedad Española de Epidemiología, 2017; Sureda et al., 2017).

In addition, smoking prevalence observed in our follow-up survey was higher than that observed in another studies (23.6% (Gutiérrez-Abejón, Rejas-Gutiérrez, Criado-Espegel, et al., 2015) and 20.7% (Pérez-Ríos, Fernández, Schiaffino, et al., 2015)), with information gathered at national level in 2011–2012. This could be because our study was carried out in the city of Barcelona while the other study includes information about all the regions in Spain, and historically it has been reported slight differences in smoking prevalence among regions in Spain (Observatorio Español de las drogas y las toxicomanías, 2015). Another possible explanation is that young and smoker participants in our sample could have been overestimated because of the loss of older and no-smoker participants.

Nevertheless, the impact of the two National smoke-free legislations is in line with previous studies conducted in Spain (Jiménez-Ruiz et al., 2014; Tarrazo et al., 2016). Specifically, with a national Spanish study based on a representative sample, in which it has been seen a drop in prevalence of smoking between 2005 and 2011 (from 21.2% to 18.7%) as well as in exposure to SHS in all the analyzed settings (Jiménez-Ruiz et al., 2014). Another Spanish work also showed a decrease in prevalence of smoking between 2006 and 2011 (from 23.4 to 20.7%) (Pérez-Ríos et al., 2015). Moreover, a study carried out in Galicia (Spain) showed a decrease in the prevalence of smoking between 2007 and 2015 (from 25.4% to 21.8%) (Tarrazo et al., 2016). As well, a study carried out in Barcelona (Spain) reported a decline in the overall self-reported exposure from 75.7% in 2004–05 to 56.7% in 2011–12 (Sureda, Martínez-Sánchez, Fu, et al., 2014). Similarly, a previous study carried out in three Spanish regions showed that secondhand smoke exposure, assessed with nicotine and PM2.5 concentrations, decreased by > 90% in hospitality venues after the Law 42/2010 came into force (López et al., 2013). Our results then give more evidence on the conclusions of a systematic review (Hoffman & Tan, 2015) that highlights that smoke-free policies and smoking restrictions in public spaces, workplaces or residences lead to a decrease in smoking prevalence and cigarette consumption.

However, in our study we didn't observe any significant change in the cigarette dependence after the enactment of the two Spanish smoking legislations (Law 28/2005 and Law 42/2010), counteracting the hardening hypothesis, which suggests that when smoking

Table 2
Changes in the type of tobacco product smoked among participants who were current smokers before and after both Spanish smoke-free laws.

		Conventional cigarettes				Hand-rolled tobacco				Other tobacco products			
		PRE %	POST %	PR	*p*-value	PRE %	POST %	PR	*p*-value	PRE %	POST %	PR	*p*-value
Overall	166	92.6	74.4	0.80 (0.73–0.88)	0.001	6.1	30.9	5.07 (2.67–9.33)	< 0.001	17.1	32.8	1.92 (1.34–2.59)	< 0.001
Sex													
Men	94	87.4	68.2	0.78 (0.67–0.91)	0.001	7.4	33.6	4.54 (2.09–9.42)	< 0.001	26.1	39.6	1.52 (1.12–2.22)	0.009
Women	72	98.7	81.8	0.83 (0.74–0.93)	0.001	4.6	27.7	6.02 (1.99–18.24)	< 0.001	6.7	24.5	3.66 (1.55–9.14)	0.003
Age													
26–44	121	94.4	71.7	0.76 (0.67–0.86)	< 0.001	7.0	37.8	5.40 (2.60–11.13)	< 0.001	15.5	32.7	2.11 (1.30–3.14)	0.002
45–64	39	90.1	82.6	0.92 (0.80–1.03)	0.133	4.6	12.7	2.76 (1.17–7.77)	0.022	17.2	30.9	1.80 (1.02–3.08)	0.043
≥ 65	6	78.9	78.8	1.00 (−)	–	0.0	0.0	–	–	42.3	45.5	1.08 (0.80–2.10)	0.296
Educational level													
Low	50	93.6	80.0	0.85 (0.74–0.99)	0.033	4.4	26.1	5.93 (1.77–12.39)	0.002	16.8	22.8	1.36 (0.74–2.38)	0.339
Intermediate	57	94.2	68.8	0.73 (0.60–0.88)	0.001	7.8	37.4	4.79 (1.87–12.36)	0.001	14.5	32.9	2.27 (1.26–3.78)	0.005
High	59	90.4	74.9	0.83 (0.71–0.97)	0.018	5.5	28.7	5.22 (1.70–16.12)	0.004	19.9	41.4	2.08 (1.18–3.53)	0.010

PR: Prevalence Ratio.
Other tobacco products: cigars, little cigars, pipes, hookah and e-cigarettes.
p-value: Generalized Estimating Equation (GEE) model.

Table 3
Changes in self-reported exposure to secondhand smoke in non-smokers[a] before and after the implementation of both Spanish smoke-free bans.

	% self-reported exposure	PR	aPR	*p*-value
Any setting				
PRE	74.2 (70.0–78.0)	Ref.	Ref.	
POST	58.4 (54.1–62.5)	0.74 (0.68–0.81)	0.77 (0.73–0.82)	< 0.001
Home				
PRE	17.1 (13.9–20.9)	Ref.	Ref.	
POST	10.2 (7.9–13.1)	0.59 (0.45–0.79)	0.90 (0.78–1.05)	< 0.001
Work				
PRE	36.1 (30.6–42.0)	Ref.	Ref.	
POST	29.8 (24.8–35.4)	0.83 (0.64–1.07)	0.82 (0.63–1.07)	0.045
Public transport				
PRE	14.2 (11.1–18.0)	Ref.	Ref.	
POST	4.4 (2.7–7.0)	0.31 (0.17–0.54)	0.23 (0.14–0.38)	< 0.001
Leisure time				
PRE	71.7 (67.4–75.6)	Ref.	Ref.	
POST	52.2 (47.9–56.5)	0.73 (0.66–0.80)	0.75 (0.70–0.81)	< 0.001

PR: Prevalence Ratio, aPR: Prevalence Ratio adjusted for sex, age and educational level. *p*-value: Adjusted Generalized Estimating Equation (GEE) model.
[a] Non-smokers PRE: (n = 482); Non-smokers POST: (n = 544).

prevalence decreases in the population, the smokers who quit are less dependent, and the remaining smokers are those with hard smoking dependence (Hughes, 2011). Similar results can be found in Italy (Gallus, Pacifici, Colombo, et al., 2005) and Norway (Lund, Lund, & Kvaavik, 2011). Moreover, a European study with data from 18 countries suggests that the lower the country-specific smoking prevalence, the lower the dependence (Fernández, Lugo, Clancy, et al., 2015), giving more evidence to reject the hardening hypothesis.

Nevertheless, we observed a statistically significant decrease in the prevalence of consumption of conventional cigarettes, we also observed a significant increase in the consumption of hand-rolled tobacco and other tobacco products, especially among young people; in fact, according to our results, older people were not smoking hand-rolled tobacco neither before nor after the implementation of the Spanish smoke-free legislations. In this sense, a previous study carried out in Galicia (North West in Spain), showed an increase in consumption of hand-rolled tobacco between 2007 and 2015, from 1.8% to 18.6% (Tarrazo et al., 2016). Moreover, another work showed the prevalence of use of hand-rolled tobacco rose between 2006 and 2011, from 1.5% to 15.6% (Pérez-Ríos et al., 2015). In Europe, a similar pattern can be found at ecological level, obtaining a negative correlation between the level of implementation of smoke-free legislation and smoking prevalence of conventional cigarettes but a positive correlation with the usage of other tobacco products, particularly hand-rolled tobacco (Lidón-Moyano, Martin-Sánchez, Saliba, et al., 2016). A similar pattern has been found in other countries like Canada, USA, UK, Australia (Young, Yong, Borland, et al., 2012) and New Zealand (Young, Wilson, Borland, et al., 2010). Thereby, our results provide more support to the hypothesis of a change in the smoking pattern in using cheaper tobacco products, such as hand-rolled tobacco, especially among young people. In Spain, the sale to the public of hand-rolled tobacco increased by 60% between 2010 and 2011 (200% between 2007 and 2011) (Granda-Orive & Jiménez-Ruis, 2011). Taking this into account, there is a need to equalize the prices of all tobacco products by applying the same taxing level as, indeed, is recommended by the article 6 of the FCTC (Tarrazo et al., 2016; World Health Organization, 2003).

Regarding self-exposure to SHS exposure, our results show a significant decrease in the exposure at workplaces, during leisure time, at home, and public transport after the application of the two Spanish smoking legislations (Law 28/2005 and Law 42/2010), In line with some previous cross-sectional surveys at local and national level (Jiménez-Ruiz et al., 2014; Sureda, Martínez-Sánchez, Fu, et al., 2014; Villaverde-Royo, Marin-Izaguerri, Requeno-Jarabo, et al., 2012). Moreover, previous results from our research group showed a significant increase in the prevalence of voluntary adoption of smoke-free rules in homes between 2004 and 05 (55.6%) and 2013–14 (72.6%) (Lidón-Moyano, Martínez-Sánchez, Fu, et al., 2016). A previous study also found a significant decrease in the mean of SHS exposure hours, as a consequence of the Spanish legislation implementation (Villaverde-Royo et al., 2012). Similarly, a systematic review (Hoffman & Tan, 2015) reported reductions in SHS exposure after the implementation of smoke-free policies, in both adults and children, and across various settings including workplaces, public spaces and hospitality establishments. None of the above results support a displacement of tobacco consumption to private venues, like home, counteracting the displacement hypothesis. Nonetheless, the highest prevalence of self-exposure to SHS, before and after the implementation of the two Spanish smoke-free bans, as well as the lower reduction, was obtained in the leisure time and in work. These results are consistent with another Spanish study, which showed that more than one-third of the population were passively exposed at work and at leisure time two years after the Spanish smoking legislations (Sureda, Martínez-Sánchez, Fu, et al., 2014). In this regard, previous studies have shown that both consumption and self-reported SHS exposure were very low in indoor settings regulated by the Spanish legislation, therefore, the exposure of non-smokers to SHS mostly occurs in outdoor areas where smoking is allowed (Sureda, Fernández, Martínez-Sánchez, et al., 2015). Taking this into account, future smoking control legislations should consider including some outdoor public and workplaces to ensure higher protection against SHS exposure.

4.1. Limitations to our study

The main limitation of our study is the potential participation bias due to the attrition of the cohort of participants. In this sense, there were statistically significant differences between the participants who were followed-up and those participants lost according to age, level of education, and smoking status. Participants who were followed-up overestimate young people and smokers in comparison with lost participants; for this reason, the reduction of conventional cigarettes consumption and the increase of hand-rolled tobacco consumption could be higher among lost participants. In addition, regardless its longitudinal nature, the study does not allow establishing strong causal inferences regarding the effectiveness of the smoke free legislation. On the other hand, our final sample overestimated the older people compared with the distribution of population in Barcelona. However, we weighted the sample to minimize these limitations and to generate estimations representative of the general population. Moreover, the baseline sample size was representative of the city of Barcelona (Fu et al., 2009; Martínez-Sánchez et al., 2009) and the longitudinal design of our work maximizes the internal validity of the study. Other potential limitations are those related to survey-based studies, as the use of a questionnaire to collect self-reported information, and bias due to non-response. Nevertheless, by using a face-to-face questionnaire with trained interviewers we potentially increase the internal validity of our results as compared with internet and self-administered surveys.

4.2. Conclusion

The implementation of the two smoke-free legislations in Spain is related to a reduction in smoking prevalence and SHS exposure. However, the use of other tobacco products, particularly hand-rolled tobacco, has increased among young population. In addition, the main setting of SHS exposure occurs during the leisure time and at work, where most of the exposed ones declared expending most of the time.

Therefore, future tobacco control measurements should consider applying the same taxing level to all tobacco products in order to equalize their prices, as well as including some outdoor restrictions to ensure higher protection against SHS exposure.

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Contributors

CLM analyzed the data and drafted the first manuscript with the supervision of JMMS. MF, MB, EF and JMMS contributed to the design and coordination of the study. All authors contributed substantially to the interpretation of the data and the successive versions of the manuscript. All authors contributed to the manuscript and approved its final version. JMMS conceived the study and is the principal investigator of the project.

Competing interests

Authors declare that they have no conflicts of interest.

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5.2 Assessment of the Spanish smoking legislations among smokers: A longitudinal study with biomarkers in Barcelona (Spain)

Assessment of the Spanish smoking legislations among smokers: A longitudinal study with biomarkers in Barcelona (Spain)

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ABSTRACT

Objective: To evaluate the impact of both Spanish smoking legislations in the tobacco consumption and the displacement to other tobacco products by using a cohort study of adult smokers in Barcelona (Spain) along with biomarker information (salivary cotinine concentration).

Methods: This is a longitudinal study, before and after the implementation of the two national smoking bans (in 2006 and 2011), in a representative sample of adults (≥ 16 years old) from Barcelona (Spain) surveyed in 2004-2005 and followed-up in 2013-2014 (n=736). For the purposes of this study we only analyzed continuing smokers; hence, the final sample analyzed was 116 individuals. We conducted a survey and obtained 9 ml sample of saliva for cotinine analysis following the same protocol. We also obtained information about the self-reported cigarette number smoked daily, kind of tobacco smoked, stage of change, and Fagerström Test for Cigarette Dependence (FTCD) score. We calculated geometric means of salivary cotinine concentration and their geometric standard deviation. We used linear mixed effect models with individuals as random effects to model the percentage change in salivary cotinine concentrations and their 95% confidence intervals.

Results: The salivary cotinine concentration significantly increased 28.7% (GM from 91.7 ng/ml to 117.3 ng/ml, p=0.015) after the implementation of the two Spanish smoke-free bans. Statistical significant decrease was found in the proportion of individuals classified as medium FTCD (from 23.3% to 9.1%, p=0.017) when comparing pre and post legislation. Nonetheless, there was no pattern of change observed in the number of cigarettes smoked daily. Even though, an increase in the number of cigarettes smoked daily could be observed in those who switch from conventional to dual use consumption (conventional and hand-rolling cigarettes, RYO) when differentiating between kinds of tobacco smoked.

Conclusions: Our study shows a significant increase in the salivary cotinine concentration among adult continuing smokers after both Spanish legislations. Moreover, we observed a shift to other tobacco products, particularly RYO cigarettes.

Keywords: Smoke-free legislation; *Smoking; Cotinine; Biomarker*

INTRODUCTION

Tobacco is the first single leading cause of preventable death in the world (1), being related to more than 25 diseases and being responsible for 30% of all cancers, respiratory diseases and cardiovascular diseases (2). In 2015, WHO estimated that about 15% (1.1 billion people) of worldwide population smoked (3) and that tobacco use is responsible for about six million deaths across the world each year, which includes about 600,000 deaths from the effects of second-hand smoke (SHS) (4). In Spain, the latest data reported showed that 23.6% of Spanish population were tobacco users in 2012 (5) and that more than 60,000 deaths per year were attributable to active smoking (5).

Consequently, two smoke-free laws have been passed in Spain after the approval of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) (6). On the 1st of January, 2006, a smoke-free legislation came into effect (Law 28/2005). This law was a great advance for public health in Spain; however, it was not complete in terms of health protection from SHS exposure, because it allowed smoking in hospitality sectors according to the size of venues (7), for this exception the Spanish smoking law was known as the "Spanish model" (8). The scientific evaluation of this law showed the need to promote a total ban (9-11). On the 2nd of January, 2011, a new law came into effect (Law 42/2010), extending the smoke-free regulation to all hospitality venues without exception (12) and to some outdoor areas, including hospital premises, educational campuses, and playgrounds.

The principal aim of both Spanish tobacco control legislations was to protect non-smoking population from tobacco smoke exposure. Therefore, their scientific evaluation focused on their effect on SHS reduction, often neglecting research about the effect on active smokers. In this sense, previous studies (13,14) suggest that active smokers could be changing their smoking pattern in consuming cheaper tobacco products, such as hand rolled tobacco, which is subject of little taxation in Spain. To our knowledge, there are scarce studies that assess the impact of smoking legislation among the general smoking population using a specific biomarker such as cotinine concentration.

Therefore, the objective of this study is to evaluate changes on tobacco consumption and displacement to other tobacco products among smokers before and after both Spanish smoking legislations by using a cohort study of adult smokers in Barcelona (Spain) along with biomarker information (salivary cotinine concentration).

METHODS

We used the follow-up data of a cohort from a representative sample of the adult population (≥16 years) of the city of Barcelona (Catalonia, Spain). The baseline study was carried out during the years 2004-2005 (15,16) (n = 1,245) and the follow-up took place in 2013-2014, after both Spanish smoking legislations.

From the baseline sample, we excluded 235 subjects: 150 after checking their data in the Insured Central Registry of Catalonia (101 died and 49 migrated out of the province of Barcelona) and 85 who did not give consent to be followed up or were minors (<18 years old)

in 2004-2005 to whom no consent to re-contact was asked. The follow-up was conducted in 2013-2014. In total, 72.9% of the eligible sample (n=1010) agreed to participate, 18.5% refused to participate, 7.2% had moved elsewhere and 1.4% had died. The final sample included 736 individuals (Figure 1) and was skewed as slightly older in comparison with the general population of Barcelona. For this reason, we weighted our data according to age distribution of the city of Barcelona to maintain its representativeness.

We asked the participants to provide a 9 ml sample of saliva for cotinine analysis, using the same protocol before and after the Spanish smoking legislations. Participants were asked to rinse their mouths and then suck a lemon candy (Smint) to stimulate saliva production. Saliva samples were frozen and sent to the IMIM-Hospital del Mar Medical Research Institute in Barcelona. Saliva samples were analyzed using liquid chromatography-tandem mass spectrometry (LC/MS/MS) with multiple reaction monitoring. The limit of quantification was 0.4 ng/ml (quantification error was <15%) (17).

We used the same core questionnaire in both surveys to gather relevant information on smoking characteristics. For this analysis, we used self-reported smoking status for the identification of current smokers, along with the information on their cotinine concentration. Thus, we considered smokers those participants who identified themselves as current smokers and had salivary cotinine concentration consistent with active smoking (≥ 35 ng/ml per cigarette smoked (18)). The percentage of smokers with salivary cotinine higher than 35 ng/ml per cigarette smoked daily was 3.4% before the legislations and 12.1% after the legislations.

The final sample for this analysis consists of 116 individuals, who were smokers before and after the legislations (Figure 1).

From the same questionnaire before and after the two laws, we also obtained information about the kind of tobacco smoked), obtained through the question: “What kind of tobacco product do you habitually consume?” with the possible answers: “cigarettes”, “hand-rolling tobacco”, “cigars”, “little cigars”, “pipes”, “hookah” and “e-cigarettes”. The answers to this question were dichotomized as ‘Always conv.’, indicating those who only smoked conventional cigarettes before and after the two laws, ‘Conv. - RYO’, indicating those who switched from conventional to hand-rolling tobacco or Roll Your Own (RYO) cigarettes, ‘Conv. – dual use’, indicating those who switched from conventional to dual use (conventional and RYO cigarettes) and ‘Other’, indicating other possible options. Moreover, we collected information about the smokers’ stage of change (19): precontemplation, when smokers were not seriously considering quitting within the next 6 months; contemplation, when smokers were seriously considering quitting within the next 6 months but not within the next 30 days; and preparation, when smokers were planning to quit within the next 30 days and had attempted to quit for at least 24 hours in the past year. We also gathered information about the number of cigarettes smoked daily (either conventional or RYO cigarettes) and the Fagerström Test for Cigarette Dependence (FTCD) score (20), categorized as ‘low’ (≤4), ‘medium’ (5) and ‘high’ (≥6). Finally, we gathered information about several smoking characteristics, such as use of regular or non-regular cigarettes (light, ultralight, etc.), type of tobacco smoked (blond or black), use of cigarettes with or without filter, length of cigarettes left after smoking (in centimeters), and

depth (superficial, intermediate, deep) and frequency of inhalation (continuous, regular, scarce).

For statistical analysis we calculated geometric means (GM) and their geometric standard deviation (GSD), given the skewed distribution of cotinine concentration. We used linear mixed effect models with individuals as random effects to model the change in cotinine concentration (after log10 transformation), their 95% confidence intervals and the p-value, adjusted for sex, age, and educational level. The results were stratified by sex, age, educational level, kind of tobacco smoked, FTCD score and stages of change. We also used generalized lineal mixed models with individuals as random effects to calculate the prevalence ratio of the change in smoking characteristics. The statistical programs used were R-3.0.2 and Stata v14.

RESULTS

We observed a general increase in salivary cotinine concentration after the implementation of the two Spanish smoke-free bans (figure 2). Salivary cotinine concentration significantly increased by 28.7% (GM from 91.1 ng/ml to 117.3 ng/ml, p=0.015) after the implementation of the two Spanish smoke-free bans (Table 1). The increase in the salivary concentration was statistically significant among young people, high educated and in those who switched from conventional to RYO (Table 1). In addition, statistical significant decrease was found in the proportion of individuals classified in the medium category of FTCD score (from 23.3% to 9.1%, p=0.017) when comparing pre and post legislation. Nonetheless, no clear pattern of change was observed in the number of cigarettes smoked daily (figure 2). Even though, a non-

significant increase in the number of cigarettes smoked daily can be observed in those who switched from conventional cigarettes only to dual use (from 16.6 cigarettes/day to 24.3 cigarettes/day, p=0.270) when differentiating between kinds of tobacco smoked (figure 2). In this regard, 8.3% of smokers switched from conventional to dual use, 13.0% switched from conventional to RYO, and 59.1% smoked only conventional cigarettes before and after the two laws and.

Regarding other smoking characteristics (Table 2), we observed an increase in the use of regular cigarettes (from 66.6% to 76.3%, p=0.019), in the length of cigarettes left after smoking (from 1.13 cm to 2.26 cm, p=0.023) and in deep inhalations when smoking at the expense of the reduction of intermediate depth of inhalation (deep inhalation from 42.4% to 57.5%, p=0.001) along with a reduction in low frequency of inhalation (from 28.2% to 10.1%, p=0.036) (Table 2).

DISCUSSION

Our study shows an increase in salivary cotinine concentration of around 29% among continuing smokers after both Spanish smoking legislations, particularly among younger and high educated smokers. We also observed a switch in the type of tobacco used, from conventional to RYO cigarettes or to dual use in 21.3% of smokers. In addition, statistical significant decrease was found in the proportion of individuals classified as medium in the FTCD score.

The hardening hypothesis (21) suggests that smokers in the populations who quit over the time are those who are less dependent, and the remaining smokers are more dependent. However, previous studies have counteracted this hypothesis (22-24) using questionnaires to measure the tobacco or nicotine dependence. In this sense, we did not find differences in salivary cotinine concentration nor in FTCD scores among smokers before Spanish smoking legislations who quit smoking and continue smoking (data not shown). On the other hand, we found that continuing smokers had higher salivary cotinine. In this sense, using biomarkers as a proxy of tobacco dependence (25), our results could indicate that continuing smokers became more dependent after Spanish smoking legislations. However, our study did not show any significant increase in the FTCD score among smokers who continue smoking, this could be due to FTCD only measures the dependence of conventional manufactured cigarettes (20). A previous study showed that the FTCD has some limitations, such as low internal consistency, floor effects, and that it does not address important aspects of addiction to cigarettes (26). Although there is a positive relation between the FTCD score, tobacco consumption and salivary cotinine (25,26), other factors might also have an effect on cotinine concentration, such as smoking topography (27). According to our results, an increase in smoking regular cigarettes, in the centimeters left without smoking and in the depth of inhalation when smoking along with a reduction in low frequency of inhalation can be observed after the application of the Spanish tobacco laws. This could be explained because, under these smoking restriction policies, smokers have fewer opportunities to smoke in public places and lesser time to do it, thus changes in the smoking topography may be evident. In addition, the low

increase in salivary cotinine found in our study in high dependent smokers in baseline could be due to a ceiling effect, since the highest value of salivary cotinine before bans was observed in this group. Furthermore, it is important to bear in mind that the information about FTCD score and the number of cigarettes smoked daily was self-reported, therefore it can be subject to potential limitations related to survey based studies. Further research is needed to analyze possible factors related to cotinine concentration, as well as to ensure cotinine concentration properly measures nicotine dependence.

According to the Tobacco Control Scale report of 2013 (28), the Spanish score for its policies related to treatment to help smokers quit was low (6 out of 10 points) in comparison with its other policies score. This could mean that smokers may not receive the help needed to succeed when trying to stop smoking or that they are not properly identified. Therefore, there is a need to implement better treatments policies to help smokers stop smoking.

Additionally, our study showed a switch from conventional to RYO cigarettes or to dual use in 21.3% of continuing smokers, after both Spanish smoking legislations. Thereby, our results could be backing the hypothesis of a switch of smokers to cheaper tobacco products, such as RYO cigarettes, because the tobacco control policies, particularly increasing of prices, are traditionally focused on conventional cigarettes. Bearing this in mind, there is a need to equalize the prices of all tobacco products by applying the same taxing level as, indeed, is recommended by the article 6 of the FCTC (30). Furthermore, the highest value of salivary cotinine after Spanish smoking bans, according to the kind of tobacco smoked, was observed in

smokers who switched from conventional to RYO cigarettes or to dual use, may counteract the popular belief that RYO cigarettes are less harmful than conventional cigarettes. This aspect may also be involved in the observed increase in salivary cotinine after the implementation of Spanish smoking bans. Given the switch of smokers to other tobacco products, the FTCD score should be redefined and validated to measure cigarette dependence.

The main limitation of our study is the potential participation bias due to the attrition of the cohort of participants. In this sense, there were statistically significant differences according to age, level of education, and smoking status between the follow-up sample and the participants lost in the follow-up (31). The followed up sample overestimated young people and smokers in comparison with lost participants, for this reason the increase in salivary cotinine could be smaller among lost participants. On the other hand, our sample, being a cohort, overestimated the older people compared with the distribution of population in Barcelona. However, we weighted the sample to minimize these limitations and to generate estimations representative of the general population. Moreover, the baseline sample size was representative of the city of Barcelona (15,16) and the longitudinal design maximizes the internal validity of the study. Other potential limitations are those related to potential information biases derived from the use of a self-reported questionnaire to collect information, and non-response. However, trained interviewers administered a face-to-face questionnaire and used the same definition of smoking status in both studies, potentially increasing the internal validity of our results. In addition, we used salivary cotinine, a specific biomarker of nicotine.

In conclusion, this study shows a significant increase in salivary cotinine concentration among adult continuing smokers after both Spanish legislations. Moreover, we observed a shift in the type of tobacco product used, particularly from conventional cigarettes to RYO. Our results, therefore, suggest the need to extend tobacco control policies, focusing on reduction of use of any kind of tobacco product (i.e. equalizing the prices of all tobacco products) and implementing better treatment policies to help smokers stop smoking.

COMPETING INTERESTS

Authors declare that they have no conflicts of interest.

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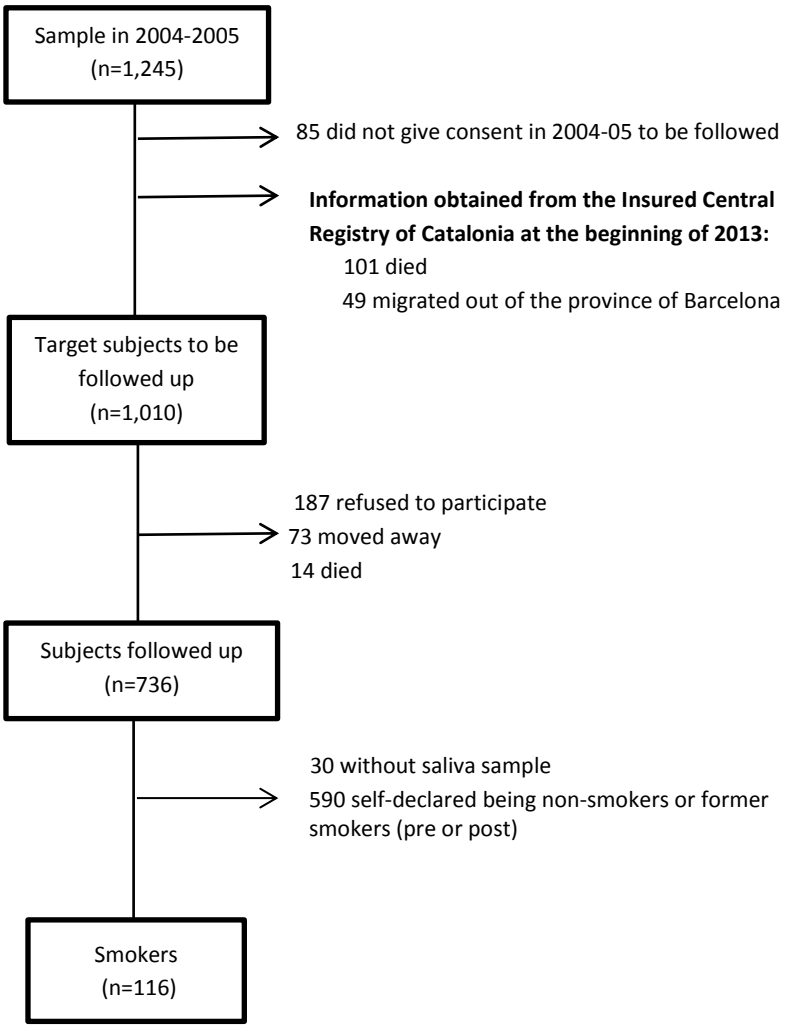
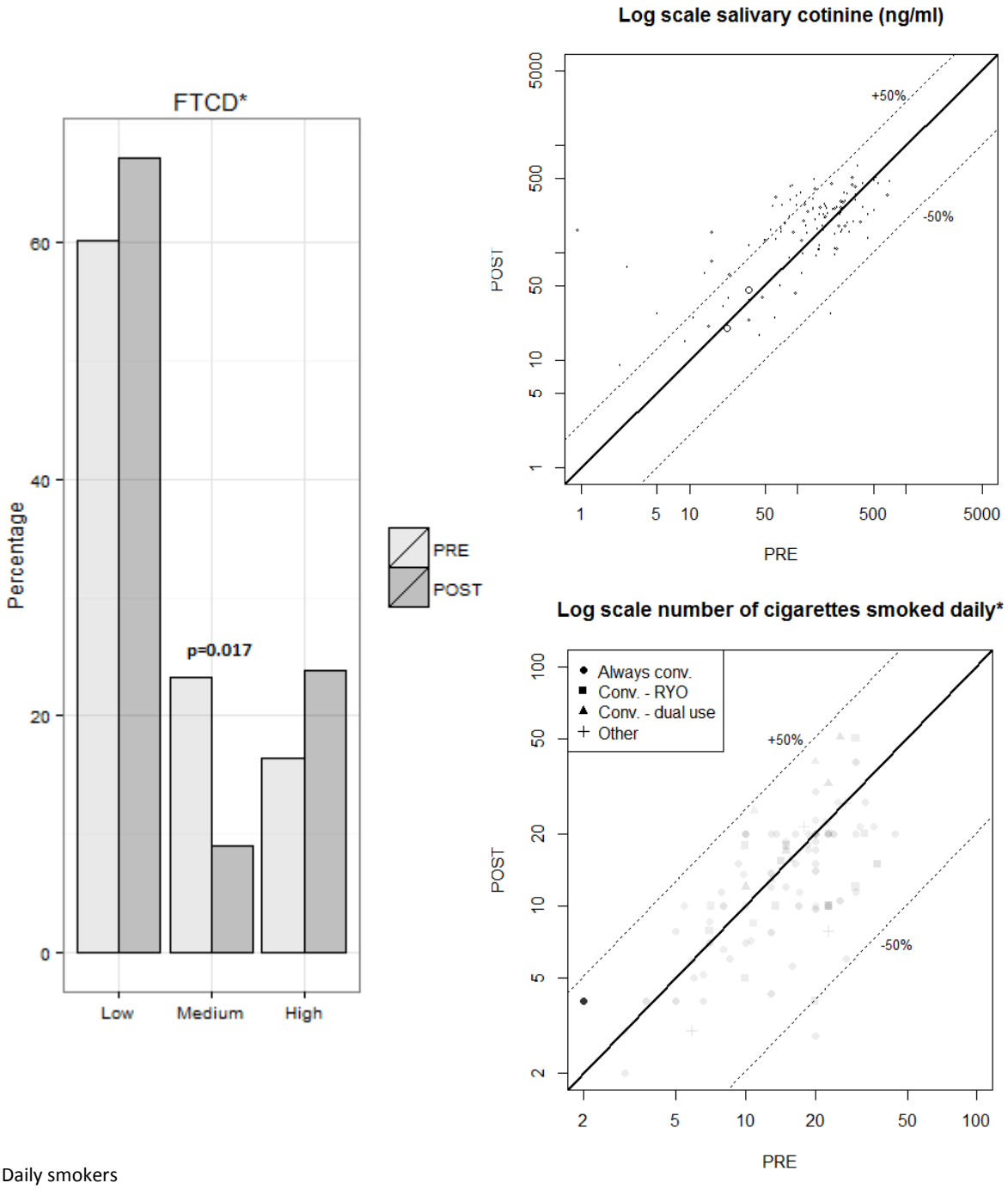
Figure1. Flow chart of sample followed-up from Barcelona, Spain, in 2013-2014.



Pre: before Spanish smoke-free bans (2004-2005).
Post: after Spanish smoke-free bans (2013-2014).

Figure 2. Changes in salivary cotinine concentration (log scale), in the number of cigarettes smoked daily (log scale), and in the Fagerström Test for Cigarette Dependence (FTCD, categorized as 'low' (≤4), 'medium' (5) and 'high' (≥6)) before and after the implementation of both Spanish smoking bans.



*Daily smokers

Statistical significant differences were only found in the 'medium' group when comparing FTCD categories pre and post legislation (proportion test).

Pre: before Spanish smoke-free bans (2004-2005).

Post: after Spanish smoke-free bans (2013-2014).

Table 1. Geometric mean (GM) and geometric standard deviation (GSD), adjusted linear mixed effect coefficient (% change*) and their 95% confidence interval (95%CIs) of salivary cotinine concentration (ng/mL) according to sociodemographic variables, kind of tobacco smoked, Fagerström Test for Cigarette Dependence score (FTCD) and stages of change before (2004-2005) and after (2013-2014) the implementation of both Spanish smoking legislations.

	n[a]	GM (GSD) ng/mL (PRE)	GM (GSD) ng/mL (POST)	% change* (95% CI)	p-value
Overall	116	91.1 (0.16)	117.3 (0.18)	28.7 (4.9; 58.0)	0.015
Sex					
Men	62	103.9 (0.26)	135.2 (0.28)	30.1 (-0.1; 69.4)	0.051
Women	54	78.3 (0.19)	99.6 (0.22)	27.2 (-7.8; 75.6)	0.143
Age					
26-44	62	104.3 (0.15)	174.3 (0.09)	67.2 (30.7; 113.8)	<0.001
45-64	34	132.7 (0.18)	112.9 (0.28)	-14.9 (-46.5; 35.2)	0.494
65-98	20	30.7 (0.22)	35.3 (0.34)	15.0 (-13.5; 52.9)	0.336
Educational level					
Low	46	102.1 (0.32)	112.5 (0.35)	10.2 (-11.8; 37.7)	0.392
Intermediate	33	100.9 (0.22)	142.2 (0.27)	40.9 (-21.1; 151.6)	0.246
High	37	72.4 (0.16)	104.0 (0.24)	43.8 (13.9; 81.4)	0.002
Kind of tobacco smoked					
Always conv.	64	106.6 (0.18)	114.9 (0.20)	7.8 (-18.0; 41.9)	0.590
Conv. – RYO	14	145.6 (0.16)	243.2 (0.12)	70.0 (16.7; 138.8)	0.005
Conv. – dual use	9	205.2 (0.16)	236.9 (0.14)	15.5 (-12.1; 51.6)	0.301
Other	21	74.3 (0.55)	80.8 (0.63)	8.8 (-15.2; 39.5)	0.509
$FTCD_d$ score (PRE)					
Low	53	115.7 (0.12)	137.4 (0.18)	18.7 (-15.3; 66.3)	0.319
Medium	20	86.6 (0.43)	103.3 (0.39)	19.3 (-0.9; 43.5)	0.062
High	14	237.6 (0.15)	272.3 (0.12)	14.6 (-12.8; 50.7)	0.329
Stages of Change (PRE)					
Precontemplation	6	186.7 (0.36)	257.1 (0.20)	37.7 (-26.0; 156.3)	0.313
Contemplation	9	136.8 (0.30)	172.5 (0.25)	26.1 (-11.5; 79.8)	0.200
Preparation	79	93.5 (0.21)	115.1 (0.23)	23.1 (-7.3; 63.6)	0.151

$FTCD_d$: FTCD daily smokers.

n[a]: The sum does not up the total for some variables because of some missing values.

Pre: Before Spanish smoke-free bans (2004-2005).

Post: After Spanish smoke-free bans (2013-2014).

% change*: Adjusted by sex, age, educational level.

P-value: Obtained through adjusted linear mixed effect coefficient.

Table 2. Prevalence and generalized linear mixed effect coefficient (Prevalence Ratio PR), or mean (standard deviation) and mean difference, about tobacco topography before (2004-2005) and after (2013-2014) the implementation of both Spanish smoking legislations.

	n[a]	PRE	POST	PR (95% CI)	p-value
Type of cigarettes (%)					
Regular	66	66.6	76.3	1.15 (1.02, 1.28)	0.019[1]
Other	33	33.4	23.7	0.71 (0.50, 0.99)	0.049[1]
Type of tobacco (%)					
Blond	82	82.2	88.1	1.07 (0.99, 1.16)	0.097[1]
Black	18	17.8	11.9	0.67 (0.42, 1.06)	0.086[1]
Filter (%)					
Yes	97	98	98	1.00 (0.98, 1.02)	0.96[1]
No	2	2	2	1.04 (0.35, 3.07)	0.94[1]
Length of cigarettes left after smoking in cm (mean, SD)	107	1.13 (0.12)	2.26 (0.39)	-	0.023[2]
Frequency of inhalation (%)					
Continuous	13	11.7	16.9	1.44 (0.83, 2.52)	0.198[1]
Regular	65	60.1	73	1.21 (0.86, 1.71)	0.264[1]
Scarce	30	28.2	10.1	0.36 (0.14, 0.93)	0.036[1]
Depth of inhalation (%)					
Superficial	17	16.2	24.7	1.56 (0.73, 3.32)	0.246[1]
Intermediate	45	41.4	17.8	0.43 (0.26, 0.72)	0.001[1]
Deep	46	42.4	57.5	1.35 (1.13, 1.61)	0.001[1]

n[a]: The sum does not up the total for some variables because of some missing values.

Pre: Before Spanish smoke-free ban of 2004-2005.

Post: After Spanish smoke-free ban of 2013-2014.

PR: Prevalence ratio

[1]Generalized linear mixed effect coefficient p-value.

[2]T-test for paired samples.

5.3 Assessment of salivary cotinine concentration among general non-smokers population: before and after Spanish smoking legislations

Assessment of salivary cotinine concentration among general non-smokers population: before and after Spanish smoking legislations

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ABSTRACT

Backgound: This study assesses the impact of Spanish smoking legislations on the second-hand smoke (SHS) exposure in an adult non-smoking population cohort in Barcelona (Spain).

Methods This is a longitudinal study, before and after the implementation of two national smoking bans, in a representative sample of adults (≥ 16 years old) from Barcelona (Spain) surveyed in 2004-2005 and followed-up in 2013-2014 (n=736). We only analyzed non-smokers (n=397). We conducted a survey about the self-reported exposure to SHS and obtained 9 ml of saliva sample for cotinine analysis following the same protocol. We calculate geometric means of salivary cotinine concentration and their geometric standard deviation. We use linear mixed effect models with individuals as random effects to model the percentage change in salivary cotinine concentrations and their 95% confidence intervals.

Results: The geometric mean of salivary cotinine concentration significantly decreased 88% (from 0.98 ng/mL to 0.12 ng/mL, p<0.001) and salivary cotinine concentration was significantly higher only among those declaring exposure to second-hand smoke at home (exposed=0.33 ng/mL vs non-exposed=0.11 ng/mL, p<0.001); after the implementation of the two Spanish smoke-free legislations.

Conclusion: There was a large reduction in the salivary cotinine concentration among adult non-smokers and higher cotinine concentrations among those declaring exposure to SHS at home after both legislations.

Keywords: Smoke-free legislation; *Secondhand smoke; Cotinine; Biomarker*

1. INTRODUCTION

The effects of secondhand tobacco smoke (SHS) on the health of non-smokers are well-known. SHS exposure has been associated with many adverse health effects [1] and it is classified as a Group I carcinogen in humans [2] by the International Agency for Research on Cancer (IARC). In 2010, WHO estimates that SHS exposure is responsible of about 600,000 deaths across the world each year [3]. In Spain, passive smoking at home and work caused 1,028 deaths in 2011 [4].

Consequently, several countries have implemented tobacco control legislations, as suggested by the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) [5]. Regarding Spain, two smoke-free laws have been passed after the approval of the WHO FCTC. On the 1st of January 2006, it came into effect a smoke-free legislation (Law 28/2005). This law was a great step forward for public health in Spain, but it was incomplete in terms of protection to SHS exposure because it allowed smoking in hospitality sectors depending on the size of venues [6]. Because of this exception this Spanish smoking law was known as the "Spanish model" [7]. The scientific evaluation of this law showed the need to promote a total ban [8-10] and motivated the modification of the law accordingly. Hence, a new law (Law 42/2010) came into effect on the 2nd of January 2011, applying the smoke-free regulation to all hospitality venues [11] without exception, and extending the prohibition to some outdoor areas, including hospital premises, educational campuses, and playgrounds.

In order to asses SHS exposure, self-reported data are likely to be imprecise. Thus, it is desirable to use biomarkers as they allow to objectively quantifying SHS exposure. In this

regard, cotinine, the main nicotine metabolite, has been widely used as a biomarker of tobacco exposure [12]. Cotinine concentration in biological fluids (blood, urine or oral fluid, widely referred to as saliva) [13] indicate tobacco exposure over the previous 1-2 days [14].

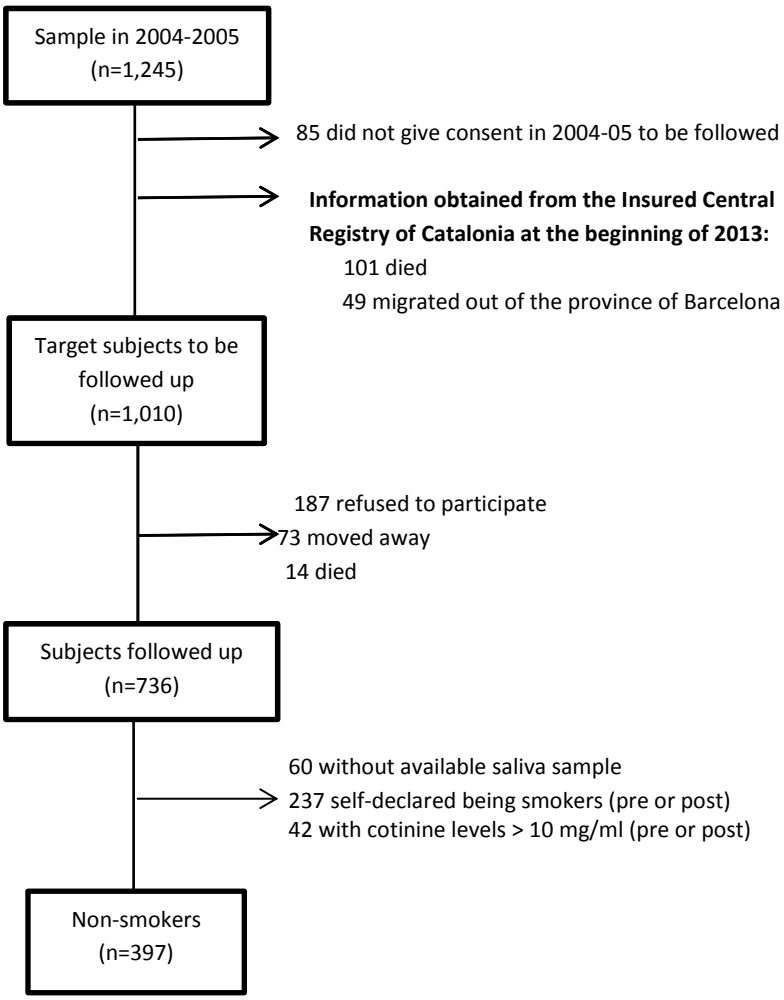
Currently, there are scarce studies that evaluate the impact of both Spanish smoking legislations using a general population cohort which increases the internal validity of the results [15]. Moreover, few studies assessed the legislations impact among general population using a specific biomarker of SHS exposure such as cotinine concentration, and only one in Spain using a repeated cross-sectional study [16]. In a previous Spanish cohort of hospitality workers, salivary cotinine concentration decreased significantly (by 56.6%) among hospitality workers at venues where smoking was totally banned after the Spanish partial ban (law 28/2005) took effect [17]. Therefore, the objective of this study is to evaluate the impact of both Spanish smoking legislations on the SHS exposure in an adult non-smoking population cohort in Barcelona (Spain) using salivary cotinine concentrations and information on self-reported exposure.

2. METHODS

This is a longitudinal study from a representative sample of the adult population (≥16 years) of the city of Barcelona (Catalonia, Spain). The baseline study was carried out during the years 2004-2005 [18,19] (n = 1,245) and follow-up took place in 2013-1014, after both Spanish smoking legislations (n=736).

From the baseline sample, we excluded 235 subjects, 150 after checking their data in the Insured Central Registry of Catalonia (101 died and 49 migrated out of the province of Barcelona) and another 85 without consent to be followed up or being minor (<18 years old) in 2004-2005 whose parents did not provide informed consent to be re-contacted. Follow-up was conducted between May 2013 and February 2014. In total, 72.9% of the eligible sample agreed to participate, 18.5% refused to participate, 7.2% had moved elsewhere and 1.3% had died. The final sample included 736 individuals (Figure 1).

Figure1. Flow chart of sample followed-up from Barcelona, Spain, in 2013-2014.



The final sample was skewed as slightly older in comparison with the general population of Barcelona. For this reason, we weight our data according to age distribution of the city of Barcelona to maintain its representativeness.

We administered the same questionnaire that gathered information on the smoking status, tobacco consumption and exposure to second-hand smoke before and after Spanish smoking legislations. Specifically, we obtained information about the self-reported exposure to SHS at home, work, public transport and leisure time (dichotomous variable of exposure to SHS in each setting). Exposure to SHS in any setting was defined as exposure in at least one of the above mentioned settings. We also obtained 9 ml of saliva sample (i.e. oral fluid) for cotinine analysis before and after the Spanish smoking legislations, following the same protocol before and after smoking legislations. Participants were asked to rinse their mouths and then suck a lemon candy (Smint) to stimulate saliva production. Saliva samples were frozen and sent to the 'Hospital del Mar' Medical Research Institute (IMIM) in Barcelona. Salivary samples from baseline survey (2004-2005) were analyzed 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 follow-up survey (2013-14) were analyzed with liquid chromatography coupled with tandem mass spectrometry (LC/MS/MS) [20] with multiple reaction monitoring. The limit of quantification was 0.1 ng/mL and the limit of detection was 0.03 ng/mL (quantification error <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 baseline survey (2004-2005) with cotinine concentrations below 1 ng/mL (n=

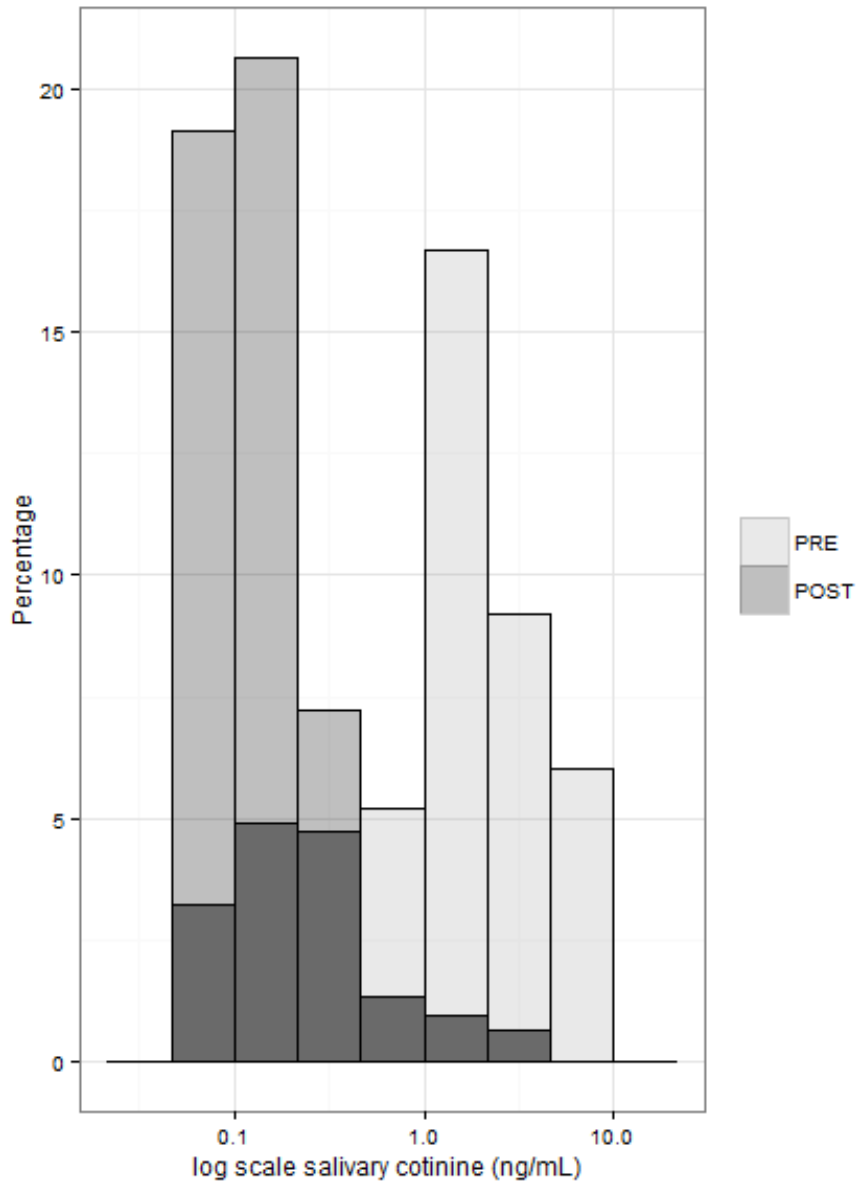
245) were reanalyzed with the LC/MS/MS method. For cotinine concentrations below the limit of quantification a value of half the level of quantification (0.05 ng/mL) was assigned.

The same definition of smoking status was used in both studies. We considered as non-smoker the person who declares to have never smoked or to have formerly smoked, and has a salivary cotinine concentration compatible with non-smoking (≤10 ng/ml) [21]. The final sample for this study consists of 397 non-smokers before and after the Spanish smoking legislations (Figure 1). Given the skewed distribution of cotinine concentration, we calculated geometric means (GM) and their geometric standard deviation (GSD). We used linear mixed effect models with individuals as random effects adjusted for sex, age and educational level to model the change percentage in salivary cotinine concentrations (after log 10 transformation) and their 95% confidence intervals. We obtained the p-value for the median difference through Wilcoxon test for paired samples and Mann Whitney test for independent samples. Moreover, the results were stratified by sex, age and educational level. The statistical program used was R-3.0.2 and Stata v14.

3. RESULTS

The percentage of participants with saliva samples with measurable concentrations of cotinine fell from 92.4% to 64.2% after both Spanish smoking legislations. We also found a leftward shift in the salivary cotinine distribution after both Spanish smoking legislations (Figure 2), i.e. it is more frequent to obtain lower values in the salivary cotinine concentration after the legislations.

Figure 2. Distribution (histogram) of cotinine in saliva (ng/mL) before and after the implementation of both Spanish smoking bans.



Pre: before Spanish smoke-free bans (2004-2005).
Post: after Spanish smoke-free bans (2013-2014).
The darker color in the histogram indicates the overlap of the two distributions.

The overall GM of salivary cotinine concentration significantly decreased 87.9% (from 0.98 ng/mL to 0.12 ng/mL, $p<0.001$) after the implementation of the two Spanish smoke-free bans (Table 1). We found a statistically significant decrease in the GM of salivary cotinine

concentration independently of the sociodemographic variables (sex, age, and level of education) (Table 1). Before both legislations, there was higher salivary cotinine concentrations among young (GM 26-44 years=1.12 ng/mL, GM 45-64 years=0.80 ng/mL, GM 65-98 years=0.87 ng/mL), men (GM men=1.22 ng/mL vs GM women=0.84 ng/mL), and with intermediate educational level (GM low level=0.78 ng/mL, GM intermediate level=1.11 ng/mL, GM high level=1.07 ng/mL). Nevertheless, after both legislations, the salivary cotinine concentration was similar according to sociodemographic variables (Table 1).

Table 1. Geometric mean (GM) and geometric standard deviation (GSD), adjusted linear mixed effect coefficient (% change*) and their 95% confidence interval (95%CIs) of salivary cotinine concentration (ng/mL) according to sociodemographic variables. Before (2004-2005) and after (2013-2014) the implementation of both Spanish smoking legislations.

	n	GM (GSD) ng/mL (PRE)	GM (GSD) ng/mL (POST)	% change *	p-value
Overall	397	0.98 (0.08)	0.12 (0.05)	-87.9 (-89.8; -85.6)	<0.001
Sex					
Men	170	1.22 (0.11)	0.12 (0.08)	-89.9 (-92.3; -86.7)	<0.001
Women	227	0.84 (0.10)	0.12 (0.06)	-86.2 (-88.9; -82.8)	<0.001
Age					
26-44	224	1.12 (0.11)	0.11 (0.07)	-90 (-92.3; -87.1)	<0.001
45-64	109	0.80 (0.11)	0.13 (0.07)	-83.8 (-87.3; -79.4)	<0.001
65-98	64	0.87 (0.16)	0.12 (0.10)	-85.6 (-90; -79.4)	<0.001
Educational level					
Low	120	0.78 (0.11)	0.14 (0.08)	-82.6 (-86.6; -77.5)	<0.001
Intermediate	100	1.11 (0.18)	0.12 (0.12)	-89.5 (-93.1; -84.1)	<0.001
High	177	1.07 (0.11)	0.11 (0.06)	-89.7 (-91.9; -86.9)	<0.001

*: adjusted by sex, age and educational level.
Pre: before Spanish smoke-free bans (2004-2005).
Post: after Spanish smoke-free bans (2013-2014).
P-value: Wilcoxon test for paired samples.

Before both legislations, salivary cotinine concentration was significantly higher among those declaring to be exposed to SHS at any setting (GM exposed=1.07 vs GM non-exposed=0.67) and at home (GM exposed=1.75 vs GM non-exposed=0.85) (data not shown). Although the higher prevalence of self-reported SHS exposure post-legislations was found in leisure time (50.8%), salivary cotinine concentration was significantly higher only among those declaring to be exposed to SHS at home (GM exposed=0.33 vs GM non-exposed=0.11) (Table 2).

Table 2. Prevalence of self-declared exposure to SHS at all the analyzed settings, geometric mean (GM) and geometric standard deviation (GSD), of salivary cotinine concentration (ng/mL) according to self-declared exposure to SHS after the implementation of both Spanish smoking legislations (2013-14).

	n[a]	% POST	Geom. Mean (POST)	p-value
SHS exposure (Any setting)				
Yes	225	56.7	0.13 (0.07)	0.080
No	172	43.3	0.11 (0.7)	
SHS exposure (Home)				
Yes	38	9.5	0.33 (0.18)	<0.001
No	359	90.5	0.11 (0.05)	
SHS exposure (Work)				
Yes	67	29.4	0.12 (0.13)	0.876
No	161	70.6	0.11 (0.08)	
SHS exposure (Public transport)				
Yes	15	4.7	0.09 (0.18)	0.542
No	291	95.3	0.12 (0.06)	
SHS exposure (Leisure time)				
Yes	201	50.8	0.13 (0.07)	0.077
No	194	49.2	0.11 (0.06)	

n[a]: The sum does not up the total for some variables because of some missing values.
Post: after Spanish smoke-free bans (2013-2014).
P-value: Mann-Whitney test for independent samples (Mann Whitney)

4. DISCUSSION

Our study shows an important reduction of salivary cotinine concentration (around 88%) among non-smokers after both Spanish smoking legislations independently of sociodemographic variables.

In this line, a previous repeated cross-sectional study showed that GM of the salivary cotinine concentration, among all adult non-smokers in Barcelona (Spain), significantly decreased, from 0.93 ng/mL before the legislations, to 0.12 ng/mL after the legislations [16]. Moreover, the change percentage in cotinine concentration obtained in this same study, after adjusting for sex, age, and educational level, was 87.9% [16]. Similarly, another Spanish study showed a significant decrease in median urinary cotinine concentrations between 2010 (0.8 ng/mL) and 2011 (0.7 ng/mL) among passive smokers [22].

Other Spanish studies showed significant decrease in the environmental nicotine in hospitals after both Spanish legislations [23] and in hospitality venues between 2010 and 2011 [24]. Moreover, another longitudinal study, showed a significant decrease in the prevalence of self-declared SHS exposure at workplaces, during leisure time, at home, and public transport after the application of the two Spanish smoking legislations [25]. Other studies, carried out in Spain using questionnaire, showed a decrease in self-declared SHS exposure in all the studied settings after the application of the smoking legislations [16,26,27]. Similar results can be found in Ireland [28], Scotland [29], Italy [30], and USA [31]. In Europe, a secondary analysis showed that the enforcement of smoke-free legislation is inversely associated with SHS exposure [32].

Although the higher prevalence of self-reported SHS exposure post-legislations was found in leisure time (50.8%), our results show higher cotinine concentrations among those declaring exposure to SHS at home. This could be because the exposure in leisure time, particularly in hospitality venues, are shifted to the entrances of venues [24] reducing the time and intensity of exposure. Moreover, in a regular day people usually spend more time at home than at leisure time, therefore, being exposed at home could be harder in terms of time and intensity. In this sense, an increase in the prevalence of smoke-free homes was observed after the implementation of the two Spanish smoke-free bans in Spain [27] and more than half (57.4%) of the population of Barcelona (Spain) had complete indoor smoke-free rules at home in 2013-2014 [33]. Moreover, in 2011, 6.7% of non-smokers reported SHS exposure at home indoors, 18.8% at home outdoors, 1.3% at work indoors, and 15.0% at work outdoors [34]. Therefore, there is a need to implement some public health interventions to continue reducing SHS exposure at home. The interventions may focus in convincing or helping smokers to quit or in getting smokers moving their smoking away from their home, that is to say, trying to promote smoke-free homes and smoke-free multi-unit housing [35,36].

The main limitation of our study is the potential participation bias due to the attrition of the cohort of participants. In this sense, there were statistically significant differences according to age, level of education, and smoking status between the follow-up sample and the participant lost in both stages of the follow-up [27]. Follow-up participants overestimate the young people and smokers in comparison with lost participants, for this reason the reduction of SHS exposure could be higher among lost participants. On the other hand, our final sample overestimated the older people compared with the distribution of population in Barcelona. However, we weighted the sample to minimize these limitations and to generate estimations representative of the general population. Moreover, the baseline sample size was

representative of the city of Barcelona [18,19] and the longitudinal design of our work maximizes the internal validity of the study. Other potential limitations are those related to survey based studies, as the use of a questionnaire to collect self-reported information, and bias due to non-response. However, we used salivary cotinine as a specific biomarker of SHS exposure, we use the same definition of smoking status in both studies, we remove individuals with a salivary cotinine concentration incompatible with non-smoking (>10 ng/ml) and we used a face-to-face questionnaire with trained interviewers potentially increasing the internal validity of our results.

5. CONCLUSION

In conclusion, this study shows a large reduction in the salivary cotinine concentration among adult non-smokers after both Spanish legislations independently of sociodemographic variables. However, our results show higher cotinine concentrations among those declaring exposure to SHS at home after both legislations, revealing the need to implement some public health interventions to continuing reducing SHS exposure in homes.

6. COMPLIANCE WITH ETHICAL STANDARDS

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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5.4 Impact of the Spanish smoking legislations in the adoption of smoke-free rules at home: a longitudinal study in Barcelona (Spain)

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Impact of the Spanish smoking legislations in the adoption of smoke-free rules at home: a longitudinal study in Barcelona (Spain)

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ABSTRACT

Objective To assess the impact of two Spanish smoking legislations in the adoption of voluntary smoke-free-homes rules in Spain.

Methods This is a longitudinal study, before and after the implementation of two national smoking bans (in 2005 and 2010), in a representative sample (n=1245) of non-institutionalised adults (≥16 years) from Barcelona (Spain) surveyed in 2004–2005 and followed up in 2013–2014. The final sample analysed was 736 individuals (400 women and 336 men). We defined smoking rules in the houses as complete (when smoking was not allowed in the household), partial (when smoking was allowed in some places inside the house) or absent (when smoking was allowed everywhere). We calculated relative changes in the prevalence of smoking rules in homes before and after 2 national smoking legislations by means of prevalence ratios (PRs) and their 95% CIs.

Results The households with voluntary smoke-free rules (complete or partial) relatively increased 31% after Spanish smoking bans (from 55.6% to 72.6%, p<0.001). The houses with complete rules relatively increased 57% (from 23.9% to 37.6%, p<0.001) whereas the houses with partial rules increased 11% (from 31.7% to 35.0%, p=0.148). The increase of any type of rules (complete and partial) was statistically significantly independent of sex (PR between 1.29 and 1.33), age (PR between 1.24 and 1.33), educational level (PR between 1.19 and 1.47) and minimum age in house (PR between 1.12 and 1.40). However, this increase was statistically and significantly higher only among never smokers (PR=1.46) at baseline.

Conclusions The implementation of the smoke-free regulations in public and work places in Spain was associated with an increasing of voluntary adoption of smoke-free rules in homes. According to our data, the Spanish smoking bans did not shift the tobacco consumption from public and work places to private places (homes).

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INTRODUCTION

According to the Tobacco Atlas, globally, about 40% of children and a third of non-smoking adults were exposed to secondhand smoke (SHS) in 2004.[1] Moreover, SHS exposure has been classified as a type I carcinogen by the International Agency for Research on Cancer,[2] being responsible for around 603, 000 deaths worldwide.[3]

This has led to several countries to implement tobacco control legislations, particularly smoke-free public and workplaces, as suggested by the WHO Framework Convention on Tobacco Control (WHO FCTC).[4] In fact, their implementation has already been associated with a reduction in the exposure to SHS, the incidence of acute coronary events, respiratory symptoms, improvements of perinatal and child health, along with a moderate decrease in tobacco smoking prevalence.[5–7] Furthermore, SHS exposure during pregnancy has harmful effects on placenta and fetal growth[8] and is associated with preterm labour,[9 10] intrauterine growth restriction and low birth weight.[8]

Nevertheless, private places (mainly cars and homes), where children are more exposed,[11] are never or rarely included in tobacco control policies. However, the household is usually the main source of exposure to SHS in children.[11] A study carried out in 21 countries showed that almost 50% of children had been exposed to SHS in the home (daily, weekly or monthly) between 2009 and 2013.[12] In addition, children are especially vulnerable to SHS exposure due to them breathing more rapidly, inhaling more pollutants per pound of body weight than adults,[13] with an increased risk of sudden infant death syndrome, acute respiratory infections, ear problems and mental disorders.[14–16]

In Spain, two smoke-free laws have been passed after the approval of the FCTC. In 2005, a smoke-free legislation (law 28/2005) came into effect. This law was a great advancement for public health in Spain. The ban was a compendium of public health measures against smoking and included regulations on publicity, sale, supply and consumption of tobacco products.[17] Smoking was banned in all indoor workplaces, public places, public transport facilities including enclosed stations, hospitals and other healthcare facilities, schools and universities as well as in retail stores and shopping centres. However, hospitality venues were subject to only a partial ban. In bars and restaurants of $<100\ m^2$, the proprietor could choose between permitting or prohibiting smoking. Bars and restaurants larger than $100\ m^2$ are defined as smoke free, but the law allows the proprietor to provide a physically separated and independently ventilated smoking area comprising <30% of the total floor area. For this exception the Spanish smoking law was known as the 'Spanish model'.[18] The scientific evaluation of this law showed the need to promote a total ban[19–21]

and motivate the modification of the law in 2010 (law 42/2010) that extended the smoke-free regulation to all hospitality venues[22] without exception and extended the ban to some outdoors areas, including hospital premises, educational campuses and playgrounds.

In Barcelona (Spain), in 2011–2012, 84% of smokers reported smoking at home, and 35.9% of them smoked in outdoor areas of the home.[23] Moreover, a common belief among smokers is that cigarette smoking in outdoor places does not affect indoor places,[23] whereas a previous study indicated that SHS from outdoors settings drifts to adjacent indoors spaces.[24] However, currently, few studies have evaluated the impact of Spanish smoke-free legislations in SHS exposure at home[25 26] and there is a lack of information in Spain, to the best of our knowledge, on the impact of the smoke-free laws in the adoption of smoke-free homes (SFHs). Therefore, the objective of this study is to assess the impact of Spanish tobacco control legislations in the voluntary adoption of SFHs rules in Spain.

METHODS

This is a longitudinal study of a representative sample of the adult (≥16 years) non-institutionalised population of Barcelona (Spain; n=1,245, 694 women and 551 men) called 'determinants of cotinine phase 3' project (dCOT3, website: http://bioinfo.iconcologia.net/es/content/estudio-dcot3). The baseline survey was conducted between 2004 and 2005, and it is detailed elsewhere.[27 28] We followed up adult participants who responded to a face-to-face questionnaire in 2004–2005 and agreed to take part in future studies. At the beginning of 2013, we updated the vital status and contact information (addresses and telephone numbers) of all participants teaming with Insured Central Registry of Catalonia. We restricted the follow-up to the participants who were alive in 2013 and still lived in the province of Barcelona.

We traced 1010 participants out of the 1245 from the baseline study (101 died, 49 migrated out of the province of Barcelona, and 85 did not give consent to be followed or were minors, <18 years, in 2004–2005 because their parents did not provide consent to be recontacted). The percentage of follow-up in this first stage was 81.1%. The follow-up survey was conducted between May 2013 and February 2014. In total, 72.9% of the eligible sample agreed to participate and answered the questionnaire (736 of 1010 traced, second stage of follow-up), 18.5% refused to participate, 7.2% moved elsewhere and 1.3% died. The final sample analysed was 736 individuals (400 women and 336 men). Finally, the percentage of participation in both stages was 59.1% (736 of 1245). There were no statistically significant differences between the followed up sample (n=736) and the participants lost in the second stage (n=274) according to age, sex, level of education and smoking status. However, there were statistically significant differences according to age, level of education and smoking status between the follow-up sample (n=736) and the participants lost in both stages of the follow-up (n=509; table 1). For this reason, the final sample was skewed as older in comparison with the population of Barcelona. Therefore, we use inverse probability weights to weigh our data according to age distribution of the city of Barcelona to maintain the representativeness of the sample.

Both questionnaires (before and after the two laws) included the following question about the smoking rules at home: 'Which of the following situations best describe the smoking rules inside your house?' with three possible answers: 'Nobody can smoke', 'You can only smoke in some places' and 'You can smoke everywhere'. According to this question we defined smoking rules inside the household as complete (when smoking was not allowed inside the house), partial (when smoking was allowed in some places inside the house) or absent (when smoking was allowed everywhere inside the house). Finally, we dichotomised the variables as 'Rules' indicating whether there were any kind of smoking rules (complete or partial) and 'No rules' indicating there were no smoking rules in the house.

We calculated the prevalence and the prevalence ratio (PR) with their 95% CIs of the voluntary adoption level of smoke-free rules in homes before and after the implementation of the two national tobacco control policies. We also used Generalized Estimating Equation (GEE) models with individuals as random effects and using Poisson family with log link, to calculate the PR adjusted for sex, age and month when the survey was conducted. Moreover, the results were stratified by sex, age, educational level (categorised as low: unschooled, elementary school completed or uncompleted and special education; intermediate: high school and training cycles and high: university education), married, minimum age in house (categorised as <5, 5–14 and ≥15 years), smoking status (current, former and never smoker) at baseline, intention to quit (indicating whether the person is trying to quit smoking at that time or not) and the Fagerström Test for Cigarette Dependence (FTCD) score. We also included information about the places where smoking is allowed in houses with partial SFH through the following open question: 'in what places of your home can you smoke?'. The statistical programs used were STATA V.14 and R V.3.0.2.

Table 1 Differences (prevalence for qualitative variables and mean (SD) for quantitative variable) between follow-up sample and lost in both stages of the follow-up

	Lost (both stages) n=509	Follow-up n=736	p Value
Sex			
Men	42.2%	45.7%	0.257*
Women	57.8%	54.3%	
Age (years) mean (SD)	58 (39.00)	49 (26.25)	<0.001†
Age			
<45	35.2%	43.9%	<0.001*
45–64	22.0%	37.5%	
≥65	42.8%	18.65	
Educational level			
Primary	53.0%	38.9%	<0.001*
Secondary	20.5%	24.2%	
Superior	26.5%	36.9%	
Smoking status (follow-up)			
Smoker	24.1%	31.1%	0.009*
No smoker	75.9%	68.9%	

*χ^2 test.
†Mann-Whitney test.

RESULTS

A 55.6% of households declared having some type of voluntary SFH (complete or partial) at baseline in 2004–2005 (before the Spanish smoking bans came into force). This percentage significantly rose to 72.6% after the implementation of the two Spanish smoke-free bans (table 2). In particular, we observed a statistically significant relative increase of 57% in the prevalence of complete SFH (from 23.9% to 37.6%, PR=1.57) while the

Table 2 Prevalence, prevalence ratio (PR), adjusted prevalence ratio (PRa) and their 95% CIs of the voluntary adoption of smoke-free homes (SFHs) rules (complete and partial) before (2004–2005) and after (2013–2014) the implementation of both Spanish smoking bans

	Any type of rules (complete and partial)					Complete rules				Partial rules			
	n[a]	Pre %	Post %	PR (95% CI)	PRa (95% CI)	Pre %	Post %	PR (95%CI)	PRa (95%CI)	Pre %	Post %	PR (95% CI)	PRa (95% CI)
Overall	731	55.6	72.6	1.31 (1.22 to 1.40)***	1.30 (1.20 to 1.41)***	23.9	37.6	1.57 (1.36 to 1.83)***	1.61 (1.35 to 1.93)***	31.7	35.0	1.11 (0.96 to 1.27)	1.07 (0.91 to 1.26)
Sex													
Men	336	51.8	68.8	1.33 (1.18 to 1.50)***	1.31 (1.14 to 1.49)***	21.5	35.7	1.66 (1.29 to 2.12)***	1.64 (1.24 to 2.16)**	30.3	33.1	1.10 (0.88 to 1.36)	1.07 (0.84 to 1.37)
Women	395	58.8	75.9	1.29 (1.18 to 1.41)***	1.28 (1.16 to 1.42)***	25.9	39.3	1.51 (1.26 to 1.82)***	1.60 (1.28 to 2.01)***	32.9	36.6	1.11 (0.93 to 1.33)	1.04 (0.84 to 1.29)
Age													
26–44	418	57.5	76.6	1.33 (1.21 to 1.47)***	1.29 (1.15 to 1.43)***	22.5	37.2	1.65 (1.32 to 2.07)***	1.63 (1.24 to 2.14)***	35.1	39.6	1.13 (0.94 to 1.36)	1.08 (0.88 to 1.33)
45–64	201	52.3	67.0	1.28 (1.14 to 1.44)***	1.34 (1.17 to 1.53)***	21.5	33.1	1.53 (1.19 to 1.98)**	1.73 (1.29 to 2.31)***	30.7	33.9	1.10 (0.89 to 1.38)	1.08 (0.84 to 1.39)
65–98	112	54.3	67.6	1.24 (1.04 to 1.49)*	1.29 (1.05 to 1.59)*	33.5	47.6	1.42 (1.09 to 1.85)*	1.48 (1.09 to 2.00)*	20.8	20.0	0.96 (0.62 to 1.51)	0.96 (0.53 to 1.73)
Educational level													
Low	239	56.4	68.5	1.21 (1.08 to 1.36)**	1.25 (1.10 to 1.43)**	25.1	35.5	1.41 (1.13 to 1.77)**	1.48 (1.10 to 1.99)**	31.2	33.0	1.05 (0.86 to 1.31)	1.07 (0.83 to 1.37)
Intermediate	206	56.9	67.9	1.19 (1.04 to 1.36)**	1.21 (1.05 to 1.40)**	23.2	35.6	1.55 (1.14 to 2.09)**	1.59 (1.13 to 2.25)**	33.8	32.1	0.95 (0.72 to 1.25)	0.96 (0.70 to 1.32)
High	286	53.9	79.6	1.47 (1.30 to 1.67)***	1.41 (1.23 to 1.60)***	23.4	40.7	1.74 (1.35 to 2.23)***	1.76 (1.31 to 2.37)***	30.5	38.9	1.27 (1.01 to 1.61)*	1.14 (0.87 to 1.50)
Married													
Yes	491	58.2	71.8	1.23 (1.13 to 1.34)***	1.26 (1.15 to 1.38)***	24.2	37.7	1.55 (1.30 to 1.86)***	1.61 (1.31 to 1.97)***	33.9	34.1	1.00 (0.85 to 1.19)	1.01 (0.83 to 1.22)
No	240	52.5	73.8	1.40 (1.24 to 1.59)***	1.34 (1.17 to 1.54)***	23.5	37.5	1.60 (1.25 to 2.04)***	1.61 (1.18 to 2.20)**	29	36.2	1.25 (0.99 to 1.58)	1.14 (0.87 to 1.50)
Minimum age in house													
0–4	62	78.6	87.6	1.12 (0.98 to 1.27)	1.06 (0.95 to 1.18)	27.3	40.5	1.48 (0.95 to 2.30)	NC	51.3	47.1	0.92 (1.67 to 1.27)	NC
5–14	112	67.4	75.9	1.13 (0.95 to 1.34)	1.13 (0.94 to 1.35)	27.8	36.9	1.32 (0.89 to 1.98)	NC	39.6	39.0	0.99 (0.71 to 1.36)	1.00 (0.72 to 1.40)
≥15	491	49.6	69.6	1.40 (1.27 to 1.54)***	1.41 (1.26 to 1.57)***	22.6	36.2	1.60 (1.33 to 1.93)***	1.62 (1.27 to 2.05)***	27	33.4	1.23 (1.02 to 1.49)*	1.23 (0.98 to 1.55)**
Smoking status (baseline)													
Current	252	55.9	62.7	1.12 (0.98 to 1.28)	1.11 (0.95 to 1.30)	14	17.8	1.27 (0.83 to 1.93)	1.33 (0.78 to 2.28)	24.8	28.1	1.07 (0.89 to 1.30)	1.07 (0.86 to 1.33)
Former	188	56.8	75.6	1.33 (1.18 to 1.50)***	1.27 (1.11 to 1.46)**	28.2	42.9	1.52 (1.18 to 1.96)**	1.36 (1.03 to 1.80)*	41.8	44.9	1.14 (0.86 to 1.50)	1.20 (0.88 to 1.63)
Never	291	54.5	79.4	1.46 (1.30 to 1.64)***	1.45 (1.29 to 1.64)***	29.7	51.4	1.73 (1.42 to 2.10)***	1.95 (1.54 to 2.46)***	28.6	32.6	1.13 (0.85 to 1.50)	0.94 (0.67 to 1.31)
Intention to quit													
Yes	23	56.2	62.3	1.11 (0.67 to 1.82)	1.09 (0.46 to 2.59)	22.1	20.3	0.92 (0.25 to 3.35)	NC	34	41.9	1.23 (0.54 to 2.80)	NC
No	174	58.3	58.9	1.01 (0.88 to 1.16)	1.04 (0.89 to 1.21)	9.4	11.5	1.23 (0.70 to 2.15)	NC	48.9	47.5	0.97 (0.81 to 1.16)	1.00 (0.80 to 1.26)
FTCD													
≥4	121	65.7	65.1	0.99 (0.85 to 1.15)	1.00 (0.82 to 1.21)	16.1	13.8	0.85 (0.49 to 1.48)	NC	49.6	51.3	1.03 (0.83 to 1.29)	1.04 (0.77 to 1.40)
5	23	51.8	43.3	0.84 (0.45 to 1.56)	NC	0	11.7	–	–	51.8	31.5	0.61 (0.32 to 1.15)	NC
>5	27	38.5	54.2	1.41 (0.85 to 2.34)	NC	0	9.3	–	–	38.5	44.9	1.17 (0.72 to 1.89)	NC

*p<0.05, **p<0.01, ***p<0.001.
n[a]: the sum does not up the total for some variables because of some missing values.
PRa: prevalence ratio adjusted for sex, age and month when the survey was conducted.
Pre: before Spanish smoke-free bans (2004–2005).
Post: after Spanish smoke-free bans (2013–2014).
NC, non-converging GEE model with random effects.

increase in the prevalence of houses with partial SFH was not statistically significant (from 31.7% to 35.0%, PR=1.11). We also observed a statistically significant decrease in the prevalence of houses without smoking rules (from 44.4% to 27.4%, PR=0.62). We obtained similar PR adjusting by sex, age, and month when the survey was conducted (table 2).

The increase of any type of rules (complete and partial) was statistically significantly independent of sex (PR man=1.33 vs PR women=1.29), age (PR 65–98 years=1.24 and PR in 26–44 years 1.33), educational level (PR intermediate level=1.19 and PR high level=1.47) and minimum age in house (PR 0–4 years=1.12 and PR ≥15 years=1.40). However, the increase was statistically and significantly higher only among never smokers (PR=1.46) at baseline (table 2). We obtained similar PR after adjusting for sex, age and month where the survey was conducted (table 2). The prevalence of any type of SFH rules before and after the implementation of the two national smoke-free legislations were the highest in house where minors lived (<15 years); however, the increase was not statistically significant (table 2). Among smokers, the highest increase of SFH was observed among those who had intention to quit and higher FTCD (>5 points) although the increase was not statistically significant (table 2).

Regarding complete SFH, we observed a higher increase among men than women (PR in men=1.66 vs PR in women=1.51), young people[26–44] (PR=1.65), with higher education (PR=1.74), with a minor member at home (<15 years) (PR=1.60) and never smokers at baseline (PR=1.73). A similar pattern was observed in the PR of partial SFH (table 2).

We observed that, in houses with partial SFH rules, outside areas of the houses (balconies, courtyard, terraces and gardens) were the places where there was increase in smoking after the Spanish smoking bans (from 32.6% to 70.0%; PR=2.15, 95% CI 1.66 to 2.86) while inside it decreased, such as common areas (from 9.9% to 2.3%, PR=0.23, 95% CI 0.05 to 0.49) and the dining room (20.7% to 2.5%; PR=0.12, 95% CI 0.03 to 0.23). Similar results were observed in the PR of the places where smoking is allowed in houses adjusting by sex, age and the month where the survey was conducted.

DISCUSSION

Our results show that there is an increase in the prevalence of SFH, particularly in the case of a complete SFH, after the implementation of the two Spanish smoke-free bans in 2006 and 2011. This result is in agreement with previous ecological studies conducted in Europe[29 30] which found a positive correlation between the level of implementation of the smoke-free legislation and the prevalence of SFH rules adoption. At individual level, data from Scotland,[11] Ireland, France, Germany and the Netherlands[31] show a significant increase in SFH prevalence after the implementation of tobacco control laws. Similar results were found in the USA,[32] Canada, the UK and Australia.[33] Confirming the positive impact of smoke-free bans in adopting SFH rules in a Southern Mediterranean population with still a relatively high prevalence of smoking is of importance to reassure the power of smoke-free bans for tobacco control.

Our results show a greater impact of complete SFH than partial SFH. In this line, the study conducted in five European countries among adult smokers,[31] showed a greater impact of complete SFH while the PR of houses with partial rules remained more stable. The Scottish study conducted among children showed that children surveyed after the implementation of the smoke-free legislation were 25% less likely to have partial home rules than those surveyed before its introduction.[11] Moreover, a US study found a dose–response relationship between the implementation of tobacco control laws and the voluntary adoption of SFH, being full coverage laws associated with higher odds of adopting a complete SFH than partial coverage laws.[34]

Furthermore, previous studies showed that the SFH rules are more common in households inhabited with married people,[31] non-smoking adults[33 35–37] and with children.[31 33 35–37] Some studies also showed the SFH can result in a reduced exposure to SHS in children[37 38] and in a reduction in consumption over time, and increased quitting among smokers helping them to remain abstinent.[39] We found a higher increase of SFH after the implementation of Spanish smoking bans among men, young people, persons with high educational level, singles and never smokers. However, we found the lowest increase of SFH rules in houses where a minor lives and an indirect relation between the minimum age at home and the prevalence of SFH (data not shown). This result could be due to a 'ceiling effect', since the prevalence of SFH in these households was the highest before the bans.

Our results also show an increased prevalence of allowing smoking in most ventilated places or outside areas, in houses with partial SFH after the implementation of the Spanish smoke-free legislations. This could be due to an increasing risk perception of SHS exposure in the population. However, although this could lead to a decrease in the SHS exposure at homes, it could also result in an increase in the SHS exposure between neighbours. In a study carried out in 2010 in Denmark, 22% of those living in multiunit dwellings reported exposure to neighbour smoke and 58% of the exposed people preferred to live in smoke-free buildings.[40] In any case, currently smoke-free multiunit housing are still uncommon in Europe although are gaining popularity in the USA where multiunit housing operators reported having complete or partial smoke-free building policies for at least some of their properties.[41]

The tobacco industry and the hospitality sector, during the debate on implementation of smoke-free policies in different countries, argued that the restriction of smoking in public places will displace tobacco consumption to private venues, particularly in homes.[42] Hence, it was expected that the exposure to SHS among children in households would have increased after the implementation of the two national smoking bans. In this sense, there are only two studies,[14 43] to the best of our knowledge, conducted in the USA and Hong Kong supporting that hypothesis. Our results, and the results from other studies,[11 29–34] counteract the displacement hypothesis. Moreover, we observed a higher increase in complete SFH and in the outdoor places as the venues designed to smoking in partial SFH. In addition, some other studies[44 45] have shown a widespread support to smoking restrictions in all public places in those countries where tobacco control policies are more advanced. In particular, an ecological study, found a positive strong correlation between the level of smoke-free legislation across European countries and the support to smoking bans in restaurants, bars, pubs and clubs.[44] Similar results were observed in the USA, where increasing antismoking climate correlates with the decline in smoking prevalence, the increase in antismoking policies and public health awareness reports.[45]

Although the prevalence of SFH has increased, our data showed that currently around 30% of households did not have any voluntary smoke-free rules after the implementation of the Spanish smoking legislation in 2010. Moreover, around half of

the houses with SFH rules have a partial rule. In this sense, a previous study[46] using cotinine as a biomarker of SHS exposure concluded that the home continues to be the main source of SHS exposure for non-smokers who live in non-SFHs. Therefore, there is a need to implement some public health interventions to continuing reducing SHS exposure in homes. The interventions may focus in convincing or helping smokers to quit or in getting smokers moving their smoking away from their home, that is to say, trying to promote SFHs and smoke-free multiunit housing.[47 48]

The main limitation of our study is the potential of participation bias due to the attrition of the cohort of participants. In this sense, there were statistically significant differences according to age, level of education and smoking status between the follow-up sample and the participants lost in both stages of the follow-up. Follow-up participants overestimated the young people and smokers in comparison with lost participants (table 1), for this reason the increase of SFH could be higher among lost participants. On the other hand, our final sample overestimated the older people compared with the distribution of population in Barcelona. However, we weighted the sample to minimise these limitations and to generate estimations representative of the general population. Moreover, the baseline sample size was representative of the city of Barcelona[27 28] and the longitudinal design of our work maximises the internal validity of the study. Other potential limitations are those related to survey-based studies, as the use of a questionnaire to collect self-reported information, the potential for over-reporting of SFH due to social desirability (unlikely, since it has received few or null attention by the media) and bias due to non-response. However, by using a face-to-face questionnaire with trained interviewers we potentially increased the internal validity of our results as compared with internet and self-administered surveys in order to avoid misinterpretation of the questions.[49] Finally, we have not gathered information about the prevalence of SFH between both surveys to assess the impact of both Spanish legislations (independently or combined)

In conclusion, the implementation of the two smoke-free legislations in Spain is related to an increasing of voluntary adoption of SFH rules, in particular with an increase in complete SFH rules. According to our data, the Spanish smoke-free bans did not shift the tobacco consumption from public and work places to private places (homes). Unfortunately, one of three households in Spain still do not have any type of smoke-free rule. For this reason, in Spain, a public health priority should be promoting the adoption of SFH rules.

What this paper adds

- The implementation of the smoke-free regulations in public and workplaces in Spain (law 28/2005 and law 42/2010) was associated with an increase in voluntary adoption of smoke-free rules in homes, particularly complete smoke-free homes.
- In houses with partial smoke-free rules, outside areas of the houses (balconies, courtyard, terraces, and gardens) were the places that showed increase in smoking after Spanish smoking bans.
- According to our data, the Spanish smoke-free bans did not shift the tobacco consumption from public and work places to private places (homes).

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Impact of the Spanish smoking legislations in the adoption of smoke-free rules at home: a longitudinal study in Barcelona (Spain)

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Notes

5.5 Secondhand smoke risk perception and smoke-free rules in homes: A cross-sectional study in Barcelona (Spain)

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Secondhand smoke risk perception and smoke-free rules in homes: a cross-sectional study in Barcelona (Spain)

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ABSTRACT

Objective: To describe the voluntary adoption of smoke-free homes in Spain among general population and to identify variables associated with its voluntary adoption.

Methods: Cross-sectional study of a representative sample (n=731) of the adult population (>26 years) of Barcelona, Spain, in 2013–2014. We defined smoking rules inside the households as complete indoor rules (when smoking was not allowed inside the house), and partial or absent indoor rules (when smoking was allowed in some designated places inside the house or when smoking was allowed everywhere) and described them according to the perceived risk of the secondhand smoke (SHS) exposure. We calculated the prevalence and prevalence ratios (PR) according to sociodemographic variables.

Results: 57.4% of households had complete indoor smoke-free rules. The prevalence of households with complete indoor rules was higher among women (PRa: 1.15; 95% CI 1.00 to 1.33), married (PRa: 1.18; 95% CI 1.01 to 1.38), never-smokers (PRa: 2.68; 95% CI 2.06 to 3.50) and in households where a minor lived (PRa: 1.40; 95% CI: 1.20–1.65). Believe that breathing tobacco smoke from smokers is dangerous for non-smokers (PRa: 1.77; 95% CI: 1.06–2.97) is associated with the voluntary adoption of complete indoor smoke-free home.

Conclusions: Risk perceptions of SHS exposure were associated with the voluntary adoption of indoor smoke-free homes.

Strengths and limitations of this study

- There is scarce evidence about the relationship between voluntary adoption of smoke-free homes and the risk perception of secondhand smoke exposure.
- One strength of our study is the use of a face-to-face questionnaire with trained interviewers, we potentially increase the internal validity of our results when compared with internet and self-administered surveys because avoid misinterpretation of the questions.
- The main limitation of this study is the potential bias of participation due to the attrition of the cohort of participants. However, all analyses used weighted data to generate representative estimates of the city of Barcelona.
- The study was conducted only in the city of Barcelona, and generalisation of the results to the rest of Spain should be cautious.
- Another potential limitation is the cross-sectional nature of the data, which allows one to establish associations but not to infer causality.

INTRODUCTION

The health consequences of secondhand smoke (SHS) exposure on non-smoker's are well known.[1] Moreover, passive exposure could be due to different settings such as workplaces, public places (bars, restaurants, etc), public transport or private places. For this reason, since the introduction of the WHO Framework Convention on Tobacco Control (WHO FCTC), many countries have implemented smoke-free policies in public and workplaces to reduce the impact of SHS exposure in non-smoker's health; consequently, there has been a reduction in SHS exposure after their implementation in workplaces and public places.[2] However, private settings (mainly cars and homes) are never or rarely included in tobacco control policies. Nevertheless, the household is usually the main source of exposure to SHS in children.[3 4] In addition, children are especially vulnerable to SHS exposure because they breathe more rapidly and inhale more pollutants per pound of body weight than adults.[5] In addition, SHS exposure is a risk for infant death syndrome, acute respiratory infections, ear problems and mental disorders in

children.[6 7] Accordingly, the harmful effects of passive exposure in private venues have received scant attention in public health policies, including the promotion of voluntary smoke-free homes.

In Europe, according to the Eurobarometer 332,[8] 61% of households had some kind of smoke-free home rules in 2009. The highest prevalence of smoke-free homes was observed in Finland (95%) and the lowest in Macedonia (30%), whereas 44% of the Spanish households had smoke-free home rules. However, these results are previous to the last smoke-free legislation in Spain (Law 42/2010),[9] that bans smoking in public places and extends the ban to all hospitality venues without exception and to some outdoor public areas, including healthcare premises, children educational campuses and playgrounds. This new regulation makes Spain one of the countries with the most stringent national smoke-free laws in Europe.

Currently, to the best of our knowledge, there are no national descriptive studies about the adoption of smoke-free homes in Spain after the Spanish tobacco control legislations. Moreover, there is scarce evidence about the relationship between voluntary adoption of smoke-free homes and the risk perception of SHS exposure. Therefore, the objective of this study is to describe the voluntary adoption of smoke-free homes in Spain and to identify variables associated with its voluntary adoption, including risk perception towards SHS exposure.

METHODS

We used the follow-up data of a cohort study from a representative sample of the adult population (≥16 years) of the city of Barcelona (Catalonia, Spain). The objective of the cohort study was to assess the impact of the Spanish smoking bans on tobacco consumption and SHS exposure. The baseline study was carried out during the years 2004–2005 through a representative random sample of the adult (≥16 years old) non-institutionalised population of Barcelona (Spain)[10 11] (n=1245). We obtained the personal data and addresses from the updated official Census, as provided by the Institute of Statistics of Barcelona. We sent a personal letter to introduce the study; afterwards trained interviewers administered a face-to-face questionnaire (in Spanish or Catalan) at the participant's home to gather information on sociodemographic data and active and passive smoking. The follow-up took place in 2013–2014.

For this study, we exclusively used the follow-up data. From the baseline sample, we excluded 235 participants; 150 after checking their data in the Insured Central Registry of Catalonia (101 had died and 49 had migrated out of the province of Barcelona) and another 85 did not give consent to be followed up or were <18 years old in 2004–2005, because they were not legally adults at that time and we did not ask to their parents any consent to be recontacted. Follow-up was conducted between May 2013 and February 2014. In total, 72.9% of the eligible sample agreed to participate and answered the questionnaire, 18.5% (187) refused to participate, 7.2% (73) had moved elsewhere and 1.3%[14] had died. The final sample included 736 individuals. There were statistically significant differences between the follow-up sample and the participant lost in the follow-up according to age, level of education and smoking status. Followed-up participants overestimate the young people and smokers in comparison with lost participants, for this reason, the increase in smoke-free homes could be higher among lost participants. On the other hand, the final sample overestimated the older people compared with the distribution observed in the population of Barcelona. Therefore, we used inverse probability weights to balance our data according to age distribution of the city of Barcelona to maintain its representativeness of the sample.

For this analysis, we have available data from 731 out of the 736 individuals, due to missing data in the variable of interest. The primary outcome was the voluntary adoption of smoking rules at home, which was obtained from the question: 'Which of the following situations best describe the smoking rules in your house?' with three possible answers: 'Nobody can smoke', 'Smoking is allowed in some places' and 'Smoking is allowed everywhere'. According to this question, we defined smoking rules inside the households as 'complete indoor rule' (when smoking was not allowed inside the house), and 'partial or absent indoor rule' (when smoking was allowed in some designated areas inside the house or when smoking was allowed everywhere).

We also obtained information about the risk perception of SHS exposure through the degree of agreement with a set of statements: (1) SHS bothers you; (2) breathing tobacco smoke from others is harmful; (3) SHS is dangerous for adults; (4) SHS is dangerous for children; and (5) tobacco smoke is dangerous for non-smokers. The answers were collected in a five-point Likert scale ('Totally agree', 'Agree', 'Neither agree nor disagree', 'Disagree' and 'Totally disagree'). Finally, we dichotomised each statement as 'Agree', indicating the participant answered either 'Totally agree' or 'Agree', and 'Disagree' otherwise. We also included information about nicotine dependence of smokers using the Fagerström test for cigarette dependence (FTCD).[12]

We calculated the prevalence of smoke-free rules at home, prevalence ratios (PR) and their 95% CIs, stratified by sociodemographic variables and selected smoking characteristics. We also fitted log-binomial regression models to calculate the PR, adjusted for sex and age (PRa). The statistical programs used were R-3.0.2 and STATA V.14.

RESULTS

About 57.4% of participants lived in households with complete indoor rules, while 42.6% lived in households

Table 1 Level of voluntary adoption of smoke-free rules at home in Barcelona (Spain) in 2013–2014 according to sociodemographics and selected smoking characteristics

		Complete indoor ban			Partial or absent indoor ban		
	n	Per cent	PR (95% CI)	PRa (95% CI)	Per cent	PR (95% CI)	PRa (95% CI)
Overall	731	57.4	–	–	42.6	–	–
Sociodemographic variables							
Sex							
Men	336	53.4	1	1	46.6	1	1
Women	395	60.8	1.14 (0.99 to 1.30)	1.15 (1.00 to 1.33)*	39.2	0.84 (0.70 to 1.01)	0.84 (0.71 to 1.01)
Age (years)							
26–44	299	60.4	1.09 (0.93 to 1.28)	1.11 (0.95 to 1.30)	39.6	0.88 (0.71 to 1.10)	0.89 (0.71 to 1.11)
45–64	237	55.4	1.00 (0.86 to 1.17)	1.00 (0.86 to 1.17)	44.6	1.00 (0.82 to 1.20)	1.00 (0.83 to 1.21)
65–98	195	55.2	1	1	44.8	1	1
Educational level							
Low	129	54.8	1	1	45.23	1	1
Intermediate	275	50.4	0.92 (0.76 to 1.11)	0.93 (0.76 to 1.13)	49.6	1.10 (0.82 to 1.36)	1.06 (0.83 to 1.35)
High	327	64.4	1.17 (0.99 to 1.39)	1.17 (0.97 to 1.40)	35.6	0.79 (0.62 to 1.00)	0.77 (0.58 to 1.03)
Employment							
Yes	458	61.1	1.20 (1.04 to 1.37)*	1.15 (1.00 to 1.31)	38.9	0.80 (0.67 to 0.95)*	0.69 (0.54 to 0.87)***
No	273	51.1	1	1	48.9	1	1
Married							
Yes	491	60.1	1.16 (1.00 to 1.35)	1.18 (1.01 to 1.38)*	39.9	0.83 (0.69 to 0.99)*	0.80 (0.67 to 0.97)*
No	240	51.8	1	1	48.2	1	1
Minor at home							
Yes	193	72.0	1.41 (1.23 to 1.62)***	1.40 (1.20 to 1.65)***	28.0	0.57 (0.44 to 0.75)***	0.56 (0.42 to 0.75)***
No	435	50.9	1	1	49.1	1	1
Smoking-related variables							
Smoking status							
Current	191	28.4	1	1	71.6	1	1
Former	250	62.7	2.21 (1.69 to 2.89)***	2.36 (1.79 to 3.10)***	37.3	0.52 (0.43 to 0.63)***	0.39 (0.34 to 0.46)***
Never	290	72.0	2.53 (1.95 to 3.29)***	2.68 (2.06 to 3.50)***	28.0	0.39 (0.32 to 0.48)***	0.31 (0.26 to 0.37)***
FTCD (among smokers)							
≤4	89	29.7	1.60 (0.65 to 3.95)	1.69 (0.68 to 4.18)	70.3	0.70 (0.60 to 0.81)***	0.78 (0.65 to 0.92)**
5	15	0.0	–	–	100.0	–	–
>5	34	18.6	1	1	81.4	1	1
Intention to quit (among smokers)							
Yes	13	40.4	1.85 (0.85 to 3.99)	1.95 (0.89 to 4.28)	59.6	0.76 (0.47 to 1.23)	0.81 (0.50 to 1.31)
No	146	21.9	1	1	78.1	1	1

n not always sum up due to missing data.
*p<0.05, ** p<0.01, ***p<0.001.
PR, prevalence ratio; PRa, prevalence ratio adjusted for sex and age.

with partial or absent indoor rules. Voluntary adoption of complete indoor rules at home was statistically significantly more frequent among women (PRa: 1.15; 95% CI 1.00 to 1.33), married (PRa: 1.18; 95% CI 1.01 to 1.38), never-smokers (PRa: 2.68; 95% CI 2.06 to 3.50) and in households where a minor lived (PRa: 1.40; 95% CI 1.20 to 1.65) (table 1). Similarly, voluntary adoption of partial or absent indoor rules was statistically significantly less frequent among working individuals (PRa: 0.69; 95% CI 0.54 to 0.87), married (PRa: 0.80; 95% CI 0.67 to 0.97), never-smokers (PRa: 0.31; 95% CI 0.26 to 0.37), smokers with lower FTCD score (PRa: 0.78; 95% CI 0.65 to 0.92) and participants living with a minor (PRa: 0.56; 95% CI 0.42 to 0.75) (table 1).

Smokers were those with the lowest prevalence of adoption of complete indoor smoke-free home rules. Among them, those with a medium and high dependence (FTCD), and those who did not attempt to stop smoking (table 1).

Table 2 shows the association between voluntary adoption of smoke-free homes rules and the risk perception of SHS exposure. The prevalence of complete indoor smoke-free home rules was higher among participants who perceived SHS exposure as a risk for health. Particularly, voluntary adoption of complete indoor smoke-free rules at home was statistically significantly more frequent among those who agree with the statement 'breathing tobacco smoke from smokers is dangerous for non-smokers' (PRa: 1.77; 95% CI 1.06 to 2.97) (table 2). Moreover, voluntary adoption of partial or absent indoor smoke-free rules at home was statistically significantly less frequent among those who agree with the statements 'SHS bothers you' (PRa: 0.70; 95% CI 0.50 to 0.98), 'breathing tobacco smoke from smokers is harmful' (PRa: 0.67; 95% CI 0.51 to 0.87), 'SHS is dangerous for adults' (PRa: 0.72; 95% CI 0.54 to 0.96) and 'SHS is dangerous for non-smokers' (PRa: 0.63; 95% CI 0.49 to 0.81) (table 2).

DISCUSSION

More than half (57.4%) of the population of Barcelona (Spain) had complete indoor smoke-free rules at home in 2013–2014. This prevalence is higher than that obtained in the Eurobarometer[8] (44%), maybe because the Eurobarometer considers as complete smoke-free homes those households where smoking is not allowed, without distinction between indoor and outdoor areas. On the other hand, there are some studies showing that this EU survey generates estimates that are in some cases widely discrepant from more substantive national sources and does not provide age or gender-specific data by country.[13] Similarly, our result is also higher than what was observed in other countries like Scotland (51.8%)[3] and the USA, where this percentage was 53% in states with lax tobacco control legislations and higher in states with comprehensive policies.[14] Moreover, as observed in previous studies,[15–19] the adoption of smoke-free homes in our study was higher among never-smokers and among those who lived with a minor. The prevalence of adoption of smoke-free homes among households with non-smokers was 23.5% in the UK, 39.2% in the USA, 39.1% in Canada and 44.3% in Australia.[15] The prevalence of adoption of smoke-free home among households with infants and preprimary children was 29% and 26% in the UK, 38.9% and 51.5% in the USA, 41% and 48.8% in Canada and 60.3% and 52.7% in Australia, respectively.[15] Our study showed that 28.4% of smokers had complete indoor smoke-free home rules. In this line, the prevalence of complete smoke-free home rules observed among smokers in other European countries is 16% in Ireland, 25% in France, 38% in Germany, 17% in the Netherlands and 25% in the UK;[19] thus, there is room for improvement in this regard.

During the debate about the implementation of smoke-free policies in different countries, the tobacco industry and the hospitality sector argued that the restriction of smoking in public places would displace tobacco consumption to private settings, particularly to home. We have previously found a decrease in SHS exposure at home in non-smoker adults after the national comprehensive legislation.[20] In this line, this analysis show high prevalence of complete indoor smoke-free rules (57.4%). This could be due to an increasing perception of the harmful effects of SHS exposure among the general population. In fact, we observed the highest prevalence (72%) of complete indoor smoke-free home rules in households with minors.

Our data show that the voluntary adoption of complete indoor smoke-free home rules is higher among never-smokers and among people who lived with minors. Never smokers present statistically significant higher risk perception of SHS exposure than smokers and former smokers (data not shown). This could be one reason why complete indoor smoke-free home rules are higher among never smokers. However, we found similar prevalence of SHS risk perception among people who lived with and without minors (data not shown). On the other hand, people who had some kind of risk perception of SHS exposure showed higher adoption of complete smoke-free homes rules. Similar results were obtained in a study in Italy about the support for tobacco regulation and consumption in private vehicles in the presence of minors.[21]

Our results highlight the need to increase awareness of the health risks of SHS in private settings, especially among smokers. In this regard, the awareness campaigns should inform about the health risks of SHS exposure, especially in private settings. Besides, smoking prevention among adolescents at schools should also consider including the prevention of exposure to SHS.[22] Furthermore, it should also be reported the health benefits of having a smoke-free home by health system and social media.

Table 2 Level of voluntary adoption of smoke-free rules at home in Barcelona (Spain) in 2013–2014, according to the perceived risk of the exposure to secondhand smoke

		Complete indoor ban			Partial or absent indoor ban		
	n	Per cent	PR (95% CI)	PRa (95% CI)	Per cent	PR (95% CI)	PRa (95% CI)
SHS bothers you							
Disagree	31	40.8	1	1	59.2	1	1
Agree	700	58.2	1.42 (0.88 to 2.30)	1.44 (0.89 to 2.33)	41.8	0.71 (0.50 to 0.99)*	0.70 (0.50 to 0.98)*
Breathing tobacco smoke from smokers is harmful							
Disagree	36	37.7	1	1	62.3	1	1
Agree	690	58.7	1.56 (1.01 to 2.40)*	1.51 (0.97 to 2.34)	41.3	0.66 (0.50 to 0.87)**	0.67 (0.51 to 0.87)**
SHS is dangerous for adults							
Disagree	35	40.7	1	1	59.3	1	1
Agree	692	58.4	1.43 (0.95 to 2.16)	1.38 (0.91 to 2.10)	41.6	0.70 (0.52 to 0.94)*	0.72 (0.54 to 0.96)*
SHS is dangerous for children							
Disagree	25	52.0	1	1	48.0	1	1
Agree	705	57.8	1.11 (0.74 to 1.67)	1.09 (0.72 to 1.66)	42.2	0.88 (0.57 to 1.37)	0.89 (0.58 to 1.38)
Secondhand smoke is dangerous for non-smokers							
Disagree	35	32.5	1	1	67.5	1	1
Agree	692	59.0	1.81 (1.09 to 3.02)*	1.77 (1.06 to 2.97)*	41.0	0.61 (0.47 to 0.79)***	0.63 (0.49 to 0.81)***

n not always sum up due to missing data.
*p<0.05, **p<0.01, ***p<0.001.
PR, prevalence ratio; PRa, prevalence ratio adjusted for sex and age.

The main limitation of this study is the potential of participation bias due to the attrition of the cohort of participants; our data are, particularly, older than the population of the city of Barcelona. For this reason, all analyses used weighted data to generate representative estimates of the city of Barcelona. Moreover, the study was conducted only in the city of Barcelona and generalisation of the results to the rest of Spain should be cautious. Another potential limitation is the cross-sectional nature of the data, which allow to establish associations but not to infer causality.

In conclusion, 6 out of 10 households in Barcelona (Spain) have complete indoor smoke-free rules after comprehensive tobacco control legislation in Spain. In addition, we observed an association between complete indoor smoke-free homes adoption and the perceived risk of SHS exposure. Improving the proportion of homes with smoke-free rules through different social interventions should be considered in the strategy towards the endgame.[23] In addition, warning campaigns about the harmful effects of SHS exposure at home, especially in the presence of children, should be promoted in Spain.

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5.6 Correlation between tobacco control policies and consumption of rolled tobacco and e-cigarettes, and intention to quit conventional tobacco, in Europe

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Correlation between tobacco control policies, consumption of rolled tobacco and e-cigarettes, and intention to quit conventional tobacco, in Europe

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ABSTRACT

Objective To analyse the correlation between the implementation of tobacco control policies and tobacco consumption, particularly rolling tobacco, electronic cigarettes (e-cigarettes) users and the intent to quit smoking in 27 countries of the European Union.

Design Ecological study with the country as the unit of analysis.

Data sources We used the data from tobacco control activities, measured by the Tobacco Control Scale (TCS), in 27 European countries, in 2010, and the prevalence of tobacco consumption data from the Eurobarometer of 2012.

Analysis Spearman correlation coefficients (r_{sp}) and their 95% CIs.

Results There was a negative correlation between TCS and prevalence of smoking (r_{sp}=−0.41; 95% CI −0.67 to −0.07). We also found a negative correlation (r_{sp}=−0.31) between TCS and the prevalence of ever e-cigarette users, but it was not statistically significant. Among former cigarette smokers, there was a positive and statistically significant correlation between TCS and the consumption of hand-rolled tobacco (r_{sp}=0.46; 95% CI 0.06 to 0.70). We observed a similar correlation between TCS and other tobacco products (cigars and pipe) among former cigarette smokers. There was a significant positive correlation between TCS and intent to quit smoking in the past 12 months (r_{sp}=0.66; 95% CI 0.36 to 0.87).

Conclusions The level of smoke-free legislation among European countries is correlated with a decrease in the prevalence of smoking of conventional cigarettes and an increase in the intent to quit smoking within the past 12 months. However, the consumption of other tobacco products, particularly hand-rolled tobacco, is positively correlated with TCS among former cigarette smokers. Therefore, tobacco control policies should also consider other tobacco products, such as rolling tobacco, cigars and pipes.

INTRODUCTION

Tobacco is the single greatest cause of preventable death in the world.[1] Several countries have implemented smoke-free legislation focused on the reduction of secondhand smoke exposure (SHS). However, the adoption of tobacco control policies focuses (eg, the increase of price) mainly on manufactured cigarettes and often neglects other tobacco products, such as hand-rolled tobacco.[2] In fact, the consumption of hand-rolled tobacco has increased in the past few years[3–5] and hand-rolled cigarettes were smoked by one in three European smokers in 2011.[6] Moreover, the use of electronic cigarettes (e-cigarettes) has rapidly increased worldwide.[7]

A previous study conducted in Europe[8] showed a negative relationship between tobacco control policies and the smoking of conventional cigarettes as well as exposure to SHS in workplaces. Moreover, the tobacco control policies in Europe were not correlated with an increase of tobacco consumption in private venues[9] and were correlated with a rise in the prevalence of smoke-free homes.[10] However, there is a lack of evidence, to the best of our knowledge, about the impact of tobacco control bans on the consumption of other tobacco products, such as rolling tobacco and the use of e-cigarettes. The objective of this study is to analyse the correlation between the implementation of tobacco control policies and tobacco consumption, particularly rolling tobacco, e-cigarettes users and the intent to quit smoking in 27 countries of the European Union (EU).

METHODS

This is an ecological study with each country as the unit of analysis. We used data from tobacco control activities, measured by the Tobacco Control Scale (TCS)[11] proposed by Joossens and Raw,[12] in 27 European countries, in 2010, and the data of the prevalence of tobacco consumption from the Eurobarometer of 2012.[13] The Special Eurobarometer 385[13] is a cross-sectional study (n=26 751) conducted between February and March of 2012 among the adult population (>15 years old).

We obtained the following variables through different questions from the Eurobarometer:

Information regarding cigarette consumption obtained through the specific question: 'Regarding smoking cigarettes, cigars or a pipe, which of the following applies to you?'. In which the possible answers were: 'You currently smoke'; 'You used to smoke but you have stopped' and 'You have never smoked', and were measured by way of the prevalence of smoking. We defined current smokers as people who answered 'You currently smoke'.

Additionally, we obtained information on other tobacco product consumption (boxed cigarettes, hand-rolled cigarettes, cigars and pipe) through the question: 'How often do/did you use the following tobacco products?'. The answers to this question were grouped as regular users (daily, weekly or monthly) and non-regular users, and differentiating between smokers and former cigarette smokers.

Eurobarometer also provided information on other ways of smoking through the question: 'Have you ever tried any of the following products? Water pipe, oral tobacco, chewing or nasal tobacco, e-cigarettes, and smokeless cigarettes', and the answers to this question were grouped as either 'Yes' or 'No'. This question was given to the whole population (smokers, former smokers and non-smokers).

Previous intent to quit smoking was measured by way of the prevalence of the answer 'Yes, in the past 12 months' from the question: 'Have you ever tried to quit smoking?'.

Self-reported exposure to SHS at work among non-smokers was obtained asking the question: 'How often are you exposed to tobacco smoke indoors at your workplace?', where the answers were grouped as either exposed or non-exposed.

We used the TCS from 2010 to measure the level of the six most cost-effective tobacco control policies in European countries in 2010.[12]

We analysed the correlation between TCS score (and their six policies) and the different rates of prevalence (eg, cigarette consumption, use of other tobacco products, previous intent to quit, etc) by calculating Spearman correlation coefficients (r_{sp}) and their 95% confidence intervals (CIs).

RESULTS

There was an inverse and statistically significant correlation between TCS and prevalence of smoking of conventional cigarettes (table 1). The correlation between TCS and intent to quit smoking within the past 12 months was positive and statistically significant (r_{sp}=0.66; 95% CI 0.36 to 0.87). The correlation between TCS and SHS exposure at work was negative (r_{sp}=−0.59; 95% CI −0.81 to −0.22).

Among current smokers, there were positive correlations, only statistically significant in the case of pipe smoking (r_{sp}=0.49; 95% CI 0.13 to 0.73), between TCS and consumption of other tobacco products. Among former cigarette smokers, there were positive and statistically significant correlations between TCS and other tobacco products with the exception of boxed cigarettes (table 1).

We found statistically significant negative correlation between TCS and the prevalence of having ever tried a water pipe (r_{sp}=−0.39; 95% CI −0.62 to −0.06). The correlation of TCS with the prevalence of ever e-cigarette use was not statistically significant (r_{sp}=−0.31; 95% CI −0.61 to 0.03).

DISCUSSION

Our results, at the ecological level, show that there is an inverse correlation between the levels of tobacco control policies implemented across European countries and the consumption of conventional cigarettes and exposure to SHS at work. These results are in agreement with previous ecological,[8 9] multilevel[10] and individual studies.[14] However, there is positive correlation between the different levels of tobacco control policies implemented among countries and the consumption of other tobacco products among former cigarette smokers, particularly hand-rolled tobacco. This correlation should be interpreted with caution because the question of the Eurobarometer does not permit the restriction of this analysis to former cigarette smokers who had quit smoking cigarette after the implementation of tobacco control policies. Therefore, the prevalence of other tobacco products, including hand-rolled tobacco, among former cigarette smokers cannot be guaranteed to be a consequence of the six tobacco control policies measured in the TCS. However, previous studies showed an increase of daily consumption, per capita, of hand-rolled tobacco and market share of rolling tobacco in the past decade.[3 15]

Thereby, our results could be backing the hypothesis of a switch of smokers to cheaper tobacco products, such as hand rolled cigarettes, because the tobacco control policies, particularly increasing of prices, are focused on conventional cigarettes. Previous studies showed that daily per capita consumption of hand-rolled cigarettes increased on average by 14.1% per year from 1991 to 2012 in Spain, while the consumption of manufactured cigarettes decreased by 3% on average.[3] A similar pattern has been found in other countries such as Canada, the USA, the UK, Australia[4] and New Zealand.[5] These changes in the consumption of tobacco could also be due to the belief that this tobacco product is healthier than conventional manufactured cigarettes.[16]

Furthermore, price increase is consistently reported as one of the most effective means of reducing tobacco consumption;[17] nevertheless, the real prices of the cheapest cigarettes have remained largely unchanged since 2006, and the gap between the cheapest and the most expensive cigarettes has been widened.[18] In fact, hand-rolled cigarettes were taxed at half the level of manufactured cigarettes in 2014.[18] Bearing this in mind, there is a need to equalise the prices of all tobacco products by applying the same taxing level as, indeed, is recommended by the article 6 of the Framework Convention on Tobacco Control.[19]

Regarding the consumption of e-cigarettes, the public awareness has grown substantially in recent years.[20] However, we observed unexpected negative correlation between TCS and the prevalence of having ever tried e-cigarettes, although it was not statistically significant. This result could be due to the fact that the countries with larger TCS are more active in tobacco control and therefore may have prevented the widespread use of the e-cigarettes by, for instance, better consumer information.

We found a positive correlation between TCS and the previous intent to quit smoking (in the past 12 months). This correlation could underestimate the real correlation between TCS and intention to quit because the question of Eurobarometer measured only the previous intention to quit and not the current intention. However, the mean score for Europe in the policies of the treatment to help quit smoking was very low (5.11 up to 10) in comparison with other policies. This could mean that, although the smokers may have the intention to quit, they may not receive the help needed to succeed.

The main limitation of this study derives from its ecological design, which yields to the fact that no information about the intensity of association at individual level can be inferred. Moreover, there are some studies showing that the main EU survey generates estimates that are in some cases widely discrepant from more substantive national sources and does not provide age or gender-specific data by country.[21] In addition, the 2-year gap between the measure of TCS and the Eurobarometer survey does not allow detecting the effect of measures adopted between 2010 and 2012. Nevertheless, the design of the Eurobarometer was the same for all countries, increasing comparability across countries at an ecological level, and the sample size was satisfactorily large and representative by country, and the interviews were face-to-face. In addition, individual studies backing our results exist.[22 23]

In conclusion, our results suggest the need to revise the current legislation, particularly increasing the prices, in order to consider all tobacco products and not only conventional cigarettes.

Table 1 Spearman correlation coefficients (r_{sp}) between TCS (and the six policies of TCS) and prevalence of smoking, prevalence of consumption of other tobacco products (among smokers and former cigarette smokers), prevalence of the intent to quit smoking in the past 12 months and prevalence of self-reported to SHS exposure at work

	TCS	Price	Public place bans	Public information campaigns	Advertising bans	Health warnings	Treatment
Current cigarette consumption							
Smoking cigarettes	−0.41 (−0.67 to −0.07)*	−0.09 (−0.44 to 0.28)	−0.35 (−0.63 to 0.07)	−0.36 (−0.63 to −0.03)	−0.17 (−0.56 to 0.23)	0.03 (−0.3 to 0.36)	−0.47 (−0.75 to −0.08)*
Other tobacco products (smokers)							
Boxed cigarettes	−0.30 (−0.64 to 0.11)	−0.19 (−0.55 to 0.25)	−0.26 (−0.60 to 0.14)	−0.54 (−0.76 to −0.22)*	0.04 (−0.31 to 0.38)	−0.12 (−0.52 to 0.34)	−0.33 (−0.64 to 0.08)
Hand-rolled cigarettes	0.27 (−0.11 to 0.60)	0.14 (−0.26 to 0.51)	0.32 (−0.06 to 0.62)	0.46 (0.12 to 0.72)*	−0.09 (−0.44 to 0.31)	0.15 (−0.35 to 0.54)	0.07 (−0.37 to 0.47)
Cigars	0.28 (−0.10 to 0.62)	−0.09 (−0.49 to 0.32)	0.41 (0.06 to 0.72)*	0.39 (0.06 to 0.65)*	0.16 (−0.22 to 0.52)	0.06 (−0.36 to 0.46)	0.15 (−0.24 to 0.53)
Pipe	0.49 (0.13 to 0.73)*	0.12 (−0.25 to 0.44)	0.52 (0.10 to 0.81)*	0.41 (0.05 to 0.68)	0.15 (−0.31 to 0.61)	−0.01 (−0.01 to 0.30)	0.31 (−0.10 to 0.62)
Other tobacco products (former cigarette smokers)							
Boxed cigarettes	−0.04 (−0.41 to 0.37)	0.10 (−0.30 to 0.45)	−0.12 (−0.51 to 0.29)	−0.07 (−0.44 to 0.30)	0.08 (−0.36 to 0.45)	−0.04 (−0.04 to 0.37)	−0.22 (−0.63 to 0.17)
Hand-rolled cigarettes	0.46 (0.06 to 0.70)*	0.14 (−0.28 to 0.53)	0.51 (0.11 to 0.77)*	0.65 (0.40 to 0.78)**	0.21 (−0.18 to 0.60)	0.19 (−0.33 to 0.59)	0.35 (−0.08 to 0.69)
Cigars	0.41 (0.08 to 0.66)*	0.0007 (−0.41 to 0.39)	0.41 (0.05 to 0.68)*	0.70 (0.47 to 0.81)**	0.25 (−0.12 to 0.56)	0.19 (−0.27 to 0.57)	0.34 (−0.08 to 0.68)
Pipe	0.41 (0.03 to 0.66)*	−0.01 (−0.37 to 0.35)	0.44 (0.01 to 0.70)*	0.64 (0.34 to 0.81)**	0.25 (−0.19 to 0.61)	0.09 (−0.32 to 0.46)	0.29 (−0.11 to 0.63)
Other ways of smoking (all populations: smokers, former cigarette smokers and non-smokers)							
Water pipe	−0.39 (−0.62 to −0.06)*	−0.42 (−0.71 to −0.02)*	−0.23 (−0.61 to 0.20)	−0.1 (−0.46 to 0.25)	−0.03 (−0.44 to 0.36)	−0.18 (−0.54 to 0.26)	−0.16 (−0.54 to 0.25)
Oral tobacco	−0.01 (−0.47 to 0.40)	−0.19 (−0.54 to 0.25)	0.06 (−0.37 to 0.47)	0.13 (−0.29 to 0.48)	0.03 (−0.45 to 0.52)	−0.01 (−0.32 to 0.32)	0.13 (−0.24 to 0.51)
E-cigarettes	−0.31 (−0.61 to 0.03)	−0.07 (−0.44 to 0.30)	−0.4 (−0.70 to −0.04)*	−0.14 (−0.54 to 0.29)	−0.04 (−0.44 to 0.35)	0.04 (−0.38 to 0.41)	−0.05 (−0.47 to 0.41)
Smokeless cigarettes	0.12 (−0.31 to 0.52)	−0.27 (−0.64 to 0.13)	0.23 (−0.16 to 0.59)	0.13 (−0.28 to 0.50)	0.3 (−0.13 to 0.66)	0.02 (−0.35 to 0.40)	0.23 (−0.22 to 0.60)
Intent to quit smoking							
Past 12 months	0.66 (0.36 to 0.87)**	0.39 (−0.01 to 0.70)*	0.52 (0.14 to 0.92)*	0.59 (0.30 to 0.78)*	0.40 (−0.04 to 0.73)*	0.48 (0.17 to 0.72)*	0.45 (0.08 to 0.74)*
Exposure to SHS at work							
	−0.59 (−0.81 to −0.22)*	−0.19 (−0.59 to 0.23)	−0.67 (−0.85 to 0.35)**	−0.64 (−0.84 to −0.35)*	−0.42 (−0.72 to −0.007)*	−0.15 (−0.54 to 0.30)	−0.37 (−0.70 to 0.03)

TCS, Tobacco Control Scale (maximum 100 points) quantifies the full implementation of tobacco control policies at country level and collects information about of the six most cost-effective tobacco control policies. Price: price increases through higher taxes on tobacco products (maximum 30 points); Public place bans: bans/restrictions on smoking in public and work places (maximum 22 points); Public information campaign spending: better consumer information including public information campaigns, media coverage and publicising of research findings (maximum 15 points); Advertising bans: comprehensive bans on the advertising and promotion of all tobacco products, logos and brand names (maximum 13 points); Health warnings: large direct health warning labels on cigarette boxes and other products (maximum 10 points); Treatment: treatment to help dependent smokers to quit, including increased access to medications (maximum 10 points).
*p<0.05; **p<0.001.
SHS, secondhand smoke exposure.

What this paper adds

- There is positive correlation between the different levels of tobacco control policies implemented among European countries and the consumption of other tobacco products among former cigarette smokers, particularly hand-rolled tobacco.
- There is an indirect, but not statistically significant, correlation between the prevalence of ever e-cigarette use and the levels of tobacco control policies implemented in Europe.
- The level of smoke-free legislation among European countries is correlated with a decrease in the prevalence of smoking of conventional cigarettes and an increase in the previous intent to quit smoking (in the past months).

Contributors JMM-S conceived the study. CL-M collected the data, prepared the database and analysed the data. CL-M drafted the manuscript, which was critically revised by JMM-S. All the authors contributed substantially to the interpretation of the data and to revising the manuscript. All the authors approved its final version.

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Correlation between tobacco control policies, consumption of rolled tobacco and e-cigarettes, and intention to quit conventional tobacco, in Europe

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5.7 Attitudes towards policies of the tobacco product directive implemented in Europe in 2016 and the relationship with the tobacco control policies

Attitudes towards policies of the tobacco product directive implemented in Europe in 2016 and the relationship with the tobacco control policies

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ABSTRACT

Objective: To describe the acceptability of the recently implemented tobacco products regulations and to explore their relation with tobacco control legislation levels in Europe.

Design: We used data on tobacco control activities in 27 European countries in 2007, 2010 and 2013 measured by the Tobacco Control Scale (TCS) and data regarding attitudes about tobacco control regulations from the Special Eurobarometer of 2009, 2012 and 2014 (n= 80,831).

Analysis: We calculated the prevalence ratio (and 95% confidence intervals (CI)) of favorable attitudes towards tobacco products restrictions in 2009 vs. in 2014, and the effect of previous TCS on the attitudes towards tobacco products regulations, adjusted for sex, age and age at finishing education (PRa). Moreover, we analyzed the correlation between previous TCS and the prevalence of support for tobacco products regulations by calculating Spearman correlation coefficients (r_{sp}) and the 95% CI.

Results: Great support for the studied tobacco products regulations, which modestly increased over time, was observed. The highest support was seen for health warnings (80.8% in 2012) while the lowest was found in increasing taxes (58.6% in 2012). Moreover, a positive relation was generally observed between TCS and support for the studied tobacco products regulations at both ecological and individual level.

Conclusions: In conclusion, our results show great support for the studied tobacco products regulations which were positively related with European tobacco control levels of implementation at both ecological and individual level.

Keywords: *Tobacco Control, Tobacco Control Scale, Tobacco Control Legislations, Attitudes*

INTRODUCTION

In 2009, the European Commission (EC) made the decision to revise the outdated 2001 Tobacco Products Directive (TPC), which regulates the manufacture, sale and presentation of controlled tobacco products, in light of new market and scientific developments and at the recommendations of the World Health Organization Framework Convention on Tobacco Control (WHO FTCT) for countries to implement and manage tobacco control interventions (1). The update of the Tobacco Products Directive (2,3), passed in 2014 and implemented in 2016, was a significant success in European tobacco control and aimed to strengthen tobacco control policies across all European Members while still allowing the European tobacco control leaders to regulate even further. This update includes, among others, the following regulations: Increasing the size of graphic health warnings; banning images of tobacco products targeted at consumers; banning characterizing flavors of tobacco products; regulation of electronic cigarettes; banning promotional and misleading descriptions on tobacco products packaging; and introducing EU-wide tracking and tracing to combat illicit trade.

However, a key element in the implementation of any tobacco control policy is the public's support, as levels of acceptability may critically influence their effectiveness. In this regard, a recent review (4) found that smoking restrictions acceptability increased with time and was associated with the stage of implementation, becoming generally more acceptable once they had been introduced. In addition, the same review (4) showed that support was generally higher for interventions perceived as less intrusive and for measures aimed at commercial business rather than individuals. Acceptability also varies with the respondent's characteristics; those engaging in the targeted behavior being less supportive of interventions and women and older individuals more likely to endorse more restrictive measures (4).

To our knowledge, there is a lack of updated information at the European level on the attitudes towards the latest tobacco products regulations. Therefore, the objective of this

study is to describe the acceptability of the recently implemented tobacco products regulations and to explore their relation with tobacco control legislation levels in Europe.

METHODS

This is a repeated cross-sectional study. We used data on tobacco control activities in 27 European countries in 2007 (5), 2010 (6) and 2013 (7) measured by the Tobacco Control Scale (TCS) and the data regarding attitudes about tobacco control regulations from the Special Eurobarometer of 2009 (8), 2012 (9) and 2014 (10). The TCS is a tool proposed by Joossens and Raw (11) to quantify and assess the strength of tobacco control policies implemented in European countries. The Special Eurobarometer is a cross-sectional study conducted in 27 Member States of the European Union by TNS Opinion & Social. The fieldwork of each Eurobarometer was performed in October 2009, between February and March of 2012, and between November and December of 2014, respectively. The final sample was 80,831 (sample of Eurobarometer of 2009: 27,288; sample of Eurobarometer of 2012: 26,751; and sample of Eurobarometer of 2014: 26,792) adults (older than 15 years old). The interviews were conducted face-to-face at the participants' homes in their native languages.

Variables

The following variables were obtained through different questions from the Eurobarometer:

Attitudes towards tobacco products regulations: Would you be in favour of or opposed to any of the following measures? Banning advertising of tobacco products in points of sale/shops; keeping tobacco products out of sight in shops/points of sale; banning the sale of tobacco products via the Internet; banning the sale of tobacco products through vending machines; putting picture health warnings on all packages of tobacco products; banning flavors that make tobacco products more attractive; banning colors, logos and promotional elements from packets of tobacco products; increasing taxes on tobacco products; introducing an extra fee on

manufacturers of tobacco products to cover the health costs of tobacco use; banning the use of electronic cigarettes in environments where smoking is prohibited; and improving the traceability of tobacco products in order to reduce their illicit trade even if this makes them a few cents more expensive. Through this question, the prevalence of people in favour of each regulation was obtained.

Tobacco control policies: we used the TCS of 2007, 2010 and 2013 to measure and quantify the level of implementation of tobacco control activities of European countries. The TCS is a score (maximum 100 points) developed by a group of experts from the Association of European Cancer Leagues (ECL) and the European Network for Smoking Prevention (ENSP). This scale quantifies the full implementation of tobacco control policies at the country level and collects information about the six most cost-effective tobacco control policies: price increases through higher taxes on cigarettes and other tobacco products (maximum 30 points); bans or restrictions on smoking in public and work places (maximum 22 points); better consumer information (maximum 15 points); comprehensive bans on the advertising and promotion of all tobacco products, logos and brand names (maximum 13 points); large, direct health warning labels on cigarette boxes and other tobacco products (maximum 10 points); treatment to help dependent smokers stop, including increased access to medications (maximum 10 points).

Statistical analysis

We calculated the prevalence of favorable attitudes towards tobacco products regulations in 2009, 2012 and 2014. We used Generalized Lineal Mixed Models (GLMM) with country as a random effect and using Poisson family with log link, to calculate the prevalence ratio (and 95% confidence intervals (CI)) of favorable attitudes towards tobacco products restrictions in 2009 vs. 2014, and the effect of previous TCS on attitudes towards tobacco products regulations, adjusted for sex, age and age at finishing education (PRa). Moreover, we analyzed

the correlation between previous TCS and the prevalence of different attitudes towards tobacco products regulations by calculating Spearman correlation coefficients (r_{sp}) and the 95% confidence intervals (CI) at the ecological level. All the analyses used weighted data to obtain more representative results for each country. The statistical programs used were R-3.0.2 and STATA v.14.

RESULTS

Great support was obtained for the studied tobacco products regulations, this support being stronger among non-smokers or former smokers than smokers (Table 1). The highest support overall was observed for adding picture health warnings on all packages of tobacco products (80.8% in 2012) while the lowest was observed for increasing taxes on tobacco products (60.7% in 2014). Similarly, regarding smokers, the highest support was also observed for health warnings on tobacco products (65.2% in 2012) while the lowest was observed for increasing taxes on tobacco products (20.6% in 2014). Moreover, a modest increase in support of tobacco products regulations was observed for all studied regulations with the exception of increasing taxes on tobacco products, which showed a statistically significant decrease among non-smokers (PRa: 0.96; 95%CI: 0.93, 1.00), former smokers (PRa: 0.91; 95%CI: 0.86, 0.97) and smokers (PRa: 0.85; 95%CI: 0.73, 0.99) (Table 1).

In addition, at the ecological level a positive relation was generally observed between TCS and support for the studied tobacco products regulations; being statistically significant in the case of keeping tobacco products out of sight in shops/points of sale (r_{sp}: 0.22; 95%CI: 0.00, 0.43); banning colors, logos and promotional elements from packets of tobacco products (r_{sp}: 0.25; 95%CI: 0.01, 0.46); and increasing taxes on tobacco products (r_{sp}: 0.29; 95%CI: 0.10, 0.48) (Table 2). Similar results were obtained when studying the tobacco control policies included in the TCS individually. However, the bans or restrictions on smoking in public and work places seemed to be the most related with increasing support for the studied tobacco products

regulations, showing the strongest correlations (statistically significant in 6 out of the 11 studied tobacco products regulations) (Table 2).

At the individual level, similar results were obtained through adjusted prevalence ratios of increasing TCS 10 units in 10 units as the direction of the association was generally the same as at the ecological level (Table 3).

DISCUSSION

Our results show great support for the studied tobacco products regulations which modestly increased over time. The highest support, both overall and among smokers, was observed for adding picture health warnings on all packages of tobacco products while the lowest was observed for increasing taxes on tobacco products. Moreover, a positive relation was generally observed between TCS and support for the studied tobacco products regulations at both the ecological and individual levels.

Similar results were found in a recent systematic review (4) which shows that smoking restrictions acceptability increased with time. Moreover, a previous ecological study (12) included in the systematic review found that EU countries with higher overall TCS scores had greater public support for smoke-free legislations. Similar results were found in a cross-sectional study (13) carried out in UK, US, Canada and Australia which showed the greatest support in countries with the strongest regulations. These results may suggest that increasing tobacco control legislations is positively related to the social denormalisation of tobacco. In addition, the cross-sectional study (13) analyzed 12 questions relating to aspects of tobacco industry and tobacco product regulations in 2008, showing highest overall support for preventing industry promotion of their products (67-86% across countries) and lowest for plain packaging (24-37%). However, the systematic review (4) showed that support was generally higher for interventions perceived as less intrusive. For instance, warning labels and educational campaigns were consistently more likely to be supported than policies introducing

disincentives designed to influence behavior such as tax based incentives to discourage smoking (4).

Regarding the price increase on cigarettes and other tobacco products, similar results were found in a recent cross-sectional study (14) in Norway which also shows that more intrusive interventions, such as limitations on sale and increased taxes, received lower support. However, price increase has been proven to be the most effective and cost-effective intervention in reducing smoking consumption (15) and therefore strategies to increase support for tax measures should be considered.

On the other hand, the high support of health warnings observed in our study, even among smokers, suggests plain packaging may be successfully implemented in Europe. Plain packaging involves the removal of all branding and advertising from packs, such that packs are relatively indistinguishable from one another, other than the brand name in mandated text, size and style (16). Moreover, available evidence suggests that plain packaging may reduce smoking prevalence (17). In 2012, Australia implemented laws requiring plain (standardized) packaging of tobacco products. Scientific evaluation shows support for plain packaging increased significantly among Australian smokers after implementation of the law (being 28.2% after the implementation and 49% before) (18). Moreover, support for plain packaging is associated with higher levels of quitting activity while opposition mainly comes from those who smoke heavily and those who underestimate the risk of future smoking related harms (18). In addition, a recent systematic review shows plain packaging is associated with a reduction in package attractiveness and smoking appeal, and that it will make the legally required health warnings to be more salient (19). Since then, France, Ireland and UK have passed laws to implement plain packaging and several other countries have initiated legislative processes with the same goal (16). Furthermore, evidence to support the implementation of plain packaging

was obtained in Australia, New Zealand, Canada, UK, Norway, Belgium, France, Italy, Brazil and India (20).

The main limitations of this study are those related to survey based studies, as the use of a questionnaire to collect self-reported information, the potential for over-reporting of support for studied tobacco products regulations due to social pressures and bias due to non-response. Moreover, there are some studies that show that the main EU survey generates estimates that are in some cases widely discrepant from more substantive national sources and does not provide age or gender-specific data by country (21). Nevertheless, the design of the Eurobarometer was the same for all countries and years increasing comparability across countries at the ecological level, the sample size was satisfactorily large and representative by country in each year and the interviews were face-to-face. In addition, the time intervals between the TCS measurements and the carrying out of the Eurobarometer allow us to see the effect that the application of the tobacco policies had in the different countries and years. In addition, the main strength of our study is the use of Generalized Lineal Mixed Models (GLMM) with country as a random effect to analyze individual level effect. Moreover, we used Poisson family in the GLMM as they provide more robust results and we obtained prevalence ratio despite obtaining high prevalences to avoid possible overestimation of the studied effect.

In conclusion, our results show great support for the studied tobacco products regulations which were positively related with European tobacco control levels of implementation at both the ecological and individual levels. The high support observed for health warnings encourages plain packaging implementation in Europe. Moreover, the lowest support was observed in increasing taxes on tobacco products showing the need to implement strategies to increase support for such measures.

What this paper add

- Our results show great support for the recently implemented Tobacco Products Directive regulations which modestly increased over time.
- The highest support, both overall and among smokers, was observed for adding picture health warnings on all packages of tobacco products (80.8% in 2012) while the lowest was observed for increasing taxes on tobacco products (58.6% in 2012).
- Moreover, a positive relation was generally observed between TCS and support for the studied tobacco products regulations at both the ecological and individual levels.

COMPETING INTERESTS

Authors declare that they have no competing interests.

AUTHOR'S CONTRIBUTION

CLM analyzed the data and drafted the first manuscript with the supervision of JMMS. All authors contributed substantially to the interpretation of the data and the successive versions of the manuscript. All authors contributed to the manuscript and approved its final version. JMMS conceived the study and is the principal investigator of the project.

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Table 1. Prevalence, and the adjusted prevalence ratio (PRa) in 2009 *vs.* in 2014 when possible (in 2009 vs. in 2012 otherwise) with their 95% confidence intervals, of favorable attitudes towards tobacco products regulations.

		Overall (n=80,831)				Non Smokers (n=41,715)				Former Smokers (n=16,357)				Smokers (n=22,582)			
	n[a]	2009	2012	2014	PRa	2009	2012	2014	PRa	2009	2012	2014	PRa	2009	2012	2014	PRa
Advertising	53,912	71.9	71.6	75.3	1.04 (1.00, 1.08)*	80.1	79.9	83.2	1.04 (1.00, 1.07)*	73.8	73.7	76.9	1.04 (1.00, 1.08)	56.9	54.6	56.9	1.00 (0.93, 1.08)
Keep out of sight	48,279	63.1	64.9	68.5	1.08 (1.03, 1.13)**	74.2	74.7	78.2	1.05 (1.02, 1.09)**	63.9	66.6	69.9	1.09 (1.04, 1.15)**	44.6	46.2	46.9	1.07 (0.98, 1.17)
Sales via Internet	50,333	69.6	70.4	72.9	1.04 (1.01, 1.08)*	77.6	78.0	80.4	1.04 (1.01, 1.07)*	70.3	71.4	74.3	1.06 (1.02, 1.10)**	55.3	55.5	55.6	1.01 (0.94, 1.09)
Sales via vending machines	29,354	60.3	60.5	-	1.00 (0.97, 1.04)	72.4	71.3	-	0.99 (0.95, 1.02)	62.2	62.5	-	1.01 (0.97, 1.05)	39.1	39.1	-	1.02 (0.94, 1.11)
Put health warnings	40,735	79.7	80.8	-	1.02 (0.99, 1.04)	87.8	88.6	-	1.01 (0.99, 1.03)	79.3	82.5	-	1.04 (1.00, 1.07)*	66.4	65.2	-	0.99 (0.95, 1.04)
Flavors	49,757	68.8	69.6	70.6	1.02 (0.98, 1.06)	78.8	79.7	80.3	NC	70.6	71	72.9	1.03 (0.98, 1.09)	51.3	50.5	48.2	NC
Promotional elements	45,340	62.8	64.3	65.5	1.03 (0.99, 1.08)	74.1	75.3	76.1	1.03 (0.99, 1.07)	64.5	65.5	66.5	1.03 (0.98, 1.08)	43.1	43.6	42.4	NC
Increase taxes	45,409	62.1	58.6	60.7	0.96 (0.92, 1.00)	81.7	78.7	78.9	0.96 (0.93, 1.00)*	71.6	66.5	65.6	0.91 (0.86, 0.97)**	24.7	18.7	20.6	0.85 (0.73, 0.99)*
Extra manufactures fee	37,894	73.0	80.2	-	1.10 (1.07, 1.12)***	86.1	89.0	-	1.03 (1.02, 1.05)***	78.8	82.8	-	1.05 (1.02, 1.08)***	47.6	62.5	-	1.32 (1.22, 1.43)***
Use of e-cigarettes	16,891	-	-	71.6	-	-	-	80.8	-	-	-	72.7	-	-	-	51.4	-
Reduce illicit trade	18,913	-	-	79.7	-	-	-	88.0	-	-	-	83.3	-	-	-	59.4	-

n[a]: Available information of each question.

PRa: Adjusted by sex, age and age of finishing education.

* p-value <0.05, ** p-value<0.01, *** p-value<0.001

P-value: Obtained through adjusted Generalized Linear Multilevel Model effect coefficient.

NC: Non-convergent Generalized Linear Multilevel Model.

Tobacco products regulations: banning advertising of tobacco products in points of sales/ shops (advertising); keeping tobacco products out of sight in shop/ points of sale (keep out of sight); banning the sales of tobacco products via the Internet (sales via Internet); banning the sales of tobacco products through vending machines (sales via vending machine); putting picture health warnings on all packages of tobacco products (put health warnings); banning flavors that make tobacco products more attractive (flavors); banning colors, logos and promotional elements from packets of tobacco products (promotional elements); increasing taxes on tobacco products (increase taxes); introducing an extra fee on manufacturers of tobacco products to cover the health costs of tobacco use (extra manufactures fee); banning the use of electronic cigarettes in environments where smoking is prohibited (use of e-cigarettes); and improving the traceability of tobacco products in order to reduce their illicit trade even if this makes them a few cents more expensive (reduce illicit trade).

Table 2. Spearman correlation, with 95% confidence intervals, between previous TCS (and the six most cost-effective tobacco control policies) and favorable attitudes towards tobacco products regulations.

	TCS	Price	Public Bans	Campaigns	Advertising	Health warnings	Treatment
Advertising	0.18 (-0.07, 0.39)	0.22 (0.00, 0.42)*	0.25 (0.02, 0.45)*	0.02 (-0.30, 0.31)	0.20 (-0.03, 0.40)	0.01 (-0.21, 0.23)	0.10 (-0.10, 0.30)
Keep out of sight	0.22 (0.00, 0.43)*	0.11 (-0.14, 0.34)	0.37 (0.16, 0.55)***	0.21 (-0.09, 0.50)	0.16 (-0.08, 0.38)	-0.04 (-0.25, 0.18)	0.12 (-0.09, 0.34)
Sales via Internet	0.18 (-0.04, 0.39)	0.19 (-0.02, 0.38)	0.28 (0.06, 0.47)*	0.03 (-0.26, 0.33)	0.15 (-0.09, 0.38)	0.00 (-0.22, 0.22)	0.06 (-0.15, 0.27)
Sales via vending machines	0.25 (-0.02, 0.48)	0.25 (-0.02, 0.47)	0.18 (-0.08, 0.44)	0.08 (-0.27, 0.44)	0.23 (-0.04, 0.47)	0.07 (-0.22, 0.32)	0.21 (-0.08, 0.42)
Put health warnings	0.16 (-0.12, 0.44)	0.24 (-0.03, 0.48)	0.21 (-0.10, 0.45)	0.09 (-0.26, 0.40)	0.09 (-0.19, 0.36)	0.05 (-0.24, 0.33)	-0.15 (-0.43, 0.12)
Flavors	0.22 (0.00, 0.42)	0.30 (0.08, 0.50)**	0.30 (0.07, 0.51)**	0.13 (-0.18, 0.42)	0.04 (-0.18, 0.25)	0.02 (-0.19, 0.25)	0.04 (-0.18, 0.25)
Promotional elements	0.25 (0.01, 0.46)*	0.30 (0.08, 0.48)**	0.34 (0.11, 0.55)**	0.21 (-0.11, 0.48)	0.12 (-0.12, 0.33)	0.05 (-0.18, 0.27)	0.04 (-0.19, 0.27)
Increase taxes	0.29 (0.10, 0.48)**	0.15 (-0.05, 0.34)	0.16 (-0.10, 0.39)	0.12 (-0.17, 0.40)	0.39 (0.19, 0.56)***	0.17 (-0.05, 0.38)	0.24 (0.03, 0.44)*
Extra manufactures fee	-0.01 (-0.26, 0.28)	0.06 (-0.23, 0.31)	0.26 (-0.02, 0.48)	0.14 (-0.23, 0.51)	-0.16 (-0.40, 0.09)	-0.56 (-0.73, -0.36)***	0.09 (-0.19, 0.36)
Use of e-cigarettes	-0.01 (-0.38, 0.33)	-0.14 (-0.48, 0.22)	0.22 (-0.16, 0.56)	0.21 (-0.55, 0.86)	0.19 (-0.25, 0.57)	-0.02 (-0.37, 0.33)	0.05 (-0.36, 0.42)
Reduce illicit trade	0.34 (-0.09, 0.69)	0.36 (-0.04, 0.67)	0.44 (0.06, 0.72)*	0.37 (-0.38, 0.93)	0.36 (-0.08, 0.68)	0.27 (-0.10, 0.62)	0.24 (-0.19, 0.61)

* p-value <0.05, ** p-value<0.01, *** p-value<0.001

Tobacco products regulations: banning advertising of tobacco products in points of sales/ shops (advertising); keeping tobacco products out of sight in shop/ points of sale (keep out of sight); banning the sales of tobacco products via the Internet (sales via Internet); banning the sales of tobacco products through vending machines (sales via vending machine); putting picture health warnings on all packages of tobacco products (put health warnings); banning flavors that make tobacco products more attractive (flavors); banning colors, logos and promotional elements from packets of tobacco products (promotional elements); increasing taxes on tobacco products (increase taxes); introducing an extra fee on manufacturers of tobacco products to cover the health costs of tobacco use (extra manufactures fee); banning the use of electronic cigarettes in environments where smoking is prohibited (use of e-cigarettes); and improving the traceability of tobacco products in order to reduce their illicit trade even if this makes them a few cents more expensive (reduce illicit trade).

Table 3. Adjusted Prevalence Ratios of increasing TCS 10 units in 10 units, with their 95% confidence intervals, of favorable attitudes towards tobacco products regulations.

	TCS (30-40)	TCS (40-50)	TCS (50-60)	TCS (60-70)	TCS (70-80)	TCS (90-100)
Advertising	1	1.03 (0.99, 1.08)	1.01 (0.94, 1.10)	1.02 (0.94, 1.10)	1.11 (1.07, 1.14)***	1.07 (1.03, 1.11)**
Keep out of sight	1	1.07 (1.04, 1.11)***	0.99 (0.96, 1.03)	0.96 (0.91, 1.01)	0.96 (0.92, 1.00)	0.87 (0.84, 0.90)***
Sales via Internet	1	1.04 (1.00, 1.08)*	1.05 (0.99, 1.10)	1.00 (0.92, 1.10)	1.09 (1.04, 1.14)***	1.14 (1.10, 1.19)***
Sales via vending machines	1	1.17 (1.12, 1.22)***	1.10 (1.06, 1.14)***	1.06 (1.03, 1.10)**	0.99 (0.95, 1.03)	0.92 (0.89, 0.95)***
Put health warnings	1	1.06 (1.02, 1.11)**	1.13 (1.06, 1.21)***	1.18 (1.10, 1.26)***	1.20 (1.14, 1.27)***	1.22 (1.14, 1.30)***
Flavors	1	1.08 (1.03, 1.13)**	1.08 (1.04, 1.12)***	1.06 (0.99, 1.13)	1.15 (1.12, 1.18)***	1.14 (1.10, 1.17)***
Promotional elements	1	1.09 (1.04, 1.14)***	1.10 (1.04, 1.16)***	1.00 (0.95, 1.07)	1.15 (1.07, 1.23)***	1.17 (1.12, 1.22)***
Increase taxes	1	1.00 (0.81, 1.24)	0.97 (0.74, 1.26)	0.93 (0.68, 1.27)	0.95 (0.77, 1.18)	0.94 (0.76, 1.16)
Extra manufactures fee	1	0.96 (0.91, 1.01)	0.97 (0.91, 1.05)	1.00 (0.92, 1.08)	1.01 (0.93, 1.10)	0.96 (0.97, 1.07)
Use of e-cigarettes	1	1.05 (0.94, 1.17)	1.09 (0.97, 1.22)	1.11 (1.02, 1.22)*	0.95 (0.87, 1.05)	-
Reduce illicit trade	1	0.99 (0.95, 1.02)	1.01 (0.95, 1.07)	1.04 (0.96, 1.14)	1.08 (0.97, 1.19)	1.08 (0.96, 1.22)

* p-value <0.05, ** p-value<0.01, *** p-value<0.001

P-value: Obtained through adjusted (by sex, age and age of finishing education and smoking status) Generalized Linear Mixed Model effect coefficient.

Tobacco products regulations: banning advertising of tobacco products in points of sales/ shops (advertising); keeping tobacco products out of sight in shop/ points of sale (keep out of sight); banning the sales of tobacco products via the Internet (sales via Internet); banning the sales of tobacco products through vending machines (sales via vending machine); putting picture health warnings on all packages of tobacco products (put health warnings); banning flavors that make tobacco products more attractive (flavors); banning colors, logos and promotional elements from packets of tobacco products (promotional elements); increasing taxes on tobacco products (increase taxes); introducing an extra fee on manufacturers of tobacco products to cover the health costs of tobacco use (extra manufactures fee); banning the use of electronic cigarettes in environments where smoking is prohibited (use of e-cigarettes); and improving the traceability of tobacco products in order to reduce their illicit trade even if this makes them a few cents more expensive (reduce illicit trade).

6. Joint discussion of the articles

According to the results obtained in the scientific articles that compose this doctoral thesis, the implementation of the stepwise smoke-free legislations in Spain is related to a reduction in smoking prevalence and SHS exposure. The following is a joint discussion of the seven articles of the thesis.

6.1 Impact of Spanish smoking bans on tobacco consumption

The results obtained in the first article of this doctoral thesis (77) show a reduction in smoking prevalence after both Spanish legislations, along with an increase in the consumption of other tobacco products, particularly RYO cigarettes, among young population. Moreover, the second article of this doctoral thesis (78) shows an increase in salivary cotinine concentration (around 29%) among continuing smokers, and a switch from conventional to RYO cigarettes or to dual use in 21.3% of them, after both Spanish smoking legislations. In this line, the sixth article of this doctoral thesis (79) shows an inverse correlation between the levels of tobacco control policies implemented across European countries and the consumption of conventional cigarettes in addition to a positive correlation between the different levels of tobacco control policies implemented among countries and the consumption of other tobacco products among former smokers, particularly RYO cigarettes.

The results obtained on smoking consumption trends are consistent with a recent report (43) that assess the impact of both Spanish smoking legislations which shows a decline of prevalence before the Spanish smoke-free legislations, that became a little more pronounced after their implementation among women but not among men (43). However, a recent

systematic review showed the effect of smoke-free legislations on the smoking prevalence is not consistent in all the included studies, as some studies showed reduction in the smoking prevalence while other did not find changes in the smoking prevalence or in its tendency following a smoke-free legislation (80). In regard to the increase of RYO cigarettes, the economic crisis that took place in Spain in 2008 could have affected the shift on tobacco products as has been also reported (43,81).

In addition, smoking prevalence observed in the follow-up survey of the first article of this doctoral thesis (77) was higher than that observed in other studies (23.6% (2) and 20.7% (82)), with information gathered at national level in 2011-2012. This could be because our study was carried out in the city of Barcelona while the other study includes information about all the regions in Spain, and historically it has been reported slight differences in smoking prevalence among regions in Spain (83). Another possible explanation is that young and smoker participants in our sample could have been overestimated because of the loss of older and no-smoker participants.

Nevertheless, the impact of the two National smoke-free legislations is similar to the one found in previous studies conducted in Spain (84,85) and with previous ecological (86,87), multilevel (88) and individual studies(89) in Europe. In fact a systematic review (90) has concluded that the implementation of smoke-free policies and restrictions in public spaces, workplaces or residences lead to a decrease in smoking prevalence and cigarette consumption. However, the observed increase in the prevalence of RYO cigarettes and other tobacco products provide more support to the hypothesis of a change on the smoking pattern in consuming cheaper tobacco products, especially among young people. These results agree with some previous studies in Spain (45,82,85) and can be due to tobacco control policies, particularly increasing of prices, which are mainly focused on conventional cigarettes leading

to real prices of the cheapest cigarettes have remained largely unchanged and the gap between the cheapest and the most expensive cigarettes has widened (45). Furthermore, according to our results (78), the highest value of salivary cotinine after Spanish smoking bans, according to kind of tobacco smoked, was observed in smokers who switch from conventional to RYO cigarettes or to dual use, this fact may counteract the popular belief that RYO cigarettes are less harmful than conventional cigarettes. This aspect could be involved in the observed increase in salivary cotinine after the implementation of Spanish smoking bans, being the highest increase observed in those smokers who switch from conventional to RYO cigarette (70.0%) according to our results.

Regarding the consumption of other products such as e-cigarettes, another article annexed in this doctoral thesis (91) shows a negative correlation between TCS and the prevalence of having ever tried e-cigarettes. This result could be due to the fact that the countries with larger TCS are more active in tobacco control and therefore they may have prevented the widespread of the e-cigarettes by better consumer information for instance. In addition, the use of e-cigarettes in Spain is scarce (10.3% ever users), and predominates among young people and tobacco smokers although one out of four current e-cigarette users have never smoked (91). Therefore, e-cigarette could be a gateway to the consumption of other tobacco products and dual consumption.

6.2 Impact of Spanish smoking bans in quitting smoking and dependence

According to the results obtained in this doctoral thesis (78) a significant decrease in the proportion of individuals classified as medium FTCD was found. Nonetheless, there was not

any significant change in the number of cigarettes smoked daily. In addition, a positive correlation between TCS and the previous intent to quit smoking (in the last 12 months) has been found in this doctoral thesis (79).

According to the hardening hypothesis, when smoking prevalence decreases, the smokers who quit are those less dependent, and the remaining smokers are those with hard smoking dependence (92). In this regard, our results (78) do not show any significant change in the FTCD score after the application of the Spanish smoking legislations, counteracting the hardening hypothesis. Alike results can be found in Italy (93) and Norway (94). Moreover, an 18 countries European study suggests that as the lower country-specific smoking prevalence, the lower the dependence (95), giving more evidence to reject the hardening hypothesis. However, none of these studies use salivary cotinine to assess nicotine dependence. In this sense, we didn't found differences at baseline neither in the salivary cotinine concentration nor in the FTCD among smokers who quit smoking and continue smoking (78). Moreover, no significant increase was found in the FTCD score nor in the number of cigarettes smoked daily among smokers who continue smoking, which are other conventional measures used as a proxy to cigarette dependence. Nonetheless, although there is a positive relation between the FTCD score, tobacco consumption and salivary cotinine (96,97) other factors might also have an effect on cotinine concentration.

We also found a positive correlation between TCS and the intent to quit smoking in the last 12 months (79). This seems to be in agreement with previous studies that showed that the intention to quit smoking increased by 9% after recently implemented tobacco control measures in 2006 in Greece (98). However, according to the TCS obtained in 2013 (76), the Spanish score in the policies to the treatment to help to quit smoking was low (6 up to 10) in

comparison with other policies. This could mean that smokers may not receive the help needed to succeed when trying to stop smoking.

6.3 Impact of Spanish smoking bans in secondhand smoke exposure

The results of this thesis also show an important reduction in SHS exposure in all settings (workplace, leisure time, home, and public transport) after the implementation of the two Spanish smoke-free bans in Spain (77). Similar results were obtained in the third article of this doctoral thesis (99), in which SHS exposure was assessed by salivary cotinine concentrations and information on self-reported exposure. Moreover, according to the fourth article of this doctoral thesis (100) there is an increase in the prevalence of SFH, particularly in the case of a complete SFH, after the implementation of the two Spanish smoke-free bans. Specifically, the results of the fifth article of this doctoral thesis (101) show that more than half (57.4%) of the population of Barcelona (Spain) had complete indoor smoke-free rules at home in 2013-2014. In addition, further results of this thesis show an inverse correlation between the levels of tobacco control policies implemented across European countries and work SHS exposure at ecological level (79).

The results obtained in this doctoral thesis are consistent with other studies carried out in Spain, which show a decrease in SHS exposure in all the studied settings after the application of the smoking legislations either using cotinine concentrations (102,103) or questionnaire information (84,102). Similarly, a previous systematic review (90) reported reductions in SHS exposure with smoke-free policies, in both adults and children, and across various settings including workplaces, public spaces and hospitality establishments. In Europe, a secondary

analysis showed that the enforcement of smoke-free legislation is inversely associated with SHS exposure (104).

On the other hand, our results show that the highest prevalence of self-reported exposure to SHS, before and after the implementation of the two Spanish smoke-free bans, as well as the lower reduction, was obtained in the leisure time and in work (77). In this regard, other Spanish studies showed significant decrease in the environmental nicotine in hospitals after both Spanish legislations (105) and in hospitality venues between 2010 and 2011 (106). Regarding work setting, according to our results, most of the exposed ones declared spending most of the time outdoors and not having specific areas for smokers after the implementation of the two Spanish smoke-free bans (77). These results are consistent with another Spanish study, which showed that more than one-third of the population were passively exposed at work and at leisure time two years after the Spanish smoking legislations (102). In this regard, previous studies have shown that both consumption and self-reported SHS exposure were very low in indoor settings regulated by the Spanish legislation, therefore, the exposure of non-smokers to SHS mostly occurs in outdoor areas where smoking is allowed (107).

In addition, according to the results obtained in this doctoral thesis (99), although the higher prevalence of self-reported SHS exposure post-legislations was found in leisure time, higher cotinine concentrations among those declaring exposure to SHS were found at home. This could be because in a regular day people usually spend more time at home than at leisure time, therefore, being exposed at home could be harder in terms of time and intensity. However, our results also show that the adoption of SFH was higher among never-smokers and among those who lived with a minor (101). On the other hand, we found an increased prevalence of allowing smoking in most ventilated places, or outside areas, in houses with partial SFH after the implementation of the Spanish smoke-free legislations (100). This could

be due to an increasing risk perception of SHS exposure in the population. In fact, according to our results, people who had some kind of risk perception of SHS exposure showed higher adoption of complete SFH rules highlighting the need to increase awareness of the health risks of SHS in private settings, especially among smokers (101).

During the debate about the implementation of smoke-free policies in different countries, the tobacco industry and the hospitality sector argued that the restriction of smoking in public places would displace tobacco consumption to private settings, particularly to home. Our results, and the results from other studies (61,108-112), counteract the displacement hypothesis. Nevertheless, the results obtained in two articles of this doctoral thesis (100,101) show that around half of the houses with SFH rules have a partial rule.

6.4 Attitudes toward policies of the tobacco products directive in Europe

Finally, in the last article of this doctoral thesis (113) was assessed the support of the tobacco products directive in Europe. The results of this article (113) show great support in Europe for the studied tobacco products regulations which modestly increased over time. The highest support, both overall and among smokers, was observed for adding picture health warnings on all packages of tobacco products while the lowest was observed for increasing taxes on tobacco products. Moreover, a positive relation was generally observed between TCS and support for the studied tobacco products regulations at both the ecological and individual levels.

Similar results were found in a recent systematic review (114) which shows that smoking restrictions acceptability increased with time. Moreover, a previous ecological study (86) included in the systematic review found that EU countries with higher overall TCS scores had greater public support for smoke-free legislations. Similar results were found in a cross-sectional study (115) carried out in UK, US, Canada and Australia which showed the greatest support in countries with the strongest regulations. These results may suggest that increasing tobacco control legislations is positively related to the social denormalisation of tobacco. In addition, a cross-sectional study (115) analyzed 12 questions relating to aspects of tobacco industry and tobacco product regulations in 2008, showing highest overall support for preventing industry promotion of their products (67-86% across countries) and lowest for plain packaging (24-37%). However, the systematic review (114) showed that support was generally higher for interventions perceived as less intrusive. For instance, warning labels and educational campaigns were consistently more likely to be supported than policies introducing disincentives designed to influence behavior such as tax based incentives to discourage smoking (114).

Regarding the price increase on cigarettes and other tobacco products, similar results were found in a recent cross-sectional study (116) in Norway which also shows that more intrusive interventions, such as limitations on sale and increased taxes, received lower support. However, price increase has been proven to be the most effective and cost-effective intervention in reducing smoking consumption (31) and therefore strategies to increase support for tax measures should be considered.

7. Limitations

The main limitation of our studies is the potential participation bias due to the attrition of the cohort of participants in four of the seven articles of this thesis (77,78,99,100). In this sense, there were statistically significant differences according to age, level of education, and smoking status between the follow-up sample and the participant lost in both stages of the follow-up. Followed-up participants overestimate young people and smokers in comparison with lost participants, for this reason the reduction of conventional tobacco consumption and SHS, and the increase of hand-rolled consumption and smoke-free homes could be higher among lost participants while the increase in salivary cotinine could be smaller among lost participants. On the other hand, our final sample overestimated the older people compared with the distribution of population in Barcelona. However, we weighted the sample to minimize these limitations and to generate estimations representative of the general population. Moreover, the baseline sample size was representative of the city of Barcelona (68,69) and the longitudinal design used in almost all the studies maximizes the internal validity of the study. In the case of the cross-sectional study carried out in this doctoral thesis (101), another potential limitation is that the nature of the data allows to establish associations but not to infer causality. In addition, the studies were conducted only in the city of Barcelona and generalization of the results to the rest of Spain should be cautious.

Other potential limitations are those related to survey based studies, as the use of a questionnaire to collect self-reported information, and bias due to non-response. However, we used salivary cotinine as a specific biomarker in two articles of the thesis (78,99) and we also used the same definition of smoking status in both studies, checking self-reported smoking status with a salivary cotinine concentration incompatible with non-smoking (>10 ng/ml) and we used a face-to-face questionnaire with trained interviewers potentially increasing the internal validity of our results as compared with internet and self-administered surveys

because avoid misinterpretation of the questions. In addition, in the second (78) and third (99) articles of this doctoral thesis, salivary cotinine was used as a specific biomarker of nicotine dependence and using the same definition of smoking status in both studies potentially increasing internal validity.

Regarding the ecological studies (79,113), their main limitation derives from its ecological design that yields to the fact that no information about the intensity of association at individual level can be inferred. Moreover, there are some studies that show that the main EU survey generates estimates that are in some cases widely discrepant from more substantive national sources and does not provide age or gender-specific data by country (117). In addition, in the sixth article of this doctoral thesis (79), the two years gap of time between the measure of TCS and the Eurobarometer survey doesn't allow detecting the effect of measures adopted between 2010 and 2012. Regarding the seventh article of this doctoral thesis, there exists potential over-reporting of support for the studied tobacco products regulations due to social pressures and bias due to non-response. In addition, regarding the last article of this doctoral thesis (113), the time intervals between the TCS measurements and the carrying out of the Eurobarometer allow us to see the effect that the application of the tobacco policies had in the different countries and years. In addition, the main strength of this last article of the doctoral thesis (113) is the use of Generalized Lineal Mixed Models (GLMM) with country as a random effect to analyze individual level effect, Poisson family in the GLMM was also used as they provide more robust results and it allows us to obtain prevalence ratio despite obtaining high prevalence and to avoid possible overestimation of the studied effect. Moreover, the design of the Eurobarometer was the same for all countries increasing comparability across countries at an ecological level, the sample size was satisfactorily large and representative by country and the interviews were face-to-face.

8. Conclusions

- The implementation of the two smoke-free legislations in Spain is related to a reduction in smoking prevalence and SHS exposure (either using salivary cotinine concentrations or information on self-reported exposure). However, the consumption of other tobacco products, particularly RYO cigarettes, has increased specially among young population.

- A significant increase was found in the salivary cotinine concentration among adult continuing smokers after both Spanish legislations. Moreover, we observed a shift to other tobacco products, particularly RYO cigarettes.

- After the implementation of the two Spanish smoke-free bans, the main settings of SHS exposure was leisure time and in work, where most of the exposed ones declared expending most of the time outdoor and not having specific areas for smokers. However, cotinine concentrations in non-smokers were significantly higher only among those declaring exposure to SHS at home after both legislations.

- The implementation of the two smoke-free legislations in Spain is related to an increasing of voluntary adoption of SFH rules, in particular with an increase in complete SFH rules. In addition, we observed an association between complete indoor SFH adoption and the perceived risk of SHS exposure.

- Great support for the studied tobacco products regulations was found which were positively related with European tobacco control levels of implementation at both the ecological and individual levels.

9. Public health implications

- Future tobacco control legislations should consider applying the same taxing level to all tobacco products, particularly RYO. Moreover, it should be considered to increase the resources to implement further treatments to help smoker to quit, in order to continuing reducing smoking prevalence.

- Given the switch of smokers to other tobacco products, the FTCD score should be redefined to measure nicotine dependence not only in conventional cigarette.

- Further research is needed to analyze possible factors related to cotinine concentration as well as ensure cotinine concentration properly measures nicotine dependence.

- There is a need to implement some public health interventions to continuing reducing SHS exposure. These interventions may include introducing some outdoor of public and workplaces, promoting the adoption of SFH rules and increase warning campaigns about the harmful effects of SHS exposure at home, especially in the presence of children.

- The high support observed for health warnings encourages plain packaging implementation in Europe. Moreover, the lowest support observed in increasing taxes on tobacco products shows the need to implement strategies to increase support for such measures.

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Annexes

I. Use of the directed acyclic graphs to assess the health impact of smoking legislation

Use of the directed acyclic graphs to assess the health impact of smoking legislation

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Abstract

A growing body of literature conclude that smoke-free bans are associated with a decrease in morbidity and/or mortality of smoking related diseases, although, the path is far more complicated. One common approach to represent key causal relations is Directed Acyclic Graphs (DAGs). To our knowledge, there is a lack of articles focused in a methodological approach to analyze the association between the smoke-free bans and its health effects in the population. In this article we propose a tool for the tobacco researchers and epidemiologists in order to analyze the health impact in any possible disease scenario of the smoke-free legislations, by considering all the possible pathways, intermediate variables and confounders. We conclude that key variables influencing on the described association are intention to quit, smoking prevalence and its tendency, secondhand smoke exposure, nicotine dependence (FTCD) and the sociodemographic characteristics.

Keywords: Directed Acyclic Graphs, smoke-free legislations

1. INTRODUCTION

The design of statistical analysis in epidemiological studies usually includes three different set of variables: the exposure, the outcome and the confounders. The exposure and the outcome are easily specified by the study objective. On the contrary, the selection of possible confounders is quite more difficult and if it is not done properly it can introduce bias to the results found. Consequently, when selecting confounders, it is highly recommended to understand how the variables are related between them, with the exposure and with the outcome. One common approach to represent key causal relations is Directed Acyclic Graphs (DAGs). They are a simple way to encode our subject-matter knowledge, and our assumptions, about the qualitative causal structure of a problem (1).

Summarizing, DAGs are particularly useful for presenting graphically assumed relationships between variables, visualizing and understanding confounding (common causes) and mediation (total, direct and indirect effects), identifying the minimal set of adjustments for reducing bias (bias due to unmeasured confounding, over adjustment, selection, and measurement error) (1–6).

1.1. Burden of disease attributable to tobacco

Accordingly to data from the Institute for Health Metrics from 2015, 11.5% of the total deaths and 6% of the disability-adjusted life-years (DALYs) were attributable to the tobacco, being the second risk factor of death worldwide. From the 11.5% of total deaths explained just for tobacco smoking the major causes of death are cardiovascular diseases, neoplasms, chronic respiratory diseases, lower respiratory diseases, other common infectious diseases, tuberculosis, diabetes and other endocrine diseases. In the same line, 1.6% of total deaths were attributable to tobacco secondhand smoke (SHS) exposure and 1.2% of total DALYs were attributable to SHS worldwide (7). From the 1.6% of total deaths explained just for SHS the

major causes of death were cardiovascular diseases, neoplasms, chronic respiratory diseases and lower respiratory diseases.

The association between tobacco smoking and cancer has been widely described. The International Agency for Research on Cancer (IARC) classified tobacco and SHS exposure as carcinogenic to humans (group 1) (8,9). Cancers that are considered by IARC to be causally related to tobacco are lung, oral cavity, nasal cavity and paranasal sinuses, nasopharynx, oropharynx, hypopharynx, larynx, esophagus (adenocarcinoma and squamous cell carcinoma), upper aero digestive tract combined, stomach, pancreas, liver, kidney (body and pelvis), ureter, urinary bladder, cervix and myeloid leukemia (9). Moreover, a recent meta-analysis shows that smoking is also associated with head, neck, higher colorectal gastric and breast cancer (10). Based on the existing evidence, SHS causes cancer of the lung. Moreover, there is a positive association between exposure to SHS and larynx and pharynx cancers (8).

Therefore, as it has been described tobacco smoking as well as SHS exposure is associated with many diseases. This associations share common risk factors (i.e. low quality diet or sedentary behavior), and are influenced or have similar patterns when stratified by sociodemographic characteristics (i.e. social class or sex). In consequence, when tobacco is the main variable in a study, the possible interrelationships and effects of other variables with the health effects should be taken into account.

1.2. Tobacco control legislations

During the last decade, several countries (11) have implemented tobacco control bans as suggested by the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) (12) which aims to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to SHS. This international treaty was adopted by WHO member countries in 2003 and entered

into force in 2005, after it had been ratified, accepted, or approved by 40 States; in 2015 the WHO FTCD already covered about 90% of the world's population (11).

Moreover, World Bank fact sheet, Tobacco control at a glance (13), described in 2003 six cost effective tobacco control interventions: higher taxes on cigarettes and other tobacco products; bans/restrictions on smoking in public and workplaces (schools, health facilities, public transport, restaurants, cinemas, etc.); comprehensive bans on advertising and promotion of all tobacco products, logos and brand names; better consumer information (counter-advertising, media coverage, research findings, etc.); large, direct warning labels on cigarette boxes and other tobacco products; help for smokers who wish to quit, including increased access to nicotine replacement and other cessation therapies. Price increase is the most effective and cost-effective intervention in reducing smoking consumption, however, the best results are achieved when a comprehensive set of measures are implemented (13).

1.3. Health impact of the smoke free legislation

Since the implementation of tobacco control bans, it has been widely assessed the extent to which these bans or legislations, particularly restrictions of smoking in public and workplaces (smoke-free bans), reduce exposure to SHS, reduce tobacco consumption or lower smoking prevalence and affect the health. In this regard, several systematic reviews of international institutions (14–16) have summarized the available evidence.

According to the 2009 IARC review (16), exposure to SHS harms to health include lung cancer and cardiovascular disease in adults, respiratory disease in adults and children, and sudden infant death syndrome. SHS exposure has both acute and chronic health effects and consequently, both immediate and longer-term benefits to public health can be anticipated from implementing smoke-free policies. Such policies usually obtain majority support for smoke-free public and workplaces. Public support among both smokers and nonsmokers for

smoke-free policies increases following implementation of legislation. When smoke-free policies are implemented as described in the WHO FCTC guidelines, compliance is moderate to high. Moreover, implementation of smoke-free policies leads to a substantial decline in exposure to SHS, reduces social inequalities in SHS exposure at work, appears to cause a decline in heart disease morbidity (the published data on this are consistent, but longer-term follow-up is required), and decreases respiratory symptoms in workers. Lung cancer incidence in nonsmokers can be expected to decline 10-20 years after smoke-free legislation is put into action. Smoke-free workplaces reduce cigarette consumption among continuing smokers and lead to increased successful cessation among smokers. Smoke-free policies appear to reduce tobacco use among youth. In addition, there is a greater decline in smoking when smoke-free policies are part of a comprehensive tobacco control program.

Other of these reviews (14), carried out in 2010, included 50 studies from 13 countries. 31 reported exposure to SHS, 19 of them measured by the use of biomarkers. All studies clearly showed reduced reported SHS exposure. There was consistent evidence that smoking bans reduced exposure to SHS in workplaces, restaurants, pubs and in public places. There was a greater reduction in exposure to SHS in hospitality workers compared to the general population. Concerning SHS at home, there was no change in the prevalence or duration of reported exposure to SHS as smoke free bans effect, although some studies reported positive findings. In addition, more recent studies does show a significant decrease in self-declared exposure to SHS at home, work, public transport and leisure time (17) and an increase in smoke-free homes, after the implementation of national smoke-free bans (18).

Twenty-three studies reported measures of active smoking, often as a co-variable rather than an endpoint in itself and with diverse measurements, making it difficult to compare the findings. The effect of smoking bans on smoking prevalence was inconclusive, with smoking

prevalence declining slightly in most of the population based studies. There was inconsistent evidence of a reduction in cigarette consumption, but in studies where declines in prevalence were recorded, consumption levels also fell. Furthermore, other systematic review conducted in 2012 which included 88 studies, found high or moderately strong evidence that tobacco control policies can reduce smoking prevalence in the general population (19). This review also shows evidence about the effect of tobacco control policies in increasing the smoking cessation and reducing smoking initiation.

In the review conducted by Callinan et al. in 2010 (14), twenty-five studies reported health indicators as an outcome. Self-reported respiratory and sensory symptoms were measured in 12 studies, with lung function measured in five of them. There was consistent evidence of a reduction in hospital admissions for cardiac events as well as an improvement in some other health indicators after the ban.

The review updated and conducted by Frazer et al. (15), carried out in 2016, included 77 studies from 21 countries. 15 analyzed smoking prevalence, with more consistent evidence of the impact of smoking bans on reducing smoking prevalence rates and tobacco consumption. In addition, other studies not included in these review also show a significant reduction in smoking prevalence after the implementation of national smoke-free bans (17). Moreover, 4 studies provided evidence of reduced SHS following the introduction of smoking bans, consistent with evidence from the previous version of the review (14).

Seventy-two studies reported health outcomes, including cardiovascular, respiratory and perinatal outcomes (15). There is consistent evidence of a positive impact of national smoking bans on improving cardiovascular health outcomes based on 44 studies. From those, 43 evaluated incidence of acute myocardial infarction (AMI) and acute coronary syndrome (ACS), 33 of which detected significant associations between introduction of bans and reductions in

events. 6 studies evaluated stroke incidence and 5 detected significant associations between smoke free bans and reduction in events (15). 21 studies were included for analyzing the association with respiratory outcomes, but there were conflicting results and therefore the evidence is classified as very low. Nevertheless, 6 of 11 studies reported significant reductions in COPD (Chronic Obstructive Pulmonary Disease) admissions, and 7 of 12 reported significant reductions in asthma admissions (15). Perinatal outcomes provide evidence of reduced maternal smoking and acknowledged impact on fetal health (15). But the effects on perinatal health were less consistent due to unclear study designs and possibility of biased and confounded associations (15). Another meta-analysis published found that smoke-free legislation was associated with reductions in preterm birth and hospital attendances for asthma but no significant effect was found on low birthweight (20). Therefore, it is suggested that smoke free bans are associated with perinatal health even with the limitations of the literature published. Eleven studies reported national mortality rate for smoking-related diseases (15), from those, 8 detected significant associations between introduction of bans and reduced smoking-related mortality.

1.4. Justification and objectives

Most of the studies conclude that smoke-free bans are associated with a decrease in morbidity and/or mortality of smoking related diseases, although, the path is far more complicated. Moreover, to our knowledge, there is no previous literature published that focused on assessing the impact of the smoke-free legislation in health-related outcomes. Therefore, the aim of this article is to describe a methodological approach based on DAGs in order to analyze the association between the smoke-free bans and its health effects in the population.

2. Suggested DAG to assess the impact of smoking legislation on health of population

Based on the published literature, as previously described above (in the section 1.4.), smoke-

free bans are associated with a decrease in smoking prevalence and SHS exposure which in consequence have effects in children and adult health and therefore in the increase in the life expectancy. According to that, we have proposed the DAG showed in the figure 1 to assess the total effect of the smoke-free legislation in the adult and/or child health.

Moreover, each country has passed a different level or type of legislation (more or less restrictive and comprehensive), has started applying them at different time and ways, and has different pressure of the stakeholders (i.e. lobbies, tobacco companies, and attitudes toward smoking). Also, each country has a political and economic model that influence on the socio-demographic characteristics of the population (inequities). Furthermore, it is important to take into account that smoke-free bans are associated with an increase on quit smoking of the general population and thus with a decrease on smoking prevalence and, what is more, by reducing smoking prevalence also the exposure to SHS is reduced (14–16). However, changes on smoking prevalence over time can also be due to secular trends as expected according to the four-stage descriptive model of the tobacco epidemic (21).

In addition, the hardening hypothesis suggests that tobacco control activities have mostly influenced the less dependent smokers and, thus, remaining smokers are those who are less likely to quit smoking (22). In this regard, a study based on 18 European countries suggests that the lower the dependence is, the lower the country-specific smoking prevalence, counteracting the hardening hypothesis (23). In any case, tobacco dependence may influence smoking cessation and, thus, in the smoking prevalence. For this reason, the Fagerström Test for Cigarette Dependence (FTCD) score (24) is widely used to gather information about tobacco dependence.

Furthermore, tobacco use and tobacco-related deaths are much higher in certain social groups. Inequities in smoking have been observed based on educational level, sex, occupational level, ethnicity, housing tenure and other measures of health (25). Moreover, the

impact of the smoke-free legislations has been shown to be different depending on sex (15), socioeconomic status (26) and age (15). More specifically, socioeconomic gradients indicated that men in lower socioeconomic groups took more benefit from the effect of smoke-free legislation (15). A longitudinal study based on the immediate mortality effects on the national Irish smoking ban found a reduction in the inequalities in smoking-related mortality (26). However, it is important to take into account that the impact on health inequalities is uncertain as few studies have assessed post-ban effects by sociodemographic characteristics (26). Therefore, it is important to take into account the effect of sociodemographic characteristics in the smoking prevalence and SHS, as their attributable effect in health (i.e. life expectancy).

Finally, exposure (legislation) and outcomes (children and adults' health) variables are associated with some ancestors variables that depend on the specific scenario that researchers are interested in analyze. Considering all this evidence from literature previously discussed in this section, a graphical representation of all the possible mechanisms and pathways affecting the association between smoke-free legislations and their health impact can be observed in figure 1.

The hypothesis would be that there is a causal relationship between smoking legislations and children and/or adults' health. The exposure (legislation) and the outcomes (children health and adults' health) are represented in bold font. A back door path closed can be found in the colliders (secondhand smoke and smoking prevalence), therefore, there is no need to conditioning on these variables. On the other hand, there is a confounding pathway between adults/children health and socio-demographic variables or country nodes. We could adjust for any of the two nodes, in the case of the figure 1, we are conditioning on the node socio-demographic variables (squared).

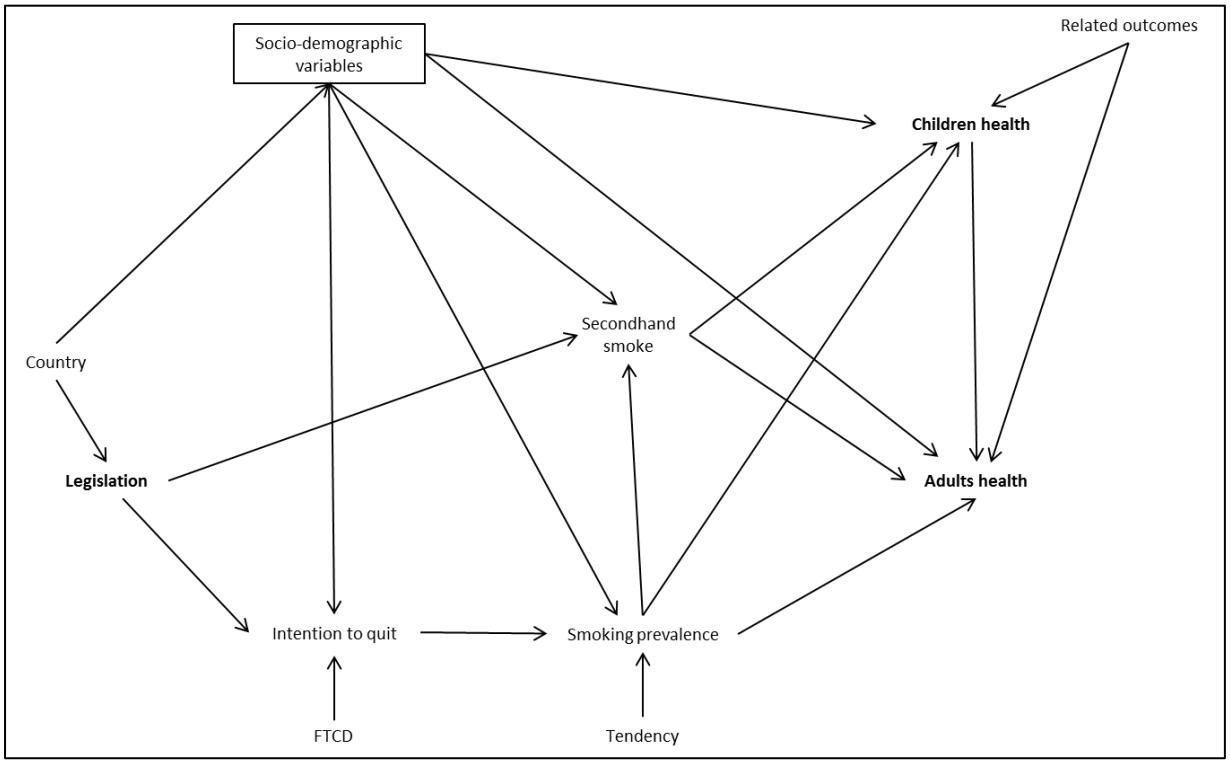

Figure 1. Directed Acyclic Graph (DAG) of the total effect of the smoke-free legislation on the incidence of children and adults health.

2.1. Scenario 1: Example of a DAG for the hypothesis that smoking legislation is causally related to acute myocardial infarction.

Assuming there is one study that wants to test the hypothesis that the implementation of smoke-free legislations has produced a decrease on the incidence of acute myocardial infarction cases. For that purpose, the information related to the predictors of the smoke-free ban (exposure) and the acute myocardial infarction (outcome) have been gathered; as other related variables in the causal pathway. As it is well known, the main factors, excluding active and passive exposure to tobacco, causing acute myocardial infarction are alcohol consumption, unhealthy diet, sedentary behavior and Body Mass Index (BMI), as well as socio-economic characteristics (i.e. age, social class). Supposing the study is carried out with a sample from a specific country, the node legislation would have a direct arrow to the node socio-economic status (Figure 2).

As there is a confounding path (unblocked back door path) between the outcome (acute myocardial infarction), the socioeconomic status and the exposure (legislation), it is necessary to condition on socio-economic status (block the back door path).

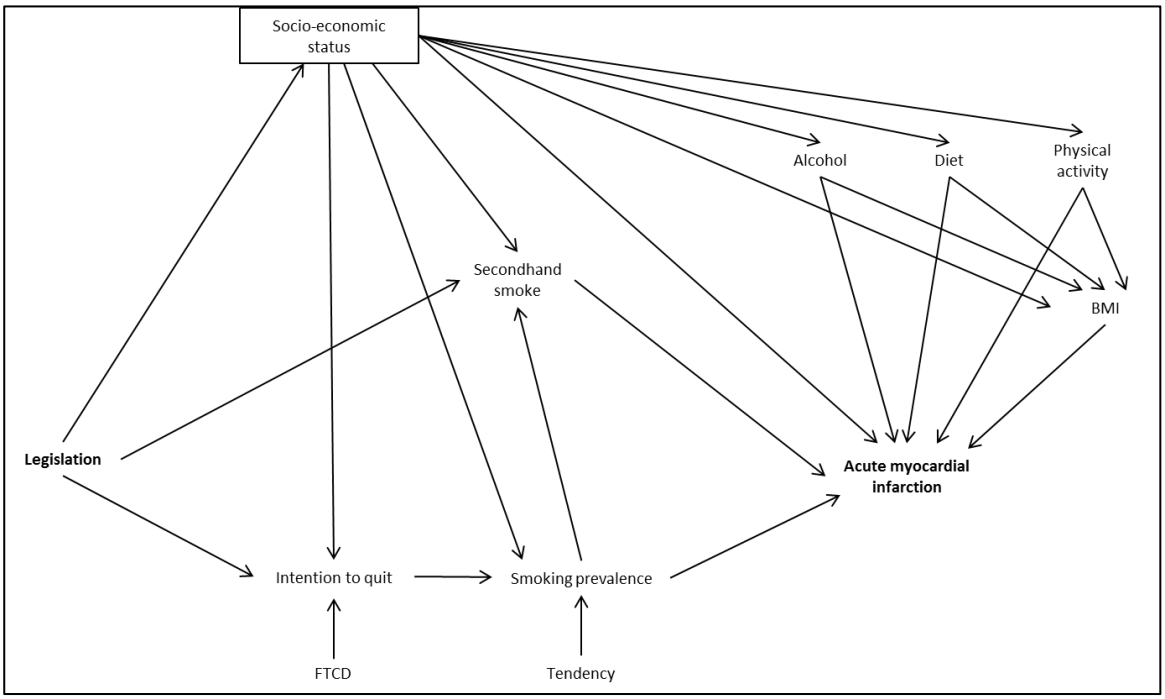

Figure 2. Directed Acyclic Graph (DAG) for total effect of the smoke-free legislation in the acute myocardial infarction incidence.

2.2. Scenario 2: DAG to assess the impact of smoking legislations in low birth weight.

Assuming there is one study that wants to test the hypothesis of the effect of the implementation of smoke-free legislation on the reduction of low birth weight incidence cases in European countries. Again we assume information related to the predictors of the smoke-free ban (exposure) and low birth weight (outcome) have been gathered, as well as information of other related variables in the causal pathway. The main predictors of low birth weight, excluding active and passive exposure to tobacco, described are the maternal life-style characteristics, such as diet, use of alcohol, physical activity, BMI, previous pregnancies (i.e. parity) and parental socio-economic characteristics (i.e. maternal age, educational or social level). Supposing the study is carried out with a sample from the 28 countries of the European

Union and the information related to socio-economic characteristics is not available (Figure 3). Therefore, the 2 possible confounding paths; (i) the outcome (low birth weight), the parental socioeconomic status and the exposure (legislation), and (ii) the outcome (low birth weight), the country and the exposure (legislation), would be reduced to the one which includes country. So, it is necessary to condition on country to block the back door path.

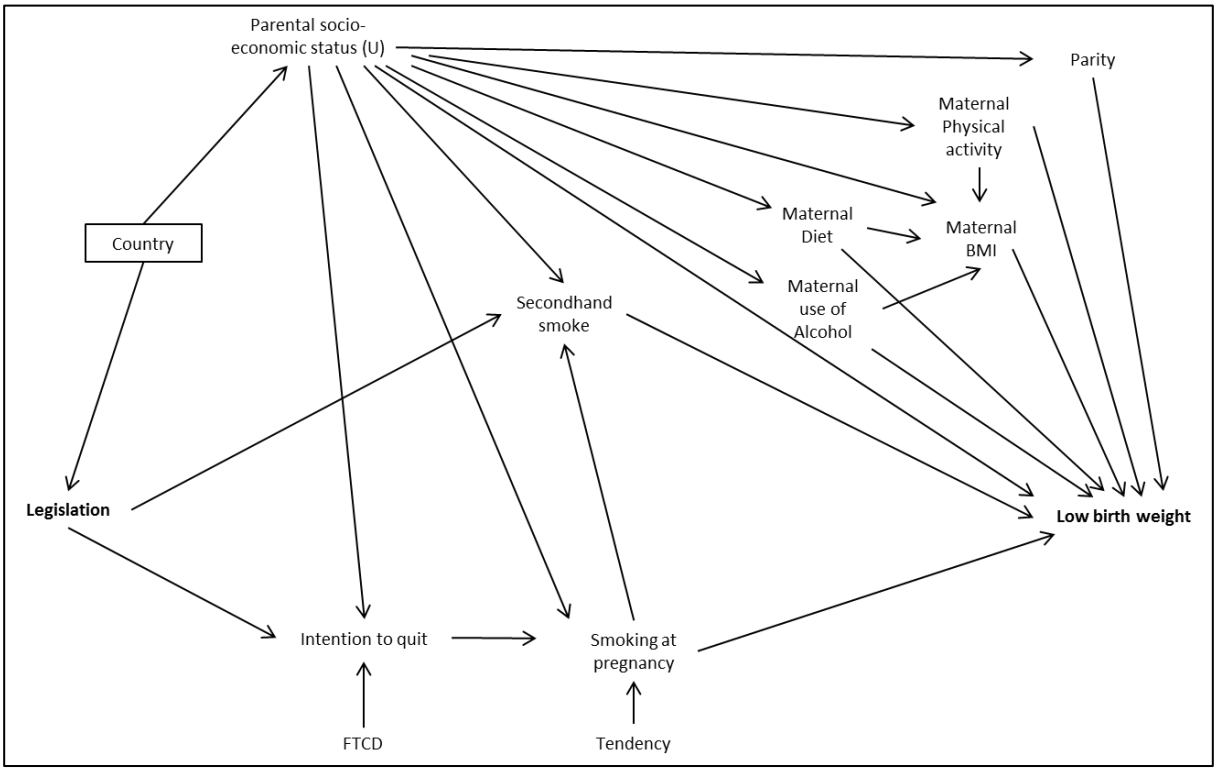

Figure 3. Directed Acyclic Graph (DAG) for total effect of the smoke-free legislation in the low birth weight incidence.

3. Discussion

To our knowledge, this is the first article focused in a methodological approach to analyze the association between the smoke-free bans and its health effects in the population. In this article we propose a tool for the tobacco researchers and epidemiologist in order to analyze the health impact in any possible disease scenario of the smoke-free legislations, by considering all the possible pathways, intermediate variables and confounders.

Almost any of the studies published used DAGs as part of their methodology. In the previous

commented review (15) the evidence found in some cases was very low due to the study design was unclear and to the possibility of confounding associations. Therefore, a major priority from public health is to improve the methodological quality of the research in order to obtain more consistent evidence to work with the stakeholders and finish with the tobacco epidemic. In this regard, there is just one study, that we know, that used a DAG to describe the recognized pathways contributing to the link between tobacco control policies and a specific health outcome based on the literature. However, the aim of the study was not to introduce a tool to the tobacco researchers but to investigate the tobacco control policies effect on key perinatal outcomes known to be associated with maternal smoking and/or SHS exposure (27). Consequently, the DAG that is shown in their study can just be applied for the objective of their study and could not be used in studies focused in other diseases.

Howbeit, it is important to keep in mind that there are other possible strategies for confounder identification. The main confounding evaluation strategies are three (28): (i) The stepwise procedure, the implicit assumption underlying this approach is that, although not all variables selected will be confounders, all important confounders will be selected. (ii) The change in effect estimates (by 5% or 10%), compares adjusted and unadjusted effect estimates, the implicit assumption is that any variable substantially associated with an estimate change is worth adjusting for. (iii) The standard confounder selection, consist on whether some necessary criteria for confounding are met. Generally, it is stated that a confounder is a variable associated with exposure in the population, associated with the outcome conditional on the exposure, and not in the causal pathway between the exposure and the outcome. The third approach does not rule out bias or unnecessary adjustment. All the three strategies may lead to bias from the omission of important confounders or inappropriate adjustment for non-confounders.

The presence of common causes, and therefore of confounding, can be represented by DAGs. Those also have some limitations per se. First of all we cannot quantify the magnitude of the effect, nor show the direction of the effect and of the interaction (synergism or antagonism). But DAGs can give us accurate information about the possible confounding variables we should take into account for our models (1). Therefore, the best approach we propose would be to combine the DAGs with the common confounding evaluation strategies.

The model we propose (figure 1) reaches all the possible factors that could be involved in the impact of the smoke-free bans and the health related outcomes by several pathways. However, there is an emerging concept in tobacco exposure, third-hand smoke (THS) made of residual tobacco smoke gases and particles that settle on surfaces and dust (29). It would have been interesting to introduce this novel concept in the DAG proposed, but the literature regarding this topic is scarce making it difficult to understand the possible relations. This reflects the need to shed more light about the THS and its health effects helping to modify or to create new tobacco legislations. In our opinion, introducing the variable THS in the DAG would not modify any of the existing arrows, instead it would open a new pathway being an intermediate factor between the SHS and smoking prevalence and the children and adult health. Moreover, it would be affected by sociodemographic variables.

In conclusion, studies that assess the effect of the smoke-free legislation on health outcomes may not forget to include key variables that could influence on their association. Those would be intention to quit, smoking prevalence and its tendency, secondhand smoke exposure, nicotine dependence (FTCD) and the sociodemographic characteristics. For this reason, DAGs and the model proposed to assess the impact of smoking legislation in the health of the population could be useful for the future research.

Competing Interests

The authors declare that they have no conflicts of interest.

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Author Contributions

NMS and CLM drafted the manuscript (both contributed equally to this article). All authors contributed substantially to the interpretation of the data and to revising the manuscript. All authors approved its final version.

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II. Prevalence and use profile of electronic cigarette in Spain (2014)

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Original

Prevalencia y perfil de uso del cigarrillo electrónico en España (2014)

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Cigarrillo electrónico
Consumo de tabaco
Prevalencia

RESUMEN

Objetivo: Describir la prevalencia y el perfil de uso de los cigarrillos electrónicos en la población adulta española y evaluar el potencial uso dual de estos dispositivos con el tabaco combustible o convencional, en España, en 2014.
Métodos: Estudio transversal en una muestra representativa de la población adulta (16-75 años de edad) española (n = 1016). Se realizó una encuesta telefónica asistida por ordenador en el año 2014. Se calcularon prevalencias y sus intervalos de confianza del 95% (IC95%) para el uso del cigarrillo electrónico estratificado por sexo, edad, consumo de tabaco y clase social. Se ponderó la muestra y se ajustó un modelo de regresión logística para calcular las *odds ratios* (OR) crudas y ajustadas por sexo, edad y clase social.
Resultados: El 10,3% (IC95%: 8,6-12,4) de la población adulta española declaró haber usado en alguna ocasión el cigarrillo electrónico (2% usuarios/as actuales, 3,2% usuarios/as en el pasado y 5,1% usuarios/as experimentadores/as). Entre los/las usuarios/as actuales de cigarrillos electrónicos, el 57,2% fumaba también tabaco combustible o convencional, el 28% nunca había fumado y el 14,8% eran ex fumadores/as. La prevalencia de uso del cigarrillo electrónico fue mayor entre la población joven (OR ajustada = 23,8; IC95%: 2,5-227,7) y entre las personas fumadoras de tabaco combustible (OR ajustada = 10,1; IC95: 5,8-17,5).
Conclusiones: El uso de cigarrillos electrónicos en España es poco frecuente y predomina en las personas jóvenes y las fumadoras de tabaco. Sin embargo, uno/a de cada cuatro usuarios/as actuales del cigarrillo electrónico nunca habían fumado. Por ello, debería reforzarse la regulación de estos dispositivos para evitar una posible puerta de entrada al uso de productos con nicotina.

Prevalence and user profile of electronic cigarettes in Spain (2014)

Keywords:
Electronic cigarettes
Tobacco consumption
Prevalence

ABSTRACT

Objective: To describe the prevalence and user profile of electronic cigarettes among Spanish adults and evaluate the potential dual use of these devices with combustible or conventional tobacco in 2014 in Spain.
Methods: Cross-sectional study of a representative sample of the Spanish adult (16-75 years old) population (n = 1,016). A computer-assisted telephone survey was conducted in 2014. The prevalence and 95% confidence intervals (95% CI) for the use of electronic cigarettes stratified by gender, age, tobacco consumption and social status were calculated. The sample was weighted and a logistic regression model adjusted to obtain the crude odds ratios (OR) adjusted by gender, age and social status.
Results: 10.3% (95% CI: 8.6-12.4) of the Spanish adult population stated being ever users of electronic cigarettes (2% current users, 3.2% past users and 5.1% experimental users). Among current electronic cigarette users, 57.2% also smoked combustible or conventional tobacco, 28% had never smoked and 14.8% were former smokers. The prevalence of electronic cigarette use was higher in the younger population (adjusted OR = 23.8; 95% CI: 2.5-227.7) and smokers of combustible tobacco (adjusted OR = 10.1; 95% CI: 5.8-17.5).
Conclusions: The use of electronic cigarettes in Spain is scarce and is most prevalent among young people and tobacco smokers. Nevertheless, one out of four current electronic cigarette users have never smoked. Hence, the regulation of these devices should be reinforced to avoid a possible gateway to nicotine products among never smokers.

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Introducción

Los primeros cigarrillos electrónicos aparecieron en 2007 y sólo podían adquirirse por Internet. Desde entonces, y especialmente en los últimos años, ha aumentado su interés y popularidad. Sin embargo, al igual que ha sucedido en otros países, en las ciudades españolas las tiendas especializadas donde pueden adquirirse los cigarrillos electrónicos y todo tipo de productos relacionados con estos dispositivos empezaron a contarse por decenas a partir de 2013, cuando se registró un máximo de 3500 tiendas[1]. Según la Asociación Nacional del Cigarrillo Electrónico (ANCE)[2], la facturación de estos dispositivos aumentó un 12% de 2014 a 2015, aunque actualmente estas tiendas se han reducido significativamente en España[1].

Los posibles riesgos y beneficios del cigarrillo electrónico a medio y largo plazo todavía son desconocidos, lo que ha generado un intenso debate en las revistas científicas y en los medios de comunicación. Algunos/as investigadores/as[3] y ciudadanos/as, en particular los/las usuarios/as de los cigarrillos electrónicos y empresarios/as con intereses económicos en ellos, defienden estos dispositivos como una herramienta útil para dejar de fumar o reducir el consumo de tabaco, como estrategia de reducción del daño para las personas fumadoras. Un reciente metaanálisis[4] basado en 13 estudios (dos ensayos aleatorizados controlados y 11 estudios de cohortes controlados) ha mostrado que los cigarrillos electrónicos podrían ayudar a prevenir la recaída entre las personas ex fumadoras o promover el abandono del tabaco entre los/las fumadores/as actuales, aunque no ha logrado demostrar que ayuden a dejar de fumar a largo plazo en comparación con el placebo. Sin embargo, un estudio longitudinal posterior[5] mostró que el abandono depende del tipo de cigarrillos electrónicos utilizados y de su frecuencia de uso. Por otro lado, investigadores/as[6] y activistas del control del tabaquismo señalan al cigarrillo electrónico como una amenaza a las legislaciones sobre espacios públicos y centros de trabajo libres de humo, además de favorecer nuevos dependientes de la nicotina (y potenciales personas fumadoras de tabaco), en especial entre la población más jóven[7–9], fomentando su uso dual con otros productos de tabaco, tal como demuestran algunos estudios[10–12].

En España, casi la totalidad de la población sabe qué son los cigarrillos electrónicos[11,13,14], pero sólo se dispone de información sobre su uso en la ciudad de Barcelona[13]. Por ello, el objetivo de este trabajo de ámbito nacional es describir la prevalencia y el patrón de uso de los cigarrillos electrónicos en la población adulta española, y evaluar el potencial uso dual de estos dispositivos con el tabaco combustible o convencional.

Métodos

Los datos utilizados proceden de la encuesta Ómnibus del Instituto DYM[15]. Se trata de un estudio transversal en una muestra representativa de la población adulta española (n = 1016) de entre 16 y 75 años de edad, residentes en municipios de más de 500 habitantes, en la Península y las Islas Baleares. El tamaño muestral se calculó con la fórmula del muestreo aleatorio simple ($N = ([Z_\alpha \cdot p \cdot (1\text{-}p)]/e)^2$) para una prevalencia (p) estimada del 50% (prevalencia que maximiza el tamaño muestral), un nivel de confianza del 95% ($\alpha = 0{,}05$; $Z_\alpha = 1{,}96$) y una precisión o error del 3,15% ($e = 0{,}0315$). Cabe destacar que al utilizar en el cálculo del tamaño muestral una prevalencia esperada que maximiza el tamaño muestral y superior a la prevalencia de uso del cigarrillo electrónico, entre el 5% y el 10%[11,16,17], aumenta la validez externa del estudio. El tamaño necesario para estudiar el uso del cigarrillo electrónico en la población española utilizando una prevalencia esperada del 10% con un error del 2%, habitualmente utilizado, sería de 865 individuos. La encuesta se llevó a cabo en octubre y noviembre de 2014 mediante entrevista telefónica asistida por ordenador. La selección de los hogares a entrevistar se realizó a partir de directorios telefónicos de municipios seleccionados aleatoriamente. Para la selección del individuo a entrevistar se utilizaron cuotas de edad, sexo y actividad laboral, por lo que la muestra final se ponderó mediante pesos de diseño basados en la distribución de los datos obtenidos del Instituto Nacional de Estadística para obtener una mayor representatividad de España. La ponderación se realizó según sexo, edad, zona de residencia (Este, Levante, Sur, etc.), tamaño del municipio de residencia y ocupación.

Variables

Para estimar la prevalencia de usuarios/as de cigarrillo electrónico se usó la pregunta «¿Ha utilizado el cigarrillo electrónico alguna vez?», con las posibles respuestas «Sí, actualmente», «Sí, pero en el pasado», «Sólo lo he probado» y «Nunca lo he probado». A partir de esta pregunta se definieron los/las usuarios/as que alguna vez habían probado los cigarrillos electrónicos como las personas que respondieron «Sí, actualmente», «Sí, pero en el pasado», «Sólo lo he probado» (o «experimentadores»). Aunque en la actualidad no existe una pregunta validada para medir el uso del cigarrillo electrónico, en nuestro estudio hemos utilizado la misma pregunta utilizada ampliamente en estudios previos[11,17–20] para aumentar la validez interna de nuestro trabajo y la comparabilidad con otros. También se preguntó por el consumo de tabaco y se clasificó a los participantes en personas fumadoras (diarias y ocasionales), ex fumadoras y nunca fumadoras.

Se recogió información sobre la edad (categorizada en los grupos de 16-45 años, 46-65 años y 66-75 años), el sexo de la persona entrevistada y su clase social (categorizada en alta, media y baja, basándose en el nivel educativo de la persona entrevistada y la ocupación de la persona sustentadora de la familia).

Se calcularon las prevalencias y su intervalo de confianza del 95% (IC95%) del uso del cigarrillo electrónico estratificado por sexo, edad, consumo de tabaco y clase social. Se utilizaron las pruebas de χ^2 de Pearson y de χ^2 de tendencia para valorar la asociación entre el uso del cigarrillo electrónico y diversas variables sociodemográficas. Se ajustó un modelo de regresión logística para calcular las *odds ratios* (OR) crudas y ajustadas por sexo, edad y clase social, junto con sus IC95%. Los análisis de los datos se realizaron con el *software* estadístico SPSS versión 21. Además, todos los análisis estadísticos incorporaron las ponderaciones derivadas del diseño muestral.

Resultados

El 24,4% (IC95%: 21,9-27,1) de las personas encuestadas afirmó ser fumador/a de tabaco, el 27,7% (IC95%: 25,0-30,5) ex fumador/a y el 47,9% (IC95% = 44,9-51,0) nunca fumador/a. Los hombres declararon fumar más que las mujeres (27,8% frente a 21%, p = 0,012), y se observó una tendencia decreciente y significativa del consumo de tabaco con la edad (p de χ^2 de tendencia <0,001).

El 10,3% (IC 95%: 8,6-12,4) de la población adulta española declaró haber usado en alguna ocasión el cigarrillo electrónico (tabla 1). La prevalencia de uso del cigarrillo electrónico en alguna ocasión fue mayor, y estadísticamente significativa, entre la población joven (OR ajustada = 23,8; IC95%: 2,5-227,7) y entre las personas fumadoras de tabaco combustible (OR ajustada = 10,1; IC95%: 5,8-17,5). No se observaron diferencias estadísticamente significativas en el uso del cigarrillo electrónico según el sexo ni la clase social (tabla 1). Los resultados obtenidos entre las OR crudas y las OR ajustadas fueron similares.

En la tabla 2 se muestra la prevalencia de uso actual, pasado y de experimentación del cigarrillo electrónico según las variables

Tabla 1
Prevalencia (%) del uso de cigarrillo electrónico, *odds ratio* cruda (OR) y ajustada (ORa), y sus intervalos de confianza del 95% (IC95%), según sexo, edad, clase social y consumo de tabaco. España, 2014

	n	% (IC95%)	p	OR (IC95%)	ORa[a] (IC95%)
Uso del cigarrillo electrónico	1016	10,3 (8,6-12,4)	-	-	-
Sexo					
Mujer	509	8,8 (6,7-11,6)	0,117[b]	1	1
Hombre	507	11,8 (9,3-15,0)		1,4 (0,9-2,1)	1,3 (0,9-2,0)
Edad (años)					
16-45	560	14,8 (12,1-18,0)	<0,001[b]	24,7 (2,6-235,5)	23,8 (2,5-227,7)
46-65	344	6,1 (4,0-9,1)	<0,001[c]	9,5 (1,0-93,2)	9,2 (0,9-90,8)
66-75	112	0,9 (0,2-5,0)		1	1
Clase social					
Alta	56	14,3 (7,4-25,7)	0,282[b]	1	1
Media	679	10,9 (8,8-13,5)	0,113[c]	1,8 (0,8-4,0)	1,2 (0,5-2,7)
Baja	281	8,3 (5,5-12,0)		1,8 (0,8-4,3)	1,3 (0,5-3,1)
Consumo de tabaco					
Nunca fumador/a	487	3,9 (2,5-6,0)	<0,001[b]	1	1
Ex fumador/a	281	5,0 (3,0-8,2)		1,3 (0,7-2,7)	1,6 (0,8-3,2)
Fumador/a	248	29,0 (23,7-35,0)		10,2 (6,0-15,5)	10,1 (5,8-17,5)

IC95%: intervalo de confianza del 95%; OR: *odds ratio*; ORa: OR ajustada.
[a] Ajustada por sexo, edad y clase social.
[b] χ^2 de Pearson.
[c] χ^2 de tendencia.

Tabla 2
Prevalencia (%) de uso actual, pasado y de experimentación del cigarrillo electrónico según sexo, edad, clase social y consumo de tabaco. España, 2014

	n	Uso actual % (IC95%)	p	Uso pasado % (IC95%)	p	Experimentación % (IC95%)	p
Uso del cigarrillo electrónico	1016	2,0 (1,3-3,0)	-	3,2 (2,3-4,5)	-	5,1 (3,9-6,6)	-
Sexo							
Mujer	509	1,2 (0,5-2,5)	0,046[a]	3,1 (1,9-5,0)	0,846[a]	4,5 (3,0-6,7)	0,559[a]
Hombre	507	3,0 (1,8-4,8)		3,3 (2,1-5,3)		5,5 (3,8-7,9)	
Edad (años)							
16-45	560	3,0 (1,9-4,8)	0,042[a]	4,1 (2,7-6,1)	0,158[a]	7,7 (5,7-10,2)	<0,001[a]
46-65	344	1,2 (0,4-2,9)	0,013[b]	2,6 (1,4-4,9)	0,055[b]	2,3 (1,2-4,5)	<0,001[b]
66-75	112	0,0 (0-3,3)		0,9 (0,2-4,9)		0,0 (0,0-3,3)	
Clase social							
Alta	56	0,0 (0,0-6,4)	0,026[a]	5,4 (1,8-14,6)	0,613[a]	8,9 (3,9-19,3)	0,754[a]
Media	679	2,8 (1,8-4,3)	0,147[b]	3,1 (2,0-4,7)	0,486[b]	5,0 (3,6-6,9)	0,734[b]
Baja	281	0,4 (0,1-2,0)		2,9 (1,4-5,5)		5,0 (3,0-8,2)	
Consumo de tabaco							
Nunca fumador/a	487	1,2 (0,6-2,7)	0,002[a]	0,0 (0,0-0,8)	<0,001[a]	2,7 (1,6-4,5)	<0,001[a]
Ex fumador/a	281	1,1 (0,4-3,1)	0,003[b]	0,7 (0,2-2,6)	<0,001[b]	3,2 (1,7-6,0)	<0,001[b]
Fumador/a	248	4,8 (2,8-8,3)		12,5 (8,9-17,2)		11,7 (8,3-16,3)	

IC95%: intervalo de confianza del 95%.
[a] χ^2 de Pearson.
[b] χ^2 de tendencia.

sociodemográficas. El 2% (IC95%: 1,3-3,0) de la muestra declaró ser usuario/a actual del cigarrillo electrónico, el 3,2% (IC95%: 2,3-4,5) usuarios/as en el pasado y el 5,1% (IC95%: 3,9-6,6) experimentadores/as. En cuanto al uso actual del cigarrillo electrónico, se observó un mayor uso en los hombres (3% frente a 1,2% en las mujeres, p = 0,046), así como una tendencia decreciente y significativa de su uso con la edad (p de χ^2 de tendencia = 0,013) y con el consumo de tabaco (nunca fumador/a: 1,2%; ex fumador/a: 1,1%; fumador/a: 4,8%). Respecto al uso pasado, únicamente se observan diferencias significativas en función del consumo de tabaco (nunca fumador/a: 0%; ex fumador/a: 0,7%; fumador/a: 12,5%). Por último, en lo referente a la experimentación, se observa una tendencia decreciente y significativa del uso del cigarrillo electrónico con la edad (p de χ^2 de tendencia <0,001) y el consumo de tabaco (nunca fumador/a: 2,7%; ex fumador/a: 3,2%; fumador/a: 11,7%).

En la figura 1 se muestra la distribución porcentual del consumo de tabaco entre las personas usuarias del cigarrillo electrónico. El 67,5% de las personas que declararon haber usado en alguna ocasión

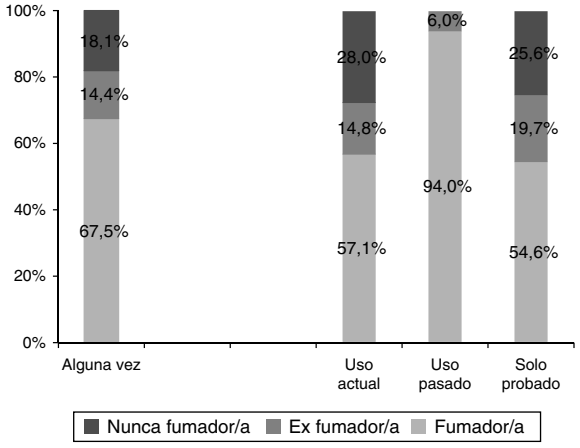

Figura 1. Distribución porcentual del consumo de tabaco entre las personas usuarias (actuales, pasadas y experimentadoras) de cigarrillos electrónicos. España, 2014.

el cigarrillo electrónico eran fumadoras de tabaco combustible, el 18,1% nunca fumadoras y el 14,4% ex fumadoras en el momento del estudio. Entre quienes usaban actualmente el cigarrillo electrónico, el 57,2% fumaban tabaco (usuarios/as «duales»), el 14,8% eran ex fumadores/as y el 28% declararon no haber fumado nunca. Además, todas las personas usuarias actuales de cigarrillo electrónico que declararon ser «nunca fumadoras» pertenecían al grupo de menor edad (16-45 años). Finalmente, de las personas que solo lo habían probado, el 54,7% eran fumadoras, el 19,7% ex fumadoras y el 25,6% nunca fumadoras (fig. 1).

Discusión

Este estudio muestra que el 10,3% de las personas españolas adultas han probado en alguna ocasión el cigarrillo electrónico. Este porcentaje es mayor que el observado en la ciudad de Barcelona (6,5%) en 2013-2014[11], lo cual puede deberse a que en el estudio de Barcelona estaba sobrerrepresentada la población adulta. Por otro lado, una reciente revisión sistemática de 21 artículos[16] mostró una variabilidad en la prevalencia del uso del cigarrillo electrónico dependiendo del grupo de edad estudiado. Por otro lado, este estudio muestra una mayor prevalencia de uso entre la población más joven y entre las personas fumadoras. En Europa[17] en general, y en Barcelona en particular[11], también se ha observado un mayor uso del cigarrillo electrónico entre la población joven. En este sentido, la revisión antes mencionada[16] mostró que solamente el consumo de tabaco fue la variable que siempre se correlacionó con el uso de los cigarrillos electrónicos.

En Europa, el 20,3% de las personas fumadoras, el 4,7% de las ex fumadoras y el 1,2% de las nunca fumadoras reportaron en 2012 haber usado alguna vez el cigarrillo electrónico[17]. En Barcelona se observaron prevalencias similares en 2013-2014 (21,1% de las personas fumadoras, 4,1% de las ex fumadoras y 0,3% de las nunca fumadoras)[11]. Sin embargo, los resultados del presente estudio de ámbito nacional muestran una mayor prevalencia en comparación con dichos estudios, en especial entre las personas fumadoras y nunca fumadoras. Esta diferencia podría deberse a una mejor representatividad de la presente muestra (sin sobrestimar la población más adulta), como comentábamos antes, o a que fue justamente en 2014 cuando se extendió más la experimentación y el uso de los cigarrillos electrónicos entre la población más joven, antes de su declive (como muestra el cierre de tiendas especializadas en estos dispositivos)[1].

Un aspecto importante, relativo a los cigarrillos electrónicos, es su uso en población nunca fumadora, en particular entre la gente más joven, lo que fomenta una nueva puerta de entrada a la dependencia de la nicotina, así como un uso dual con otros productos de tabaco (hipótesis del *gateway* de los cigarrillos electrónicos)[10]. En nuestro estudio observamos que la prevalencia de personas nunca fumadoras era mayor entre los/las usuarios/as actuales (28%) de cigarrillo electrónico y entre los/las experimentadores/as (25,6%) en comparación con los/las que lo utilizaron en el pasado (fig. 1), y además estas personas nunca fumadoras pertenecían al grupo de menor edad (18-45 años). Tales cifras apoyan la hipótesis de que los cigarrillos electrónicos pueden representar una puerta de entrada a la adicción a la nicotina, y por lo tanto también muy probablemente a ser fumadores/as de tabaco combustible. Sin embargo, debemos tomar estos resultados con precaución porque no se dispone de información a partir de la encuesta sobre el uso de los cigarrillos electrónicos con o sin nicotina. Aun así, debería aumentar la regulación de estos dispositivos (publicidad, uso en espacios públicos y acceso a menores), como recomienda la Organización Mundial de Salud[21], con el fin de prevenir que los cigarrillos electrónicos sean una nueva puerta de entrada a la adicción a la nicotina, especialmente entre los jóvenes nunca fumadores. Además, un estudio previo[13] realizado en Barcelona mostró que los canales de comunicación clásicos (prensa, radio y televisión) eran el medio a través del cual más individuos (57,8%) conocieron los cigarrillos electrónicos.

Nuestros resultados también muestran una baja prevalencia en el uso actual y pasado del cigarrillo electrónico entre ex fumadores/as, con un alto porcentaje de uso dual (57,2%) de estos dispositivos junto con tabaco convencional. Aunque estudios previos han mostrado que la principal motivación para empezar a usar el cigarrillo electrónico es dejar de fumar[18,22], el alto porcentaje de personas usuarias duales con el tabaco combustible observado en nuestro trabajo pone realmente en duda la utilidad de los cigarrillos electrónicos para ese fin. Al tratarse de un estudio transversal, sin embargo, no podemos evaluar la verdadera utilidad de los cigarrillos electrónicos para dejar de fumar o reducir el consumo de tabaco.

Por otro lado, nuestros resultados concuerdan con otros estudios, tanto transversales[12,17,23] como longitudinales[11,19,24,25], que han observado también una alta prevalencia de uso dual con otros productos del tabaco. Además, un estudio previo mostró que alrededor del 40% de las personas que han probado alguna vez el cigarrillo electrónico no estaban satisfechas con su uso[11]. Por otro lado, existe la popular creencia de que los cigarrillos electrónicos son menos perjudiciales para la salud que los convencionales[13,23,26]. Además, el 29,9% de la población general opina que estos dispositivos son útiles para dejar de fumar y el 50,6% opina que son útiles para reducir el consumo de cigarrillos convencionales[27]. En este sentido, uno de los principales mensajes utilizados para captar clientes es la utilidad de estos dispositivos para dejar de fumar o su menor nocividad en comparación con los cigarrillos convencionales[28]. La tercera oleada del Barómetro Sanitario del Centro de Investigaciones Sociológicas de 2014 mostró que el 48,6% de las personas que tienen conocimiento del cigarrillo electrónico consideran que puede suponer un riesgo para la salud[14]. No obstante, se requiere más investigación para demostrar la verdadera utilidad de estos dispositivos para dejar de fumar o reducir el consumo de tabaco. Además, sería conveniente mejorar las campañas de información a los/las consumidores/as sobre este producto y regular su publicidad basándose en la evidencia científica.

Las principales limitaciones de este estudio son las derivadas de la utilización de encuestas[29]. En concreto, al tratarse de un cuestionario mediante entrevista telefónica asistida por ordenador, existe una potencial amenaza a la validez interna derivada de un sesgo de información. Sin embargo, estimamos que este posible sesgo es mínimo debido a que el uso de los cigarrillos electrónicos no está socialmente estigmatizado. Además, podría haber un sesgo de información al utilizar como población a muestrear las personas incluidas en los listines telefónicos, que no incluyen teléfonos móviles, siendo estos el único tipo de teléfono que la población más joven suele utilizar. Cabe mencionar que en la actualidad no existe una pregunta estándar para medir el uso del cigarrillo electrónico, lo que dificulta la comparación entre diferentes estudios[30]. De todos modos, la pregunta que se utilizó en este trabajo es la misma que se ha empleado en muchos otros anteriormente[11,17–20], y esto facilita la comparación de los resultados obtenidos en diferentes estudios. Aunque no se incluyó información de Canarias, una fortaleza de nuestro estudio es que la muestra fue representativa de la población adulta española. Además, todos los análisis utilizaron datos ponderados para garantizar estimaciones representativas de la población española, aumentando así la validez externa del estudio. Sin embargo, el reducido tamaño de la muestra final impide cualquier análisis por regiones.

En conclusión, el uso de cigarrillos electrónicos en España es más frecuente en las personas más jóvenes y en las personas fumadoras de tabaco. Además, nuestros datos muestran que uno/a de cada cuatro usuarios/as actuales del cigarrillo electrónico eran nunca

fumadores/as. Por ello, debería reforzarse la regulación de estos dispositivos, en particular su acceso para los menores, con el fin de evitar que sean una posible puerta de entrada en las personas que nunca han fumado productos con nicotina.

Editora responsable del artículo

Mª Felicitas Domínguez Berjón.

Declaración de transparencia

El autor principal (garante responsable del manuscrito) afirma que este manuscrito es un reporte honesto, preciso y transparente del estudio que se remite a Gaceta Sanitaria, que no se han omitido aspectos importantes del estudio, y que las discrepancias del estudio según lo previsto (y, si son relevantes, registradas) se han explicado.

¿Qué se sabe sobre el tema?

Estudios anteriores muestran un rápido aumento del uso del cigarrillo electrónico entre los jóvenes, además de un alto porcentaje de uso dual del cigarrillo electrónico con otros productos de tabaco, particularmente con el cigarrillo convencional. No obstante, en España, solo se dispone de información sobre el uso del cigarrillo electrónico en la ciudad de Barcelona.

¿Qué añade el estudio realizado a la literatura?

Este trabajo de ámbito nacional describe la prevalencia y el patrón de uso de los cigarrillos electrónicos en la población adulta española y evalúa el potencial uso dual de estos dispositivos con el tabaco combustible o convencional. Nuestros resultados muestran que el uso de cigarrillos electrónicos en España es más frecuente entre las personas más jóvenes y las personas fumadoras de tabaco, por lo que debería reforzarse la regulación de estos dispositivos, particularmente su acceso a menores, para evitar una posible puerta de entrada en las personas que nunca han fumado productos con nicotina.

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Contribuciones de autoría

J.M. Martínez-Sánchez concibió el estudio. C. Lidón-Moyano y J.M. Martínez-Sánchez escribieron el primer borrador del manuscrito. C. Lidón-Moyano realizó los análisis. M. Fu, M. Ballbè, J.C. Martín-Sánchez y E. Fernández contribuyeron significativamente en sus versiones posteriores. Todos/as los/las autores/as han aprobado la versión final del manuscrito. J.M. Martínez-Sánchez es el investigador principal del proyecto.

Conflicto de intereses

Ninguno.

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III. Correspondence of the thesis article: Impact of the Spanish smoking laws on tobacco consumption and secondhand smoke exposure: A longitudinal population study

Cover letter to the editor of Addictive Behaviours

Barcelona, January 24rd, 2017.

Prof. Peter M. Miller
Editor
Addictive Behaviours

Dear Prof. Miller,

Please find enclosed our manuscript "Impact of the Spanish smoking laws on tobacco consumption and second-hand smoke exposure: a population longitudinal study" for your consideration in Addictive Behaviours as a *Full Length Article*.

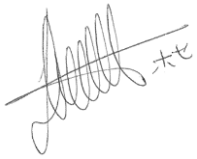
Currently, few studies have evaluated the impact of smoking legislation using a general population cohort. Our study assess the impact of both Spanish smoke-free legislations (partial and comprehensive) in active and passive smoking in a cohort of adult general population of the city of Barcelona. We found a reduction in smoking prevalence and SHS exposure. However, the use of other tobacco products, particularly hand-rolled tobacco, has increased among young population. In addition, the main setting of SHS is in the leisure time and in work, where most of the exposed ones declared expending most of the time outdoor and not having specific areas for smokers after the implementation of the two Spanish smoke-free bans. Therefore, future tobacco control legislations should consider applying the same taxing level to all tobacco products in order to equalize their prices as well as including some outdoor restrictions to ensure higher protection against SHS.

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. The authors declare there are no conflicts of interest.

We would of course be ready to provide further information about our data and methods you 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.

Yours sincerely,



Jose M Martínez-Sánchez, PhD, MPH, BSc

E-mail: jmmartinez@uic.es

Editor's response and comments from the Addictive Behaviours reviewers

-----Mensaje original-----
De: eesserver@eesmail.elsevier.com [mailto:eesserver@eesmail.elsevier.com]
Enviado el: viernes, 26 de mayo de 2017 16:13
Para: jmmartinez@uic.es
Asunto: Your Submission

Ms. Ref. No.: ADDICTBEH-D-17-00099
Title: Impact of the Spanish smoking laws on tobacco consumption and secondhand smoke exposure: a population longitudinal study Addictive Behaviors

Dear Dr. Jose M Martínez-Sánchez,

Your manuscript has been reviewed for Addictive Behaviors and our editorial decision is to ask you to revise and resubmit your paper. Attached are the comments of our referees. Please modify your manuscript according to their recommendations and provide responses to their questions. I look forward to reading your revised manuscript.

To submit a revision, please go to https://ees.elsevier.com/addictbeh/ and login as an Author.

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Sincerely,

Theodore V. Cooper, Ph.D.
Associate Editor

Reviewers' comments:

Reviewer #1: Summary: This study examined the impact of two smoking laws passed in Spain in 2005 and 2010, respectively. The first law banned smoking in public and in businesses and, following up from issues with the first law, the second law banned smoking on hospital grounds, educational campuses, playgrounds, and other outdoor areas. The authors used data collected in 2004-2005, before the first law was passed, on smoking status/frequency, nicotine dependence, and exposure to secondhand smoke. They followed the same sample in 2013-2014, retaining about half of the original participants, and administered the same questionnaires to assess change from the first time point. The results showed that after the smoking legislation was passed overall smoking rates and exposure to secondhand smoke decreased. However, consumption of other tobacco products (e.g., hand rolled cigarettes, e-cigarettes, etc.) notably increased, particularly amongst young people. The authors suggest that the increased consumption of other tobacco products may be because they are cheaper than cigarettes, which are taxed at a higher rate. They conclude that a tax increase on other tobacco products may be effective to further decrease rates of tobacco consumption.

Overall Impressions: This was a well-executed, interesting study that is within the scope of Addictive Behaviors. Examining health policy is incredibly important and this study is a solid contribution to the literature. The methodology is sound and the authors were mindful of confounds and threats to internal validity. The structure is logical, easy to follow, and each idea connects to the other. Their conclusions are supported by the data and they discuss limitations to the study. Their recommendation to raise taxes on other tobacco products and increase restrictions on outdoor smoking is grounded in the results and a logical next step for policy.

Comments:

1.The paper could benefit from some editorial work to assess correct grammar, punctuation, verb tense, and overall flow. Each section has a number of instances in which sentences could be rephrased to enhance clarity and flow.

2.What are the psychometrics of the FTCD? A sentence or two here reviewing previous validation studies should suffice.

3.The authors should further comment on other potential threats to internal validity (this can be in the paper if warranted or in a response to the reviewers) to demonstrate they considered them. For example, are there other confounding variables or history/maturation issues in the sample which could account for the results? Have there been any anti-smoking public health campaigns in Spain during the time of the study? Have there been documented changes in the attitudes/perceptions of smoking which could partially explain the decrease in smoking? Generally, what else in addition to the legislation might explain the results?

4.The authors should briefly mention in the limitations that causality cannot be established as is generally the case with policy research.

Reviewer #2: This is a population-based longitudinal study. It examines the impacts of Spanish smoking legislations on active and passive smoking. The effective indicators includes smoking prevalence ratio, daily smokers' tobacco consumption and nicotine dependence, and non-smokers' secondhand smoke exposure. Although many studies have assessed the effects of smoking control policies, this study still provides some new insights about this issue. In addition, the authors clearly state the research problems and purposes, and the design is suitable for answering the posed question. Overall, its quality is good except the analyses of smoking status. Some points in this manuscript need to be clarified and added. The deficiencies in various sections of this manuscript and specific comments and suggestions are listed as follows.

1. "Abstract"
As stated in the "Background" part of the Abstract, this study includes the impacts of smoking legislations on the active and passive smoking. However, the "Methods" part of the Abstract only focuses on the active smoking but not the passive smoking. How the data of passive smoking measured and analyzed needs to be addressed. In addition, it would be better to indicate the impacts of smoking legislations on the active and passive smoking separately in the "Results" part of the Abstract.

2. "INTRODUCTION" Section
Page 3, Line 14
The word "Consequently" as the first word of one paragraph is a little bit odd. It is better to be deleted.

3. "METHODS" Section
Page 5, Line 9
Page 4 Line 13 to Page 5 Line 10 have described the two-waves participants clearly; therefore, Fig. 1 isn't needed. To make it more concise, the words " (Fig. 1)" on Page 5 Line 9 and the corresponding Figure 1 on Pages 20-21 both could be deleted.

Page 5, Lines 10-18
To be a representative sample, the participants were randomly selected by age, sex, and district of the adult population of Barcelona (Spain) according to Reference 20. However, the authors compared differences in age, sex, level of education and smoking status between the follow-up and the lost participants in both surveys on Page 5 Lines 10-18, but not district. To represent the follow-up group with the population of Barcelona, age, sex, and district all three criteria for sample selection need to be examined and addressed here.

Page 6, Lines 1-22
There is one problem regarding "Smoking status" variable. As stated on Page 6 Lines 1-9, the participants were divided into three groups including smokers, former smokers, and never smokers. There was no daily smokers. But the "Number of cigarettes smoked per day" and "FTCD score" variables were only related to daily smokers. Since daily smokers are different from smokers, it is needed to define and mention who are daily smokers. Are those who smoke everyday (at least one cigarette per day) classified as daily smokers? If "yes", please indicate it in the text. Similarly, why and how the participants are regrouped into smokers and non-smokers for the following analysis needs to be mentioned. In addition, is the "Type of tobacco product used" variable only related to daily smokers? All of these questions need to be clarified and addressed more detail.

Page 6, Lines 20-22
The last sentence of this paragraph ("The answers to this question were dichotomized as 'cigarettes', 'hand-rolled tobacco' and 'other products'.") is confusing. Especially, the word "dichotomized" is a little bit odd. It needs to be clarified and edited.

Page 7, Lines 1-25
Are the "Exposure to SHS in different settings (home, work, public transport, and leisure time) " items related to former smokers and/or never smokers? It needs to be clarified and addressed here.

4. "RESULTS " Section
Page 9, Lines 1-6
In this study, smoking status is first mentioned and a very basic variable. Moreover, the other variables (prevalence, prevalence ratio, number of cigarettes smoked per day, nicotine dependence, types of tobacco product used, exposure to SHS) are accompanied with smoking status. Therefore, smoking status of the participants at the baseline and follow-up and its change are all important results, though smoking prevalence ratio are the main impact of smoking bans in this study. In addition, the last sentence of this paragraph ("20.2% (95% CI: 17.4-23.4) are smokers and 65.9% (95% CI: 62.3-69.3) are non-smokers at baseline and at follow-up (data not shown).") is problematical. It is recommended to show the data and address the results in detail in the first part of the "RESULTS " section.

Pages 9, 10 & 11
The titles and styles of Tables 1, 2, and 3 need to be shorten and simplified. In addition, the footnote of Tables 1 needs to add the number of daily smokers. In Table 2, it is suggested to add a column for the number of overall, sex (men & women), Age (26-44, 45-64, & >=65) and education level (Low, Intermediate, and High).

Page 11, Lines 5-8
The results regarding SHS at indoors, outdoors and specific areas in work setting ("In addition, after the implementation of the two Spanish smoke-free bans, 80.1% ... declared not having specific areas for smokers (data not shown).") are redundant because they aren't variables of this study and mentioned in the "METHODS" Section. Therefore, Page 11 Line 5-8 could be left out. If the authors would like to keep these results, justification for these variables need to be added in the "METHODS" Section. Moreover, both the baseline and the follow up data need to be considered because there might be some difference.

5. "DISCUSSION " Section
The authors have discussed most important findings of this study in some detail. However, it will be better if the authors could address more about smoking status (rate) and its change of the population in Spanish after the two smoking regulations as suggested in the "RESULTS " Section. For example, authors could compare the smoking rate of the population in Barcelona at baseline with previous studies to enhance the validity of the findings. Moreover, the prevalence rate of smoking among the participants in the baseline and follow-up was 34.5% and 26.1% , respectively (shown in Table 1), which are both higher than a previous study of Spanish population (23.6%, Reference 3). Therefore, the related findings are worth discussing and adding.

Page 14 Line 17- Page 15 Line 2
The discussion of the smoking ban regarding indoor and outdoor of workplaces ("Regarding work setting, most of the exposed ones declared spending most of the time outdoors... outdoor of public and workplaces to ensure higher protection against SHS.") should be cautious since it isn't a mentioned variable of this study (see also comments for Page 11, Lines 5-8).

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Response to the Addictive Behaviours reviewer's comments

ADDICTBEH-D-17-00099

Impact of the Spanish smoking laws on tobacco consumption and secondhand smoke exposure: a longitudinal population study

Response to the Reviewers' comments

We thank the editor and the reviewers for the useful comments.

We enclose a point-by-point response and we have highlighted the changes in the text of the manuscript.

Reviewer #1:

Summary: This study examined the impact of two smoking laws passed in Spain in 2005 and 2010, respectively. The first law banned smoking in public and in businesses and, following up from issues with the first law, the second law banned smoking on hospital grounds, educational campuses, playgrounds, and other outdoor areas. The authors used data collected in 2004-2005, before the first law was passed, on smoking status/frequency, nicotine dependence, and exposure to secondhand smoke. They followed the same sample in 2013-2014, retaining about half of the original participants, and administered the same questionnaires to assess change from the first time point. The results showed that after the smoking legislation was passed overall smoking rates and exposure to secondhand smoke decreased.

However, consumption of other tobacco products (e.g., hand rolled cigarettes, e-cigarettes, etc.) notably increased, particularly amongst young people. The authors suggest that the increased consumption of other tobacco products may be because they are cheaper than cigarettes, which are taxed at a higher rate. They conclude that a tax increase on other tobacco products may be effective to further decrease rates of tobacco consumption.

Overall Impressions: This was a well-executed, interesting study that is within the scope of Addictive Behaviors. Examining health policy is incredibly important and this study is a solid contribution to the literature. The methodology is sound and the authors were mindful of confounds and threats to internal validity. The structure is logical, easy to follow, and each idea connects to the other. Their conclusions are supported by the data and they discuss

limitations to the study. Their recommendation to raise taxes on other tobacco products and increase restrictions on outdoor smoking is grounded in the results and a logical next step for policy.

Thank you very much for the kind comments to our work.

Comments:

1. The paper could benefit from some editorial work to assess correct grammar, punctuation, verb tense, and overall flow. Each section has a number of instances in which sentences could be rephrased to enhance clarity and flow.

As suggested, we have revised carefully the last version of the manuscript and we have corrected the grammar mistakes.

2. What are the psychometrics of the FTCD? A sentence or two here reviewing previous validation studies should suffice.

Thank you for the useful comment. As suggested, we have included two sentences about the validation and psychometrics of the FTCD in the Methods section as follows:

> "Fagerström Test for Cigarette Dependence (FTCD) is a standard instrument for assessing the intensity of physical addiction to nicotine, it includes 6 items/questions and the score ranges from 0 to 10. The six items are: time to first cigarette (0 – 3 points), difficulty to refrain (0 – 1 points), hardest cigarette to give up (0 – 1 points), cigarettes smoked per day (0 – 3 points), smoking more in the morning than during the rest of the day (0 – 1 points), and smoking when ill (0 – 1 points). The FTCD was developed to decide whether or not nicotine replacement therapy is needed to treat withdrawal syndrome. A previous study has demonstrated the reliability of the test (0.66) (23). In our study, these questions were only addressed to daily smokers as recommended by guidelines (24)."

_____

New reference added in the manuscript:

(23) Becona E, Vazquez FL. The Fagerstrom Test for Nicotine Dependence in a Spanish sample. Psychol Rep 1998;83(3 Pt 2):1455-1458.

(24) 2008 PHS Guideline Update Panel, Liaisons, and Staff. Treating tobacco use and dependence: 2008 update U.S. Public Health Service Clinical Practice Guideline executive summary. Respir Care 2008;53(9):1217-1222.

3. The authors should further comment on other potential threats to internal validity (this can be in the paper if warranted or in a response to the reviewers) to demonstrate they considered them. For example, are there other confounding variables or history/maturation issues in the sample which could account for the results? Have there been any anti-smoking public health campaigns in Spain during the time of the study? Have there been documented changes in the attitudes/perceptions of smoking which could partially explain

the decrease in smoking? Generally, what else in addition to the legislation might explain the results?

As suggested, we have included more details about other factors potentially influencing the results in the Discussion section as follows:

> "Our results on smoking consumption trends are consistent with a recent evidence booklet published which shows a decline of prevalence before the Spanish smoke-free laws, that became more striking after their implementation mainly among women but not among men (13). In regards to the increase of hand-rolled cigarettes the economic crisis that took place in Spain in 2008 could have affected the shift on tobacco products as also reported (13,25)."

In addition, we have updated information about the monograph regarding Spanish smoking legislations including the last monography recently published.

_____

New reference added in the manuscript:

(13) Grupo de Trabajo sobre Tabaquismo de la Sociedad Española de Epidemiología. Evaluación de las políticas de control del tabaquismo en España (Leyes 28/2005 y 42/2010). Revisión de la evidencia. 2017; http://www.seepidemiologia.es/documents/dummy/V9.0%20-%20Libro%20Tabaquismo%202017%20-%20Abierto%20Final.pdf (accessed 14 Juny 2017).

(25) Sureda X, Fu M, Martinez-Sanchez JM, Martinez C, Ballbe M, Perez-Ortuno R, et al. Manufactured and roll-your-own cigarettes: A changing pattern of smoking in Barcelona, Spain. Environ Res 2017;155:167-174.

4. The authors should briefly mention in the limitations that causality cannot be established as is generally the case with policy research.

We completely agree with the reviewer's comment. As the reviewer suggests, we have mentioned in the limitations that causality cannot be established from our study as follows:

> "In addition, regardless its longitudinal nature, the study does not allow to establish strong causal inferences regarding the effectiveness of the smoke free legislation."

Reviewer #2:

This is a population based longitudinal study.
It examines the impacts of Spanish smoking legislations on active and passive smoking. The effective indicators include smoking prevalence ratio, daily smokers' tobacco consumption and nicotine dependence, and non-smokers' secondhand smoke exposure. Although many studies have assessed the effects of smoking control policies, this study still provides some new insights about this issue. In addition, the authors clearly state the research problems and purposes, and the design is suitable for answering the posed question. Overall, its quality is good except the analyses of smoking status. Some points in this manuscript need to be clarified and added. The deficiencies in various sections of thi manuscript and specific comments and suggestions are listed as follows.

Thank you very much for the kind comment to our work.

"Abstract"

1. As stated in the "Background" part of the Abstract, this study includes the impacts of smoking legislations on the active and passive smoking. However, the "Methods" part of the Abstract only focuses on the active smoking but not the passive smoking. How the data of passive smoking measured and analyzed needs to be addressed. In addition, it would be better to indicate the impacts of smoking legislations on the active and passive smoking separately in the "Results" part of the Abstract.

As the reviewer suggests, we have included more information about how data of passive smoking was measured and analyzed in the Methods Section of the abstract as follows:

> "**Methods** This is a longitudinal study before and after the implementation of two national smoking bans in Spain in a representative sample (n=1,245) of adults (≥16 years old) from Barcelona (Spain) surveyed in 2004-2005 and followed-up in 2013-2014. The final sample analyzed was 736 individuals. Both questionnaires (before and after the two laws) included the same variables about active and passive smoking. We calculated the prevalence and the prevalence ratio (PR, with their 95% confidence intervals, 95% CI) of smoking cigarettes and hand-rolled tobacco and also the prevalence of exposure to secondhand smoke (SHS) at home, work, public transport, leisure time and at any setting after *vs.* before Spanish legislations."

We have also indicated, as suggested, the impacts of smoking legislations on the active and passive smoking separately in the Results Section of the abstract as follows:

> "**Results** After the implementation of the two Spanish smoke-free bans, a significant decrease was observed in the smoking prevalence (from 34.5% to 26.1%, PR=0.76, p<0.001), in the average cigarettes per day (median from 15.2 to 10.0, p<0.001), in the percentage of conventional tobacco consumption (from 92.6% to 74.4%, PR=0.80, p<0.001). Furthermore, a significant increase in the use of hand-rolled tobacco (from 6.1% to 30.9%, PR=5.07, p<0.001) and other tobacco products (from 17.1% to 32.8%, PR=1.92, p<0.001) was observed. In addition, a significantly decrease in the self-reported SHS exposure was observed in all the assessed settings (home, work, transport, and leisure time)."

"INTRODUCTION"

2. Page 3, Line 14. The word "Consequently" as the first word of one paragraph is a little bit odd. It is better to be deleted.

We have removed the word "Consequently" as suggested.

"METHODS"

3. Page 5, Line 9, Page 4 Line 13 to Page 5 Line 10 have described the two-wave participants clearly; therefore, Fig. 1 isn't needed. To make it more concise, the words "(Fig. 1)" on Page

5 Line 9 and the corresponding Figure 1 on Pages 20-21 both could be deleted.

We have removed the Figure 1 as suggested.

4. Page 5, Lines 10-18. To be a representative sample, the participants were randomly selected by age, sex, and district of the adult population of Barcelona (Spain) according to Reference 20. However, the authors compared differences in age, sex, level of education and smoking status between the follow-up and the lost participants in both surveys on Page 5 Lines 10-18, but not district. To represent the follow-up group with the population of Barcelona, age, sex, and district all three criteria for sample selection need to be examined and addressed here.

Thank you for the comment. We have added the information regarding district differences between followed-up and lost participants as follows:

> "There were no statistically significant differences between the participants followed-up (n=736) and those lost in the second stage (n=274) according to age, sex, level of education, district and smoking status. However, there were statistically significant differences according to age, level of education and smoking status between the follow-up sample (n=736) and the participants lost in both stages of the follow-up (n=509) (data not shown)."

5. Page 6, Lines 1-22. There is one problem regarding "Smoking status" variable. As stated on Page 6 Lines 1-9, the participants were divided into three groups including smokers, former smokers, and never smokers. There were no daily smokers. But the "Number of cigarettes smoked per day" and "FTCD score" variables were only related to daily smokers. Since daily smokers are different from smokers, it is needed to define and mention who are daily smokers. Are those who smoke everyday (at least one cigarette per day) classified as daily smokers? If "yes", please indicate it in the text. Similarly, why and how the participants are regrouped into smokers and non-smokers for the following analysis needs to be mentioned. In addition, is the "Type of tobacco product used" variable only related to daily smokers? All of these questions need to be clarified and addressed more detail.

Thank you for the useful comment. As suggested we have clarified the definition of daily smokers and non-smokers as follows:

> "Smoking status, was obtained from the question: "Which of the following statements better describes your smoking status?" with the possible answers: "Nowadays I smoke everyday (at least one cigarette per day)", these are current daily smokers; "Nowadays I smoke occasionally (less than one cigarette per day)", these are current occasionally smokers; "I don't smoke now, but I smoked before every day", these are former daily smokers; "I don't smoke now, but I smoked before occasionally", these are former occasionally smokers; and "I have never smoked", these are never smokers. We also aggregate these categories when appropriate as "smokers" (current daily and occasionally smokers) and "non-smokers" (former daily and occasionally smokers plus never-smokers)."

Moreover, we have made clear in the text that the analysis regarding type of tobacco product used was carried out for daily and occasional smokers as follows:

> **"**Type of tobacco product used, obtained through the question: "What type of tobacco product do you usually smoke?" with the possible answers: "cigarettes", "hand-rolled tobacco", "cigars", "little cigars", "pipes", "hookah" and "e-cigarettes". The answers to this question were aggregated as 'cigarettes', 'hand-rolled tobacco' and 'other products' including cigars and little cigars. This question was gathered from daily and occasional smokers."

6. Page 6, Lines 20-22. The last sentence of this paragraph ("The answers to this question were dichotomized as 'cigarettes', 'hand-rolled tobacco' and 'other products'.") is confusing. Especially, the word "dichotomized" is a little bit odd. It needs to be clarified and edited.

Thank you for the comment, as suggested, we have clarified and edited this sentence (see comment 5, reviewer #2).

7. Page 7, Lines 1-25. Are the "Exposure to SHS in different settings (home, work, public transport, and leisure time)" items related to former smokers and/or never smokers? It needs to be clarified and addressed here.

The information about SHS exposure in different settings is provided for former and never smokers. As suggested, we have clarified that in the "methods" section.

"RESULTS"

8. Page 9, Lines 1-6. In this study, smoking status is first mentioned and a very basic variable. Moreover, the other variables (prevalence, prevalence ratio, number of cigarettes smoked per day, nicotine dependence, types of tobacco product used, and exposure to SHS) are accompanied with smoking status. Therefore, smoking status of the participants at the baseline and follow-up and its change are all important results, though smoking prevalence ratio are the main impact of smoking bans in this study. In addition, the last sentence of this paragraph ("20.2% (95% CI: 17.4-23.4) are smokers and 65.9% (95% CI: 62.3-69.3) are non-smokers at baseline and at follow-up (data not shown).") is problematical. It is recommended to show the data and address the results in detail in the first part of the "RESULTS" section.

As suggested, we have included more information about smoking status changes in the first part of the "results" section as follows:

> "Overall, it was observed a significant decrease in smoker's prevalence from 34.5% to 26.1% (PR=0.76, p-value=0.006) along with a significant increase in former smoker's prevalence from 25.6% to 34.1% (PR=1.33, p-value=0.004) (figure 1).
>
> Moreover, 20.2% (95% CI: 17.4-23.4) are smokers and 65.9% (95% CI: 62.3-69.3) are non-smokers (never and former smokers) at baseline and at follow-up. 22.6% (95% IC: 19.7-25.8) were persistent smokers (at baseline and follow-up), 10.9% (95% CI: 8.7-13.4) of smokers in the baseline quit smoking at the follow-up and 3.0% (95% CI: 1.9-4.6) of non-smokers in the baseline initiated or relapsed tobacco use at the follow-up (0.3% were never smokers at baseline and 2.7% were former smokers)."

In addition, we have added a new figure showing the prevalence and prevalence ratio (PR) of smoking status before and after the implementation of both Spanish smoke-free bans, Figure 1, which can be found at the end of this document.

9. Pages 9, 10 & 11. The titles and styles of Tables 1, 2, and 3 need to be shorten and simplified. In addition, the footnote of Tables 1 needs to add the number of daily smokers. In Table 2, it is suggested to add a column for the number of overall, sex (men & women), Age (26-44, 45-64, & >=65) and education level (Low, Intermediate, and High).

As suggested we have shortened the title of Table 1, 2 and 3; we have added a footnote in Table 1 to add the number of daily smokers; and we have added a column for the number of overall, sex, age and educational level in Table 2.

10. Page 11, Lines 5-8. The results regarding SHS at indoors, outdoors and specific areas in work setting ("In addition, after the implementation of the two Spanish smoke-free bans, 80.1% ... declared not having specific areas for smokers (data not shown).") are redundant because they aren't variables of this study and mentioned in the "METHODS" Section. Therefore, Page 11 Line 5-8 could be left out. If the authors would like to keep these results, justification for these variables needs to be added in the "METHODS" Section. Moreover, both the baseline and the follow up data need to be considered because there might be some difference.

As suggested we have removed this sentence in the “results” section.

"DISCUSSION"

11. The authors have discussed most important findings of this study in some detail. However, it will be better if the authors could address more about smoking status (rate) and its change of the population in Spanish after the two smoking regulations as suggested in the "RESULTS" Section. For example, authors could compare the smoking rate of the population in Barcelona at baseline with previous studies to enhance the validity of the findings. Moreover, the prevalence rate of smoking among the participants in the baseline and follow-up was 34.5% and 26.1%, respectively (shown in Table 1), which are both higher than a previous study of Spanish population (23.6%, Reference 3). Therefore, the related findings are worth discussing and adding.

Thank you for the useful comment. As suggested we have added the following information to the “discussion” section:

> “In addition, smoking prevalence observed in our follow-up survey was higher than that observed in another studies (23.6% (3) and 20.7% (26)), with information gathered at national level in 2011-2012. This could be because our study was carried out in the city of Barcelona while the other study includes information about all the regions in Spain, and historically it has been reported slight differences in smoking prevalence among regions in Spain (27). Another possible explanation is that young and smoker participants in our sample could have been overestimated because of the loss of older and no-smoker participants.

_____

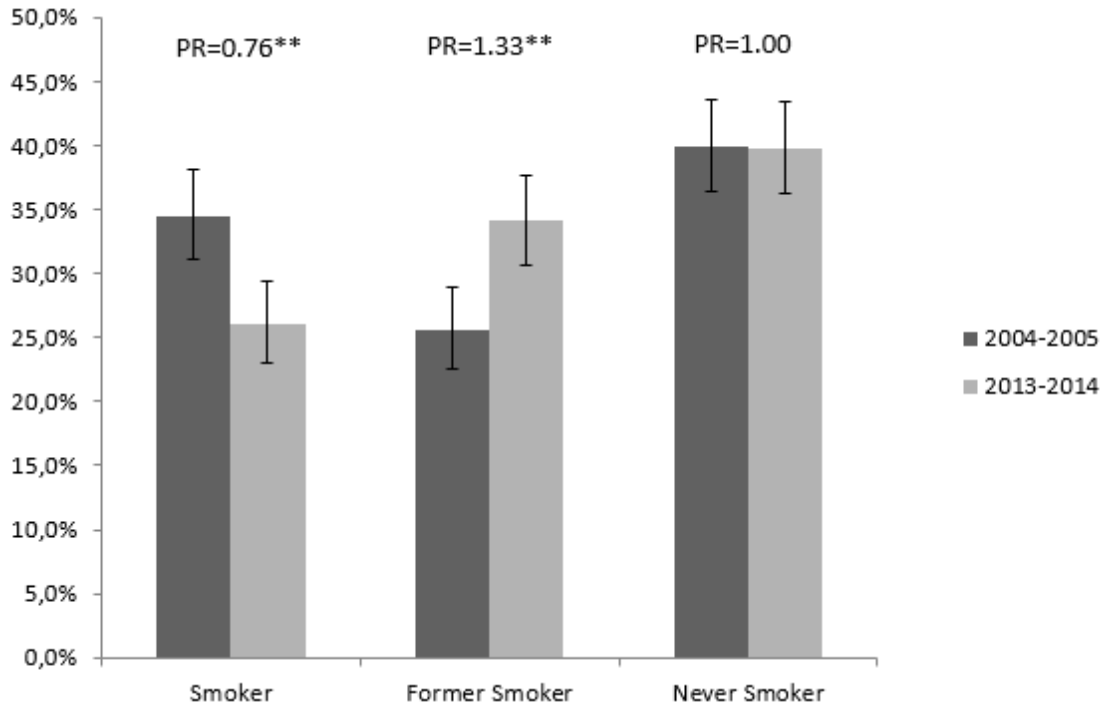
New reference added in the manuscript:

(27) Observatorio Español de las drogas y las toxicomanías. Informe 2015. Alcohol, tabaco y drogas ilegales en España. 2015; http://www.pnsd.msssi.gob.es/profesionales/sistemasInformacion/informesEstadisticas/pdf/INFORME_2015.pdf (accessed 24 Juny 2017).

12. Page 14 Line 17- Page 15 Line 2. The discussion of the smoking ban regarding indoor and outdoor of workplaces ("Regarding work setting, most of the exposed ones declared spending most of the time outdoors... outdoor of public and workplaces to ensure higher protection against SHS.") should be cautious since it isn't a mentioned variable of this study (see also comments for Page 11, Lines 5-8).

Thank you for the comment. As suggested, we have removed the sentence regarding our results not shown (see comment 10, reviewer #2) in the "discussion" section.

Figure 1. Prevalence and prevalence ratio (PR) of smoking status before and after the implementation of both Spanish smoke-free bans.



**p-value<0.01

Letter of acceptance of Addictive Behaviours journal

-----Original message-----
De: eesserver@eesmail.elsevier.com [mailto:eesserver@eesmail.elsevier.com]
Enviado el: martes, 27 de junio de 2017 22:39
Para: jmmartinez@uic.es
Asunto: Your Submission

Ms. Ref. No.: ADDICTBEH-D-17-00099R1
Title: Impact of the Spanish smoking laws on tobacco consumption and secondhand smoke exposure: a longitudinal population study Addictive Behaviors

Dear Dr. Jose M Martínez-Sánchez,

We are pleased to inform you that your manuscript has been accepted for publication in Addictive Behaviors. Congratulations. We look forward to seeing your article in print.

I am pleased to inform you about AudioSlides, a new complimentary service available to all authors publishing in <Journal>. AudioSlides are 5-minute, online presentations that are shown next to the article on ScienceDirect. This format gives you the opportunity to promote your work and summarize your research in your own words, helping readers to better understand what your paper is about and determine its relevancy. Here's an example: http://www.sciencedirect.com/science/article/pii/S1550728912000664.

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I hope that you share my enthusiasm for this new feature, and hope you will accept the invitation to create an AudioSlides presentation when your paper which will be sent to you shortly.

Your accepted manuscript will now be transferred to our production department and work will begin on creation of the proof. If we need any additional information to create the proof, we will let you know. If not, you will be contacted again in the next few days with a request to approve the proof and to complete a number of online forms that are required for publication.

When your paper is published on ScienceDirect, you want to make sure it gets the attention it deserves. To help you get your message across, Elsevier has developed a new, free service called AudioSlides: brief, webcast-style presentations that are shown (publicly available) next to your published article. This format gives you the opportunity to explain your research in your own words and attract interest. You will receive an invitation email to create an AudioSlides presentation shortly. For more information and examples, please visit http://www.elsevier.com/audioslides

Sincerely,

Theodore V. Cooper, Ph.D.

Comments from the Editors and Reviewers:

Thank you for attending meaningfully to referee suggestions. Congratulations!

For further assistance, please visit our customer support site at http://help.elsevier.com/app/answers/list/p/7923. Here you can search for solutions on a range of topics, find answers to frequently asked questions and learn more about EES via interactive tutorials. You will also find our 24/7 support contact details should you need any further assistance from one of our customer support representatives.

IV. Correspondence of the thesis article: Impact of the Spanish smoking legislations in the adoption of smoke-free rules at home: a longitudinal study in Barcelona (Spain)

Cover letter to the editor of Tobacco Control

Barcelona, April 11th, 2016.

Prof. Ruth Malone
Editor
Tobacco Control

Dear Prof. Malone,

Please find enclosed our manuscript "Impact of the Spanish smoking legislations in the adoption of smoke-free rules at home: a longitudinal study" for your consideration in Tobacco Control as a *Research Paper*.

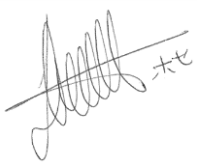
Currently, few studies have evaluated the impact of both Spanish smoke-free legislations (partial and comprehensive) in secondhand smoke exposure at home; however, there is a lack of information in Spain on the impact of the smoke-free laws in the adoption of smoke-free homes. We assess the impact of Spanish smoking bans in the adoption of voluntary smoke-free homes rules in Spain. Our results show that the implementation of the smoke-free regulations in public and workplaces in Spain was associated with an increasing of voluntary adoption of smoke-free rules in homes, particularly complete smoke-free home. Moreover, the Spanish smoking bans did not shift the tobacco consumption from public and workplaces to private places (homes).

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. The authors declare there are no conflicts of interest.

We would of course be ready to provide further information about our data and methods you 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.

Yours sincerely,



Jose M Martínez-Sánchez, PhD, MPH, BSc

E-mail: jmmartinez@iconcologia.net

Editor's response and comments from the Tobacco Control reviewers

-----Mensaje original-----
De: onbehalfof+tobaccocontrol+bmj.com@manuscriptcentral.com [mailto:onbehalfof+tobaccocontrol+bmj.com@manuscriptcentral.com]
Enviado el: lunes, 18 de julio de 2016 16:28
Para: jmmartinez@iconcologia.net
CC: clidon@uic.es; jmmartinez@iconcologia.net; mfu@iconcologia.net; mballbe@iconcologia.net; jcmartin@uic.es; cmartinez@iconcologia.net; esteve.salto@gencat.cat; efernandez@iconcologia.net
Asunto: Tobacco Control - Decision on Manuscript ID tobaccocontrol-2016-053114

18-Jul-2016

Dear Dr. Martínez-Sánchez:

Manuscript ID tobaccocontrol-2016-053114 entitled "Impact of the Spanish smoking legislations in the adoption of smoke-free rules at home: a longitudinal study Word Count: 2622" which you submitted to Tobacco Control, has been reviewed. Following review, the editors have decided that the paper requires revision. We will be happy to reconsider it after revision, providing you have responded to the comments of the referee(s) (see below).

Please note, by offering to reconsider a revised paper, we are making no commitment to publish a revised version.

Important: Please CUT AND PASTE THE REVIEW COMMENTS BELOW INTO A SEPARATE DOCUMENT. With spaces between each comment and your response, provide a specific reply to each reviewer comment, making it clear whether or not you have incorporated the changes as suggested and indicating where the relevant changes are now found in the text. If you elect not to follow reviewers' suggestions or respond to particular criticisms, please provide a response in each case so that the editors might consider your reasoning.

Tobacco Control is published six times per year, and because of the inherent delay in publication with this schedule, we are concerned to avoid overly lengthy periods between notifying authors that a paper needs revision and receipt of the revised version.

If you DO intend to resubmit a revised version, please inform us of the likely submission date.

If we do not hear from you within 4 weeks, we will assume that you do not intend to resubmit and will withdraw your paper. If you need to request an extension of this deadline, please contact us as soon as possible.

To revise your manuscript, log into https://mc.manuscriptcentral.com/tobaccocontrol and enter your Author Center, where you will find your manuscript title listed under "Manuscripts with Decisions." Under "Actions," click on "Create a Revision." Your manuscript number has been appended to denote a revision.

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You will be unable to make your revisions on the originally submitted version of the manuscript. Instead, revise your manuscript using a word processing program and save it on your computer. Please also highlight the changes to your manuscript within the document by using the track changes mode in MS Word or by using bold or colored text.

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When submitting your revised manuscript, you will be able to respond to the comments made by the reviewer(s) in the space provided. You can use this space to document any changes you make to the original manuscript. In order to expedite the processing of the revised manuscript, please be as specific as possible in your response to the reviewer(s).

You will receive a proof if your article is accepted, but you will be unable to make substantial changes to your manuscript, please take this opportunity to check the revised submission carefully.

IMPORTANT: Your original files are available to you when you upload your revised manuscript. Please delete any redundant files before completing the submission.

Because we are trying to facilitate timely publication of manuscripts submitted to Tobacco Control, your revised manuscript should be submitted before 16-Sep-2016. Your option to submit a revision expires on that date. If it is not possible for you to submit your revision by this date, we may have to consider your paper as a new submission.

We also ask that in addition to the revised paper you provide a point by point response to the reviewer comments, and upload a marked copy of your paper highlighting the changes you have made - preferably 'tracked changes' if using Microsoft word. Please upload this as a supplemental file and label it 'Marked Copy' (your paper will not be able to be processed without this).

All material submitted is assumed to be submitted exclusively to the journal unless the contrary is stated. Submissions may be returned to the author for amendment if presented in the incorrect format.

Please note that only the article text (from first word of main text to the last word in reference list) will be used to typeset your article.

All other data (known as the metadata), such as article title, author names and addresses, abstract, funding (etc) statements will be taken from the fields you have filled in at submission, so you must ensure that these are up to date and accurate.

I hope you will find the comments useful.

Respectfully,

Andrew Hyland,
Senior Editor, Tobacco Control
tobaccocontrol@bmj.com

FORMATTING AMENDMENTS
Required amendments will be listed here (if any); please include these changes in your revised version:
1. Please remove all figures from the body of the manuscript and reupload your figure files separately.

Please note that we do not accept figures in Word document, PDF or PowerPoint format.

All figures and images should be supplied as high quality image files, we recommend TIFF format. Please ensure images are a minimum of 300dpi (resolution).

Please include figure legends at the end of the main manuscript text only and label the figure files appropriately to correspond.

Reviewer(s)' Comments to Author:

Reviewer: 1

Comments to the Author
This is an important paper reviewing the impact of the Spanish smoke-free law on smoking in homes. It is significant due to the historical problems encountered in Spain with the tobacco industry and passing smoke-free laws, including the 'Spanish Model' that existed for a period of time.

In some places some editing is needed for grammar.

Abstract

I would make it clear in title that the study is city of Barcelona and not a national study (Spain)
Results - why higher among males?
I would either use the word comprehensive or complete smoke-free ban throughout, it is confusing to go back and forth.

Introduction

Other references to smoke-free could be added, e.g., Cochrane review on smoke-free laws Add in further details on study about children exposed to SHS, I think this is the % exposed a least weekly but have not re-checked reference?
Some further details about the Spanish model would be helpful, was it small or large venues that could allow smoking, it does not specify in intro. I think small..

Methods

Page 6, line 54, did 101 out of the original 1245 really die? 8.1% of sample? Or am I reading this wrong? What was the average age of the sample at baseline and follow-up? A table of sample characteristics would be helpful, even though it is stated there were no major differences between baseline and follow-up, what was the actual composition of the sample?
If the sample is representative of 16+ then why at page 7, line 2, do you say that those less than 18 were not followed?
Page 7, lines 5-10. Is it the case that the participants for follow-up were first traced, and then re-contact was attempted to survey? Seems to have been two stages to re-contact where participants were lost?
Please include detail on how smoking in specific areas was measured (e.g., terrace, dining room). There are details on this in the results, but not sure how this was measured or analysed because there are no details in the methods, and nothing in introduction about research questions related to smoking in these spaces.
There were differences in terrace smoking/outdoors - any possibility this was due to differences in time of survey (seasonal) - any adjustment for this? Should clearly outline times/months when respondents were surveyed. Generally in surveys assessing outdoor smoking, some adjustment for

season is needed.
Why was this examined using McNemar and stratified models? Would it not have made more sense to use a multivariable model with GEE?

Results
Line 31, Page 9, these results on smoking in specific areas need to be explained in intro and methods - no details for measures or why these additional analyses were conducted? Difficult to interpret.

Discussion

The results for households with minors may have been different if the ages of the minors were known, previous research has found younger children seem to have more impact on SFH.
Page 11, line 44, provide references to TI activity around smoke-free in Spain.
Again, line 3, page 12, references to bans in outdoor places is confusing due to lack of explanation of these analyses in intro and methods.
Why would face-to-face increase internal validity?

Figures and Tables

Figure needs axis titles. Slightly confusing are years survey years or ban years?
Table 1 needs to indicate years that PRs show difference between. The table should standalone without having to read a lot of additional text. I see that this is in the bottom notes but would be better in title. I would also shorten the title, no need to have all the details starting at ..according to.
Table 1 difficult to read, goes over two pages without repeating headings, PRs go over two lines. Please format correctly to make it easier to read.
Table 1. Although with 95% CIs it is possible to see where changes are significant, it would be better to add p-values, or indicate somehow where effects are significant to guide reader, again the table is just hard to read due to poor formatting.

Reviewer: 2

Comments to the Author
An interesting paper that focusses directly on the effects of a smoking ban(s) on smokers' behaviour rather than on clinical outcomes so a welcome addition to the body of evidence on smoking cessation. It appears to have been conducted well but I have some suggestions for improvement.

Introduction
There are a few grammatical errors in here and the entire manuscript would benefit from a thorough proof read. I'm not going to list them all but one example is in lines 39-41 "….they breathe…." would read better if those words were substituted with "them breathing".

Key references are missing here as well. There are no references to the well documented effect of smoking bans on asthma admissions nor on the impact on birth outcomes such as low birthweight, growth restriction, preterm birth etc. These are important omissions and should be included.

Methods
Need some more detail here on how the weights were calculated and applied. i.e were the weights probability weights, analytical weights, importance weights ..or ….?

I don't think log-binomial regression is the best method to use here as these models can have difficulty converging, and you state this later on in the manuscript. In addition confidence intervals are too narrow. It would better if you used a Poisson family with log link but make sure you use ROBUST standard errors. I suspect you will have more success with the models that fail to converge. I don't

understand why McNemars test was used to get the P value. I know you have within subject correlation but surely there are other methods that will allow you to run a regression model and produce an appropriate P value?

You have used random effects but don't state why….I'm assuming it's because you have repeated measures, in which case why did you choose random effects over a GEE model? The GEE would allow you to incorporate/model the correlation within individuals more directly and would give you a valid P value. Overall, I am not convinced by what you have written that your approach is the best approach to use. If you insist on using your approach you will need to explain in more detail what you did and why and justify (to the editors) why it would be better than the more common GEE. At the moment I am not convinced but that could be because there is a lack of detail.

Results
Line 51: should be "males" and line 52 should be "females"

I strongly believe that if models failed to converge then they should *NOT* be reported as both the point estimate and the standard errors could be out by a magnitude. It would be misleading in my opinion to report them. However, if you modify your analysis, at the very least using a Poisson family and log link, I suspect that this problem will disappear.

Why did you choose the age cut-offs that you present? Younger children/infants tend to spend more time at home so it would be interesting to know if the presence of young children has had a marked increase in SFH. I'd suggest 0-4 years 5-15 and 15+. I think these are more meaningful cut-offs. If you did consider these cut-offs then you need to say why they were not used.

Tables are a bit messy and busy. Is there any way you could present them graphically such as a forest plot? "coeffplot" command in R would do this for you. I think you could be a bit more creative here.

I'd lose figure 1 as it doesn't really add anything and would be incorporated into a forest plot anyway. The %columns are not at all useful.

I felt the discussion was a bit too long and it could be edited down

Reviewer: 3

Comments to the Author
Methods:
1. What was the response rate for the baseline survey? Is there any indication that initial response to the baseline survey differed according to smoke-free home rules? It appears that the original intent of the survey was not designed to look at chances in smoking rules between these two time points, but in changes in salivary cotinine exposures instead. Perhaps this should be mentioned in the methods section?
2. At baseline, individual ≥16 years of age were included as "adults", yet in the follow-up survey, n were excluded (or deemed ineligible) because they were <18 years old in 2004-2005. What was the reasoning behind these differences in eligibility criteria?
3. In the results (page 9, 3rd paragraph), the authors mention areas outside of the house and changes to smoking rules in these areas, particularly as they relate to homes with partial smoke-free home rules. However, there is no mention of these questions in the methods section. Can you please describe how these results were obtained?
4. Given that this is longitudinal data, I wonder why the prevalence ratio is used instead of the risk ratio? The risk ratio will give an indication of how more/less likely a group (with an exposure) is to acquire the outcome over the follow-up period relative to another, unexposed group as opposed to

strictly changes over time 5. The prevalence ratio was only adjusted for age and sex. However, these results are stratified by several covariates. Did the authors think about conducting modeling (i.e. GEE or otherwise) to look at multivariable-adjusted analyses, perhaps stratified only by smoking status at baseline? I think it would be interesting to note whether there are different covariates that would impact smoke-free home rules between current smokers and non-smokers before and after the implementation of the smoke-free air legislation.

Results:

6. Page 8, last paragraph through Page 9, line 29: The authors mention that increases in smoke-free home rules were higher among men (vs. women), young people (presumably vs. older individuals), those with higher education, etc. However, the confidence intervals overlap – for example by sex: Men: PR=33, 95% CI: 1.18-1.50 vs. Women: PR=29, 95% CI: 1.18-1.41 (Table 1, any rules by sex). Statistical testing was conducted according to the McNemar's test in figure 1 to look at changes over time (please add this in a footnote), but there is no indication in Table 1 what differences are statistically significant (i.e. men vs. woman, age groups, etc.). I think the results would be strengthened if there was some comparison completed between these characteristics as opposed to only conducting the multiple stratified analyses. Or, please re-phrase the results so as not to imply that these comparisons are being made.

8. In the footnote of table 1: there is a statement "Non-converging log-binomial regression model with random effects". What is the implication of this non-convergence? The authors make no note in the limitations or elsewhere what may have been the cause of this non-convergence. Moreover, what are the random effect(s) that were used?

9. Figure 1: It would be nice if the actual percentages were presented in this figure too (above each bar). As mentioned in #6, there should be a footnote with this figure describing the PR calculation, the McNemar's test, etc.

Discussion:

10. There were 2 distinct smoke-free laws implemented – the first in 2006 (right after this baseline assessment) and the next 5 years later in 2011. The authors are not treating these two laws as separate events, given that there was only one follow-up study (2013-2014). Therefore, it is unclear whether the increases in smoke-free home rules observed in this study occurred following the first law (2006) or whether the more comprehensive smoke-free air law with few exceptions was associated with the increases (or some combination of both). However, the authors make no mention of this in the discussion or in the limitations. It does not appear that this study was initially conceived to assess these changes due to the smoke-free air legislation, given the focus on cotinine collection, which may be why there was not follow-up after each smoke-free air law was passed.

11. The authors state that their results counteract the displacement hypothesis, but this isn't necessarily true, given that there were increases in allowing smoking in outdoor areas of the home (balconies, courtyards, gardens, etc.). So, even though there were decreases in smoking inside the home, there was an increase in smoking behaviors in private outdoor spaces.

12. Throughout the paper, there are some grammatical and linguistic errors. For example: in the results: "increasing vs. increase" and "...outside areas of the houses were the places that more increased in allowing smoking..." I'd recommend having a translator look at a final version of this paper prior to any publication.

Response to the Tobacco Control reviewer's comments

tobaccocontrol-2016-053114
Impact of the Spanish smoking legislations in the adoption of smoke-free rules at home: a longitudinal study
Response to the Reviewers' comments

We thank the editor and the reviewers for the useful comments.

We enclose a point-by-point response and we have highlighted the changes in the text of the manuscript.

FORMATTING AMENDMENTS

1. Please remove all figures from the body of the manuscript and reupload your figure files separately.

Please note that we do not accept figures in Word document, PDF or PowerPoint format.

All figures and images should be supplied as high quality image files, we recommend TIFF format. Please ensure images are a minimum of 300dpi (resolution).

Please include figure legends at the end of the main manuscript text only and label the figure files appropriately to correspond.

Current version of the manuscript has not any figure because we have removed the figure as one of the reviewers suggested.

Reviewer: 1

This is an important paper reviewing the impact of the Spanish smoke-free law on smoking in homes. It is significant due to the historical problems encountered in Spain with the tobacco industry and passing smoke-free laws, including the 'Spanish Model' that existed for a period of time.

Thank you very much for the kind comment to our work.

1) **In some places some editing is needed for grammar.**

As suggested, we have revised carefully the last version of the manuscript and we have corrected the grammar mistake.

Abstract

2) **I would make it clear in title that the study is city of Barcelona and not a national study (Spain).**

As the reviewer suggested, we have modified the title to clarify that the study was carry out in the city of Barcelona (Spain) as follows:

> "Impact of the Spanish smoking legislations in the adoption of smoke-free rules at home: a longitudinal study in Barcelona (Spain)"

Results

3) **why higher among males?**

In the abstract, we have only reported the higher increase according to the sociodemographic variables. The increase of SFH after the implementation of Spanish smoking legislations were 33% among men and 29% among women, both statistically significant. The higher increase among men could be due the low prevalence in the baseline (51.8% among men and 58.8% among women).

We have re-written the Results section of the abstract to clarify it as follows:

> "The increase of any type of rules (complete and partial) was statistically significantly independently of sex (PR between 1.29 and 1.33), age (PR between 1.24 and 1.33), educational level (PR between 1.19 and 1.47), and minimum age in house (PR between 1.11 and 1.40). However, this increase was statistically and significantly higher only among never smokers (PR=1.46) at baseline."

4) **I would either use the word comprehensive or complete smoke-free ban throughout, it is confusing to go back and forth.**

Thank you very much for the comment. We have used the word complete smoke-free ban throughout abstract and manuscript.

Introduction

5) **Other references to smoke-free could be added, e.g., Cochrane review on smoke-free laws Add in further details on study about children exposed to SHS, I think this is the % exposed a least weekly but have not re-checked reference?**

Thank you for the comment. As suggested, we have referenced the Cochrane review in the Introduction section.

> "In fact, their implementation has already been associated with a reduction in the exposure to SHS, the incidence of acute coronary events, respiratory symptoms, improvements of perinatal and child health, along with a moderate decrease in tobacco smoking prevalence (5-7)"

In addition, we have provided more details on the studies about SHS exposure among children as follows:

> "A study carried out in 21 countries showed that almost 50% of children had been exposed to SHS in the home (daily, weekly or monthly) between 2009 and 2013(12)."

Moreover, as reviewer #2 suggested (please see comment number 2), we have added more information about the effect of smoking bans in low birth weight and preterm birth as follows:

> "In fact, their implementation has already been associated with a reduction in the exposure to SHS, the incidence of acute coronary events, respiratory symptoms, improvements of perinatal and child health, along with a moderate decrease in tobacco smoking prevalence (5-7)(118,119)(118,119). Furthermore, SHS exposure during pregnancy has harmful effects on placenta and fetal growth (8) and is associated with preterm labor (9,10), intrauterine growth restriction, and low birth weight (8)."

_____

New reference added in the manuscript:

7) Frazer K, Callinan JE, McHugh J, et al. Legislative smoking bans for reducing harms from secondhand smoke exposure, smoking prevalence and tobacco consumption. Cochrane Database Syst Rev 2016;2:CD005992.

8) Mackay DF, Nelson SM, Haw SJ, et al. Impact of Scotland's smoke-free legislation on pregnancy complications: retrospective cohort study. PLoS Med 2012;9:e1001175.

9) Fantuzzi G, Aggazzotti G, Righi E, et al. Preterm delivery and exposure to active and passive smoking during pregnancy: a case-control study from Italy. Paediatr Perinat Epidemiol 2007;21:194-200.

10) Nabet C, Ancel PY, Burguet A, et al. Smoking during pregnancy and preterm birth according to obstetric history: French national perinatal surveys. Paediatr Perinat Epidemiol 2005;19:88-96.

6) Some further details about the Spanish model would be helpful, was it small or large venues that could allow smoking, it does not specify in intro. I think small.

We agree with the reviewer to provide more details about the partial ban that came into effect on January 1st of 2006. Following this recommendation, we have added the following information in the Introduction section:

> "In Spain, two smoke-free laws have been passed after the approval of the FCTC. In 2005, it came into effect a smoke-free legislation (Law 28/2005). This law was a great advance for public health in Spain. The ban was a compendium of public health measures against smoking and included regulations on publicity, sale, supply, and consumption of tobacco products (17). Smoking was banned in all indoor workplaces, public places, public transport facilities including enclosed stations, hospitals and other health care facilities, schools and universities as well as in retail stores and shopping centres. However, hospitality venues were subject to only a partial ban. In bars and restaurants of less than 100 m2, the proprietor could choose between permitting or prohibiting smoking. Bars and restaurants larger than 100 m2 are defined as smoke-free, but the law allows the proprietor

> to provide a physically separated and independently ventilated smoking area comprising less than 30% of the total floor area. For this exception the Spanish smoking law was known as the "Spanish model" (18)." (…)

_____

New reference added in the manuscript:

17) Ministerio de Sanidad y Consumo. Ley 28/2005, de 2006 de diciembre, de medidas sanitarias frente al tabaquismo y reguladora de la venta, el suministro, el consumo y la publicidad de los productos del tabaco. Madrid: Ministerio de Sanidad y Consumo; 2005.

Methods

7) **Page 6, line 54, did 101 out of the original 1245 really die? 8.1% of sample? Or am I reading this wrong? What was the average age of the sample at baseline and follow-up? A table of sample characteristics would be helpful, even though it is stated there were no major differences between baseline and follow-up, what was the actual composition of the sample?**

As the reviewer points, 8.1% of the participants in 2004-2005 died because the baseline sample overestimates the old population (Fu et al. 2009; Martínez-Sánchez et al. 2009). For this reason, we have weighted the final sample.

Moreover, we have added information about both stages of the follow-up according to recommendation of the reviewer #1 (see comment number 9). We agree with the reviewer about the importance to report the differences between lost and follow-up. We have not observed statistically significant differences according to sex, age, and educational level between follow-up (n=736) and lost (n=274) in the second stage of the follow-up. However, we have observed statistically significant differences according to age, educational level, and smoking status between follow-up (n=736) and lost (n=509) in both stages. As the reviewer suggested, we have included a table with the differences between follow-up and lost in both stages. Moreover, we have added more information about the lost in the Methods section:

> "There were no statistically significant differences between the followed-up sample (n=736) and the participants lost in the second stage (n=274) according to age, sex, level of education and smoking status. However, there were statistically significant differences according to age, level of education and smoking status between the follow-up sample (n=736) and the participant lost in both stages of the follow-up (n=509) (table 1). For this reason, the final sample was skewed as older in comparison with the population of Barcelona."

_____

Bibliography:

Fu M, et al. 2009. Salivary cotinine concentrations in daily smokers in Barcelona, Spain: a cross-sectional study. BMC Public Health;9:320.

Martínez-Sánchez et al. 2009. Assessment of exposure to secondhand smoke by questionnaire and salivary cotinine in the general population of Barcelona, Spain (2004-2005). Prev Med;48:218-23.

8) **If the sample is representative of 16+ then why at page 7, line 2, do you say that those less than 18 were not followed?**

We could not follow those under 18 because they were not legally adults and we did not ask about the possibility to be re-contacted in the future. Moreover, the consent form signed by their parents was only for the study in 2004-05, we did not required by minors (less than 18 years old) to participate in a future study. We have clarified this as follows:

> "We traced 1010 participants out of the 1245 from the baseline study (101 died, 49 migrated out of the province of Barcelona, and 85 did not give consent to be followed or were minors ,<18 years old, in 2004-2005 because their parents did not provide consent inform to be re-contacted)."

9) **Page 7, lines 5-10. Is it the case that the participants for follow-up were first traced, and then re-contact was attempted to survey? Seems to have been two stages to re-contact where participants were lost?**

As the reviewer correctly interpreted we first traced the participants for follow-up, at this point we lost some participants due to death and migration out of the province of Barcelona after linkage in the Insured Central Registry of Catalonia, or because they did not give consent to be followed-up or because they were under 18 in 2004-2005. In this stage the follow-up was 81.1% (1010 out 1245). Afterwards, we re-contacted them to be surveyed, 72.9% (736 out 1010) of the eligible sample agreed to participate and answered the questionnaire (second stage). According to the two stages the percentage of participation was 59.1% (736 out 1245). We have clarified this aspect in the manuscript as follows:

> "The percentage of follow-up in this first stage was 81.1%. The follow-up survey was conducted between May 2013 and February 2014. In total, 72.9% of the eligible sample agreed to participate and answered the questionnaire (736 out 1010 traced, second stage of follow-up), 18.5% refused to participate, 7.2% moved elsewhere and 1.3% died. The final sample analyzed was 736 individuals (400 women and 336 men). Finally, the percentage of participation in both stages was 51.9% (736 out 1245). There were no statistically significant differences between the followed-up sample (n=736) and the participants lost in the second stage (n=274) according to age, sex, level of education and smoking status. However, there were statistically significant differences according to age, level of education and smoking status between the follow-up sample (n=736) and the participant lost in both stages of the follow-up (n=509) (table 1). For this reason, the final sample was skewed as older in comparison with the population of Barcelona."

10) **Please include detail on how smoking in specific areas was measured (e.g., terrace, dining room). There are details on this in the results, but not sure how this was measured or analysed because there are no details in the methods, and nothing in introduction about research questions related to smoking in these spaces.**

As the reviewer suggested, we have added information in the Methods section about how we obtained information about smoking in specific areas through the questionnaire:

> "We also included information about the places where smoking is allowed in houses with partial SFH through the following open question: "In what places of your home can you smoke?"

Besides, we have added some information about outdoor smoking in the Introduction section as the reviewer #1 suggested in their comment number 13:

> "In Barcelona (Spain), in 2011-2012, 84% of smokers reported smoking at home, and 35.9% of them smoked in outdoor areas of the home (23). Moreover, a common belief among smokers is that cigarette smoking in outdoor places does not affect indoor places (23), whereas a previous study indicated that SHS from outdoors settings drifts to adjacent indoors spaces (24)."

_____

New reference:

23) Sureda X, Fernandez E, Martinez-Sanchez JM, et al. Secondhand smoke in outdoor settings: smokers' consumption, non-smokers' perceptions, and attitudes towards smoke-free legislation in Spain. BMJ Open 2015;5:e007554-2014-007554.

24) Sureda X, Martinez-Sanchez JM, Lopez MJ, et al. Secondhand smoke levels in public building main entrances: outdoor and indoor PM2.5 assessment. Tob Control 2012;21:543-548.

11) There were differences in terrace smoking/outdoors - any possibility this was due to differences in time of survey (seasonal) - any adjustment for this? Should clearly outline times/months when respondents were surveyed. Generally, in surveys assessing outdoor smoking, some adjustment for season is needed.

Thank you for the interesting comment. As the reviewer suggested, we have adjusted the prevalence ratio of the places where smoking is allowed in houses with partial SFH for sex, age and the month where the survey was conducted, as the best proxy for seasonal adjustment.

We add the following sentence to the Methods section:

> "We also used GEE models with individuals as random effects and using Poisson family with log link, to calculate the prevalence ratio adjusted for sex, age and month when the survey was conducted (PRa)."

And in the Result section:

> "Similar results were also observed in the prevalence ratio of the places where smoking is allowed in houses adjusting for sex, age and the month when the survey was conducted."

12) Why was this examined using McNemar and stratified models? Would it not have made more sense to use a multivariable model with GEE?

We conducted McNemar test in bivariate analysis due to the paired nature of the data (the same subjects observed in two different moments, this is, non-independent samples). We agree with the reviewer that the McNemar and bivariate analyses of stratified models could be redundant. However, we thought that provide both analyses could be useful for the potential reader. As the reviewer suggested, we have deleted McNemar test. However, if the editor considers appropriate to include the p-values of McNemar to provide more information for the potential readers we will be ready to include it again.

On the other hand, as the reviewer suggested, we have re-calculated all analyses using GEE models with Poisson family as also recommended the reviewer #2 (please see comment number 4 of reviewer #2) and taking into account the survey weights.

Results

13) **Line 31, Page 9, these results on smoking in specific areas need to be explained in intro and methods - no details for measures or why these additional analyses were conducted? Difficult to interpret.**

As the reviewer suggested, we have added information in the Introduction and in the Methods section about outdoor smoking (please see comment number 10 of reviewer #1).

Discussion

14) **The results for households with minors may have been different if the ages of the minors were known, previous research has found younger children seem to have more impact on SFH.**

Thank you for the comment. In this sense, and as the reviewer # 2 suggests (please see comment number 8), we have changed the cut-off of the minimum age at home to <5 years, 5-14 and ≥15 in order to know if the presence of young children has had a marked increase in SFH.

Moreover, we have introduced the minimum age at home as a numerical variable and added some information in the Discussion section according to the obtained results:

> "However, we found the lowest increase of SFH rules in houses where a minor live and an indirect relation between the minimum age at home and the prevalence of SFH (data not shown)".

15) **Page 11, line 44, provide references to TI activity around smoke-free in Spain.**

As reviewer suggested, we have added some references about tobacco industry around smoke-free in Spain in the Discussion section:

> "Tobacco industry and the hospitality sector, during the debate of implementation of smoke-free policies in different countries, argued that the restriction of smoking in public places will displace tobacco consumption to private venues, particularly in home (42)."

_____

New references:

(42) Muggli ME, Lockhart NJ, Ebbert JO, et al. Legislating tolerance: Spain's national public smoking law. Tob Control 2010;19:24-30.

16) **Again, line 3, page 12, references to bans in outdoor places is confusing due to lack of explanation of these analyses in intro and methods.**

As the reviewer suggested, we have added information in the Introduction and in the Methods section about smoking outdoors (please see comment number 10 of reviewer #1).

17) **Why would face-to-face increase internal validity?**

Face-to-face questionnaire, with trained interviewers, reduce the misinterpretation of the questions of the survey in comparison with internet and self-administered surveys. We have added the following sentence in the Discussion section to explain it:

> "However, by using a face-to-face questionnaire with trained interviewers we potentially increase the internal validity of our results as compared with internet and self-administered surveys because avoid misinterpretation of the questions (49)."

_____

New reference:

(49) World Health Organization. Health interview surveys: Towards international harmonization of methods and instruments, 1996. http://www.euro.who.int/__data/assets/pdf_file/0017/111149/E72841.pdf (accessed 1 August 2016).

Figures and Tables

18) **Figure needs axis titles. Slightly confusing are years survey years or ban years?**

Thank you for the comment. However, as the reviewer # 2 suggested (please see comment 10 of reviewer #2), we have removed this figure.

19) **Table 1 needs to indicate years that PRs show difference between. The table should standalone without having to read a lot of additional text. I see that this is in the bottom notes but would be better in title. I would also shorten the title, no need to have all the details starting at according to.**

Thank you very much for the comment, as the reviewer suggested, we have modified the title of the Table 1 (now Table 2) as follows:

> "**Table 2**: Prevalence, prevalence ratio (PR), adjusted prevalence ratio (PRa) and their 95% confidence interval (95%CIs) of the voluntary adoption of smoke-free homes (SFH) rules (complete and partial) before (2004-2005) and after (2013-2014) the implementation of both Spanish smoking bans."

20) **Table 1 difficult to read, goes over two pages without repeating headings, PRs go over two lines. Please format correctly to make it easier to read.**

As the reviewer suggests, we have formatted correctly the table to make it easier to read.

21) **Table 1. Although with 95% CIs it is possible to see where changes are significant, it would be better to add p-values, or indicate somehow where effects are significant to guide reader, again the table is just hard to read due to poor formatting.**

We agree with the reviewer that 95%CIs is enough to know if the differences are significant. However, as the reviewer suggested, we have indicated in the Table 1 (now Table 2) when effects are significant, to guide the reader, including the following symbols: * p-value <0.05, ** p-value<0.01, *** p-value<0.001. If the editor finds it necessary, we can as well add the p-values.

Reviewer: 2

Comments to the Author

An interesting paper that focusses directly on the effects of a smoking ban(s) on smokers' behaviour rather than on clinical outcomes so a welcome addition to the body of evidence on smoking cessation. It appears to have been conducted well but I have some suggestions for improvement.

Thank you very much for the kind comment to our work.

Introduction

1) **There are a few grammatical errors in here and the entire manuscript would benefit from a thorough proof read. I'm not going to list them all but one example is in lines 39-41 "…. they breathe…." would read better if those words were substituted with "them breathing".**

We have corrected the mistake and we have revised carefully the last version of the manuscript and we have corrected the grammar mistake, as reviewer suggested.

2) **Key references are missing here as well. There are no references to the well documented effect of smoking bans on asthma admissions nor on the impact on birth outcomes such as low birthweight, growth restriction, preterm birth etc. These are important omissions and should be included.**

Thank you for the comment. As suggested by the reviewer # 1 (see comment 5 of reviewer #1), we have referenced the Cochrane review in the Introduction section. Moreover, we have added more information about the effect of smoking bans in low birth weight between others:

> "In fact, their implementation has already been associated with a reduction in the exposure to SHS, the incidence of acute coronary events, respiratory symptoms, improvements of perinatal and child health, along with a moderate decrease in tobacco smoking prevalence (5-7). Furthermore, SHS exposure during pregnancy has harmful effects on placenta and fetal growth (8) and is associate with preterm labor (9,10), intrauterine growth restriction, and low birth weight (8)."

_____

New reference:

8) Mackay DF, Nelson SM, Haw SJ, et al. Impact of Scotland's smoke-free legislation on pregnancy complications: retrospective cohort study. PLoS Med 2012;9:e1001175.
9) Fantuzzi G, Aggazzotti G, Righi E, et al. Preterm delivery and exposure to active and passive smoking during pregnancy: a case-control study from Italy. Paediatr Perinat Epidemiol 2007;21:194-200.
10) Nabet C, Ancel PY, Burguet A, et al. Smoking during pregnancy and preterm birth according to obstetric history: French national perinatal surveys. Paediatr Perinat Epidemiol 2005;19:88-96.

Methods

3) **Need some more detail here on how the weights were calculated and applied. i.e were the weights probability weights, analytical weights, importance weights or ….?**

The weights are proportional to the inverse of the probability of being included in the sample, ie a *d_i* weight for individual *i* can be interpreted broadly, as the i individual represents *d_i* individuals in the population of the sample. Such weights are known as inverse probability weights. As the reviewer suggested, we have added this information to make this clear:

> "Therefore we use inverse probability weights to weight our data according to age distribution of the city of Barcelona to maintain its representativeness of the sample."

4) **I don't think log-binomial regression is the best method to use here as these models can have difficulty converging, and you state this later on in the manuscript. In addition confidence intervals are too narrow. It would better if you used a Poisson family with log link but make sure you use ROBUST standard errors. I suspect you will have more success with the models that fail to converge. I don't understand why McNemars test was used to get the P value. I know you have within subject correlation but surely there are other methods that will allow you to run a regression model and produce an appropriate P value?**

We agree with the reviewer comment. For this reason, we have re-analysed our data, as the reviewer suggests, and we have performed GEE models, using Poisson family with log link taking into account weights instead of log-binomial regression. Furthermore, as the reviewer mentioned, we improve the convergence problem by using a Poisson regression although some model continues without convergence. Therefore, we have made the following change in the Methods section:

> "We also used GEE models with individuals as random effects and using Poisson family with log link, to calculate the prevalence ratio adjusted for sex, age and month when the survey was conducted (PRa)."

Moreover, as the reviewer suggested, we have deleted the McNemar p-value. In this sense, we have highlighted the interval confidences which were statistically significant (please see comment number 21 of the reviewer#1).

5) **You have used random effects but don't state why. I'm assuming it's because you have repeated measures, in which case why did you choose random effects over a GEE model? The GEE would allow you to incorporate/model the correlation within individuals more directly and would give you a valid P value. Overall, I am not convinced by what you have written that your approach is the best approach to use. If you insist on using your approach you will need to explain in more detail what you did and why and justify (to the editors) why it would be better than the more common GEE. At the moment I am not convinced but that could be because there is a lack of detail.**

As the reviewer mentioned, we have used random effects due to using repeated measures (same individuals observed in different moments in the longitudinal study). In addition, as the reviewer suggests, we have performed GEE models, using Poisson family with log link taking into account weights (see comment 4 of reviewer #2).

Results

6) **Line 51: should be "males" and line 52 should be "females"**

We have re-calculated all PR using a GEE model, as the reviewers suggested. For this reason, we have changed in the text all values of PR and corrected this mistake.

7) **I strongly believe that if models failed to converge then they should *NOT* be reported as both the point estimate and the standard errors could be out by a magnitude. It would be misleading in my opinion to report them. However, if you modify your analysis, at the very least using a Poisson family and log link, I suspect that this problem will disappear.**

As the reviewer suggested, we have used GEE models, using Poisson family with log link taking into account weights (see comment 4 of reviewer #2). By doing this we have improved the convergence problem in the models as the reviewer mentioned.

8) **Why did you choose the age cut-offs that you present? Younger children/infants tend to spend more time at home so it would be interesting to know if the presence of young children has had a marked increase in SFH. I'd suggest 0-4 years 5-15 and 15+. I think these are more meaningful cut-offs. If you did consider these cut-offs then you need to say why they were not used.**

As the reviewer suggested, we have changed the cut-off of the minimum age at home by <5 years, 5-14 and ≥15.

9) **Tables are a bit messy and busy. Is there any way you could present them graphically such as a forest plot? "coeffplot" command in R would do this for you. I think you could be a bit more creative here.**

We have used the coeffplot command as suggested. The figures are in the end of this response. However, we decided to keep the table in the manuscript because it provides more information about our study for the potential readers. However, if the editor finds it better to provide the new figures created in the main text, we are available to provide it and include the current Table 2 as complementary files.

10) **I'd lose figure 1 as it doesn't really add anything and would be incorporated into a forest plot anyway. The %columns are not at all useful.**

Thank you for the comment. As the reviewer suggests we have removed this figure. However, if the editor finds it is better to provide this figure, we are available to provide it again.

11) **I felt the discussion was a bit too long and it could be edited down.**

As the reviewer suggested, we have shortened the Discussion section deleting the following paragraph:

> "In Spain, other study has shown a decrease in SHS exposure in non-smokers adults after the legislations, with exposure assessment by questionnaire and biomarkers (cotinine) (25). Specifically, the prevalence ratio of SHS exposure showed a significant decrease in the SHS in home after the legislation (PR = 0.78, 95%CI: 0.65, 0.94) (25)."

If the editor finds it better to provide this paragraph in the main text, we are available to provide it again.

Reviewer: 3

Methods

1) **What was the response rate for the baseline survey? Is there any indication that initial response to the baseline survey differed according to smoke-free home rules? It appears that the original intent of the survey was not designed to look at chances in smoking rules between these two time points, but in changes in salivary cotinine exposures instead. Perhaps this should be mentioned in the methods section?**

Thank you very much for the interesting comment. As previous reviewer mentioned (please see reviewer's #1 comment 9), we have included information of lost and follow-up sample in the Method section as follows:

> "The percentage of follow-up in this first stage was 81.1%. The follow-up survey was conducted between May 2013 and February 2014. In total, 72.9% of the eligible sample agreed to participate and answered the questionnaire (736 out of 1010 traced, second stage of follow-up), 18.5% refused to participate, 7.2% moved elsewhere and 1.3% died. The final sample analyzed was 736 individuals (400 women and 336 men). Finally, the percentage of participation in both stages was 51.9% (736 out 1245). There were no statistically significant differences between the followed-up sample (n=736) and the participants lost in the second stage (n=274) according to age, sex, level of education and smoking status. However, there were statistically significant differences according to age, level of education and smoking status between the follow-up sample (n=736) and the participant lost in both stages of the follow-up (n=509) (table 1). For this reason, the final sample was skewed as older in comparison with the population of Barcelona."

Moreover, we have compared the salivary cotinine concentration in baseline between lost and follow-up. Although there were statistically significant differences according to smoking status

there was a not statistically significant difference according to salivary cotinine concentration. We have decided not provide information about salivary cotinine concentration in the table with lost and follow-up participants because we have not information about this biomarker in the follow-up and also for not confound the reader. However, if the editor finds this information necessary, we may add it into table 1.

We have also included in the Discussion section the limitation of the differences observed between lost and follow-up as follows:

> "In this sense, there were statistically significant differences according to age, level of education, and smoking status between the follow-up sample and the participant lost in both stages of the follow-up. Follow-up participants overestimate the young people and smokers in comparison with lost participant (table 1), for this reason the increase of SFH could be higher among lost participant. On the other hand, our final sample overestimated the older people compared with the distribution of population in Barcelona."

2) **At baseline, individual ≥16 years of age were included as "adults", yet in the follow-up survey, were excluded (or deemed ineligible) because they were <18 years old in 2004-2005. What was the reasoning behind these differences in eligibility criteria?**

Please see response to comment number 8 of the reviewer #1.

3) **In the results (page 9, 3rd paragraph), the authors mention areas outside of the house and changes to smoking rules in these areas, particularly as they relate to homes with partial smoke-free home rules. However, there is no mention of these questions in the methods section. Can you please describe how these results were obtained?**

As the reviewer suggested, we have added information in the Methods section about outdoor smoking (please see comment number 10 of reviewer #1).

4) **Given that this is longitudinal data, I wonder why the prevalence ratio is used instead of the risk ratio? The risk ratio will give an indication of how more/less likely a group (with an exposure) is to acquire the outcome over the follow-up period relative to another, unexposed group as opposed to strictly changes over time.**

The objective of our study was to assess the impact of Spanish smoking bans in the prevalence of adoption of SFH, for this reason, we think more appropriate to measure the changes in the prevalence with prevalence ratio. Other interesting study could be to analyse the correlates and "risk" to adoption of SFH. In this case, we think more appropriate to use risk ratio. Due to the objective of our study we have decided to keep prevalence ratio. Moreover, we have conducted a GEE analyses as the three reviewers as suggested. However, if the editor considers more appropriate to perform a risk ratio we are available to conduct this analyses.

5) **The prevalence ratio was only adjusted for age and sex. However, these results are stratified by several covariates. Did the authors think about conducting modeling (i.e. GEE or otherwise) to look at multivariable-adjusted analyses, perhaps stratified only by smoking status at baseline? I think it would be interesting to note whether there are different covariates that would impact smoke-free home rules between**

current smokers and non-smokers before and after the implementation of the smoke-free air legislation.

Please see response to comment number 4 of the reviewer #2.

Results:

6) **Page 8, last paragraph through Page 9, line 29: The authors mention that increases in smoke-free home rules were higher among men (vs. women), young people (presumably vs. older individuals), those with higher education, etc. However, the confidence intervals overlap – for example by sex: Men: PR=33, 95% CI: 1.18-1.50 vs. Women: PR=29, 95% CI: 1.18-1.41 (Table 1, any rules by sex). Statistical testing was conducted according to the McNemar's test in figure 1 to look at changes over time (please add this in a footnote), but there is no indication in Table 1 what differences are statistically significant (i.e. men vs. woman, age groups, etc.). I think the results would be strengthened if there was some comparison completed between these characteristics as opposed to only conducting the multiple stratified analyses. Or, please re-phrase the results so as not to imply that these comparisons are being made.**

Thank you for the comment. We have only highlighted the higher increase in the prevalence ratios not compare the prevalence ratio according to the sociodemographic variables. We have re-written the results section to clarify this as follows:

> "The increase of any type of rules (complete and partial) was statistically significantly independently of sex (PR man = 1.33 *vs.* PR women =1.29), age (PR 65-98 years = 1.24 and PR in 26-44 years 1.33), educational level (PR intermediate level = 1.19 and PR high level = 1.47), and minimum age in house (PR 0-4 years = 1.11 and PR ≥15 years = 1.40). However, the increase was statistically and significantly higher only among never smokers (PR=1.46) at baseline."

Moreover, as the reviewer suggested, we have indicated in the Table 1 when effects are significant, to guide the reader, including the following symbols: * p-value <0.05, ** p-value<0.01, *** p-value<0.001. If the editor finds it necessary, we can as well add the p-values. We have also added a footnote indicating statistical test used in the tables.

7) **In the footnote of table 1: there is a statement "Non-converging log-binomial regression model with random effects". What is the implication of this non-convergence? The authors make no note in the limitations or elsewhere what may have been the cause of this non-convergence. Moreover, what are the random effect(s) that were used?**

Thank you for the comment. As the three reviewers suggested, we have performed GEE models, using Poisson family with log link taking into account weights instead of log-binomial regression obtaining convergent models in all the cases. Moreover, we have used random effects to take into account repeated individual. To clarify this, we have added the following sentence to the Method section:

> "We also used GEE models with individuals as random effects and using Poisson family with log link, to calculate the prevalence ratio adjusted by sex, age and month when the survey was conducted (PRa)."

We have also clarified it in the footnote of the table.

8) **Figure 1: It would be nice if the actual percentages were presented in this figure too (above each bar). As mentioned in #6, there should be a footnote with this figure describing the PR calculation, the McNemar's test, etc.**

We have removed this figure as suggested the reviewer #2 (please see comment number 10 of reviewer #2).

Discussion

9) **There were 2 distinct smoke-free laws implemented – the first in 2006 (right after this baseline assessment) and the next 5 years later in 2011. The authors are not treating these two laws as separate events, given that there was only one follow-up study (2013-2014). Therefore, it is unclear whether the increases in smoke-free home rules observed in this study occurred following the first law (2006) or whether the more comprehensive smoke-free air law with few exceptions was associated with the increases (or some combination of both). However, the authors make no mention of this in the discussion or in the limitations. It does not appear that this study was initially conceived to assess these changes due to the smoke-free air legislation, given the focus on cotinine collection, which may be why there was not follow-up after each smoke-free air law was passed.**

Thank you very much for the interesting comment. We agree with the reviewer, it is unclear whether the increases in smoke-free home rules observed in this study occurred following the first law (2006) or whether the more comprehensive smoke-free air law with few exceptions was associated with the increases (or some combination of both). Therefore we included the following limitation in the Discussion section:

> "Finally, we have not gathered information about the prevalence of SFH between both surveys to assess the impact of both Spanish legislations (independently or combined)."

10) **The authors state that their results counteract the displacement hypothesis, but this isn't necessarily true, given that there were increases in allowing smoking in outdoor areas of the home (balconies, courtyards, gardens, etc.). So, even though there were decreases in smoking inside the home, there was an increase in smoking behaviors in private outdoor spaces.**

Thank you very much for the comment. In our opinion, the decrease in smoking inside the home together with the increase in smoking behaviour in private outdoor spaces counteract the displacement hypothesis in the sense that, according to our results, we would expect a decrease in second-hand smoke exposure inside the house.

11) **Throughout the paper, there are some grammatical and linguistic errors. For example: in the results: "increasing vs. increase" and "...outside areas of the houses were the places that more increased in allowing smoking..." I'd recommend having a translator look at a final version of this paper prior to any publication.**

We have corrected the mistakes and we have revised carefully the last version of the manuscript and we have corrected all mistakes detected, as reviewer suggested.

NEW FIGURES CREATED

Figure 1: Any type (complete and partial) of SFH rules (prevalence ratio)

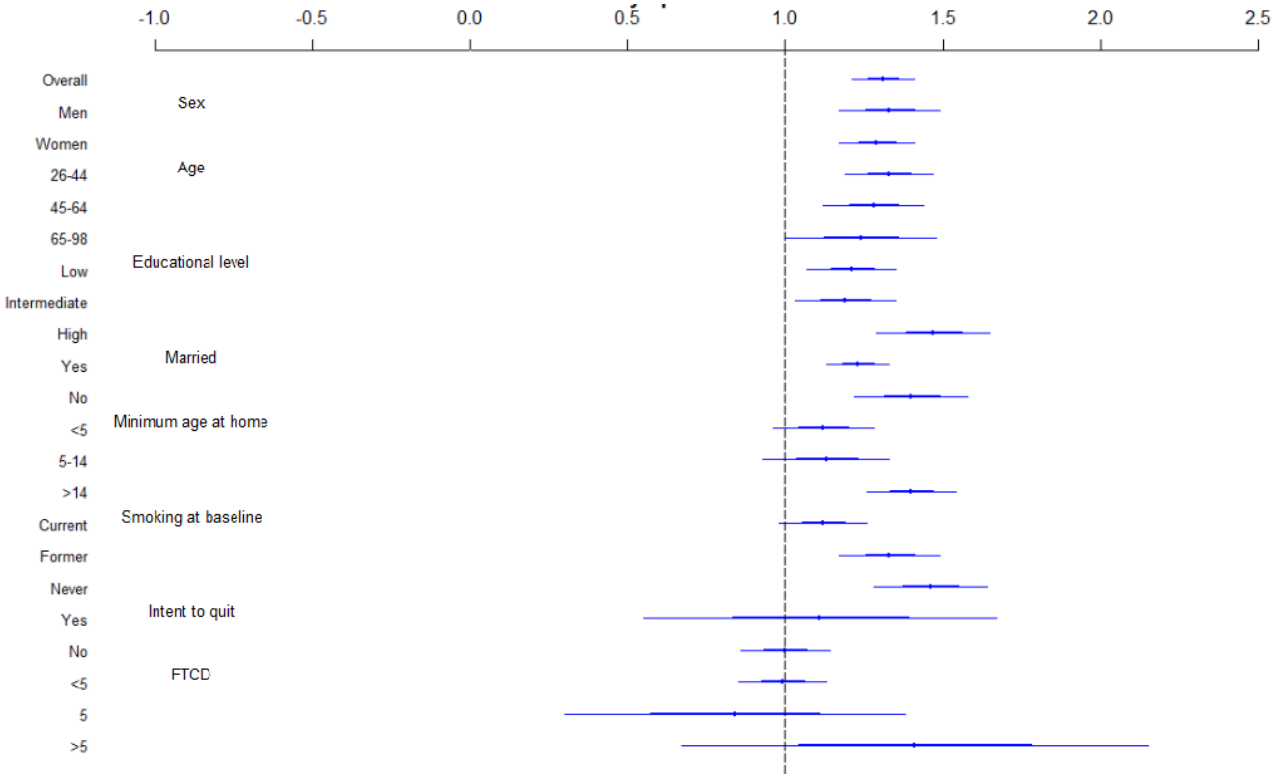


Figure 2: Complete SFH rules (prevalence ratio)

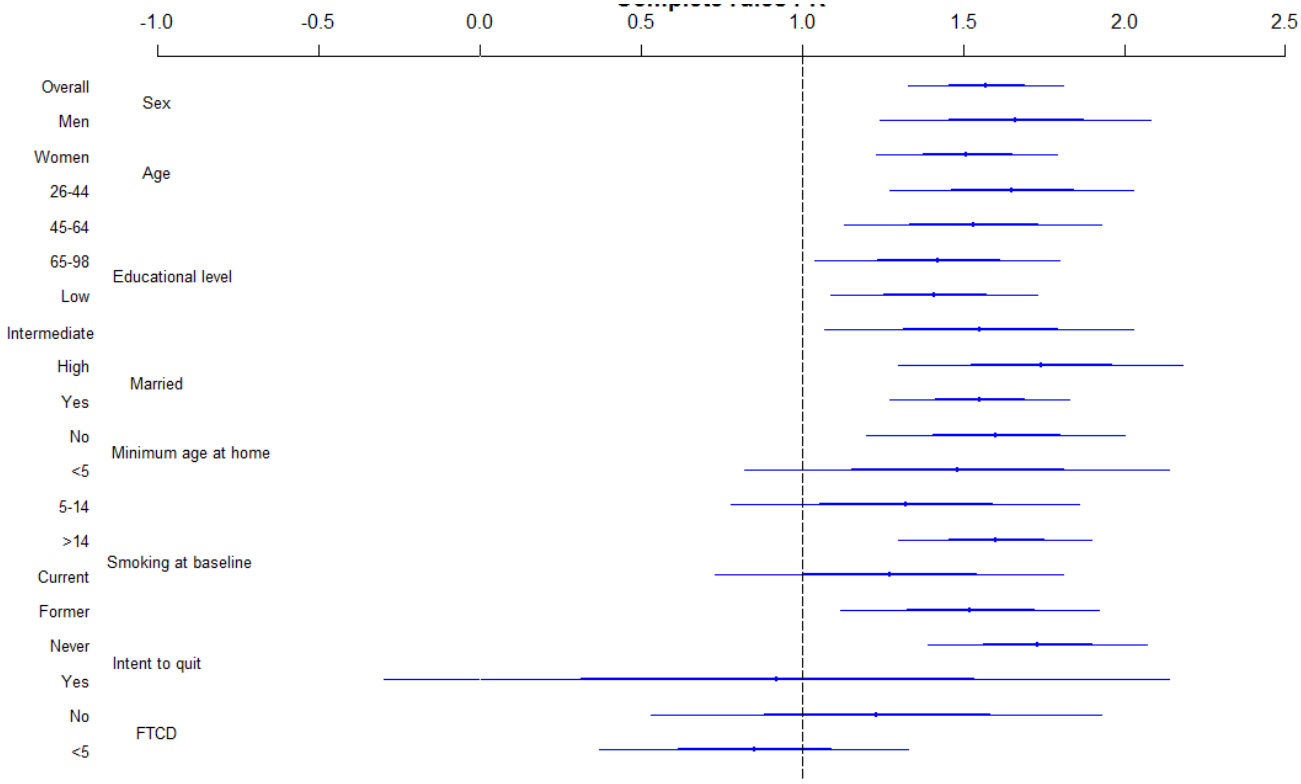
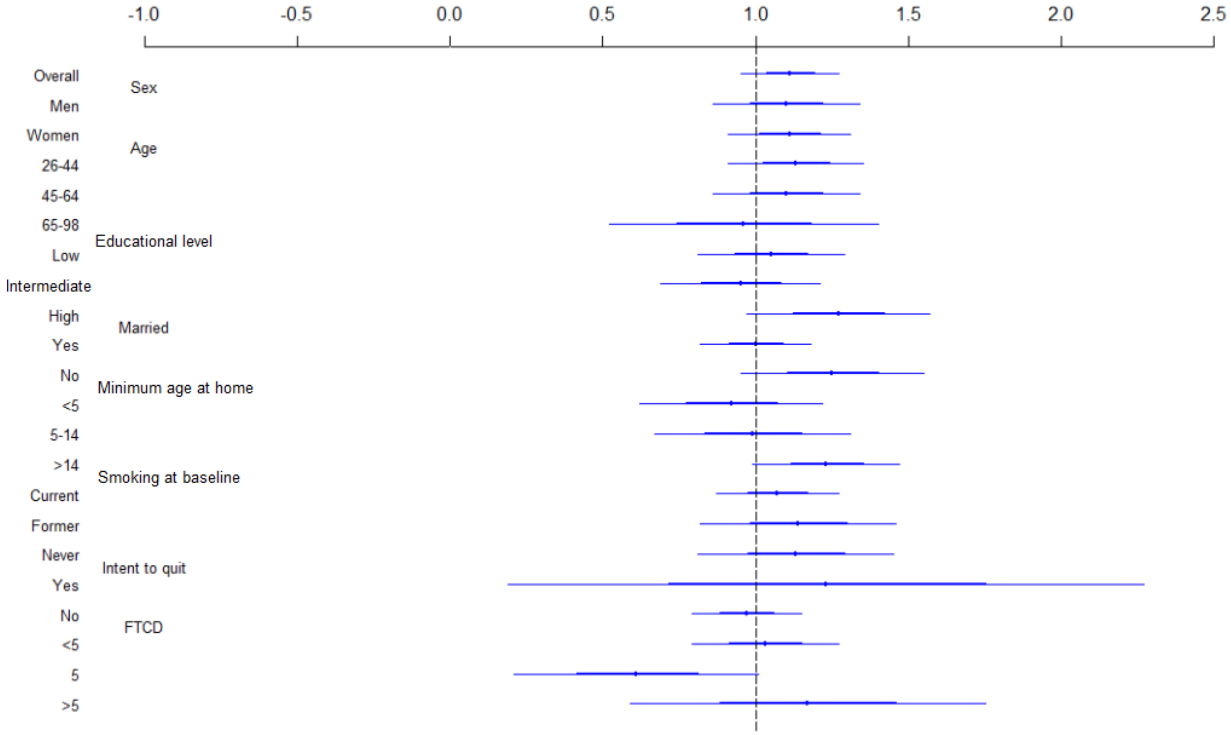


Figure 3: Partial of SFH rules (prevalence ratio)



Letter of acceptance of Tobacco Control journal

-----Mensaje original-----
De: onbehalfof+tobaccocontrol+bmj.com@manuscriptcentral.com [mailto:onbehalfof+tobaccocontrol+bmj.com@manuscriptcentral.com]
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Para: jmmartinez@iconcologia.net
CC: clidon@uic.es; jmmartinez@iconcologia.net; mfu@iconcologia.net; mballbe@iconcologia.net; jcmartin@uic.es; cmartinez@iconcologia.net; esteve.salto@gencat.cat; efernandez@iconcologia.net
Asunto: Tobacco Control - Decision on Manuscript ID tobaccocontrol-2016-053114.R1

24-Aug-2016

Dear Dr. Jose Martínez-Sánchez,

Manuscript ID tobaccocontrol-2016-053114.R1 - Impact of the Spanish smoking legislations in the adoption of smoke-free rules at home: a longitudinal study in Barcelona (Spain)

We are pleased to accept your article for publication in Tobacco Control.

Your paper will shortly be sent for editing and typesetting and you will receive a proof to check in about 10-15 working days. Please check your junk mail if you have not received your proof within this time, in case the automatic email goes there.

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Yours sincerely,

Andrew Hyland,
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Reviewer(s)' Comments to Author:

We are constantly trying to find ways of improving our peer review system and continually monitor processes and methods by including article submissions and reviewers' reports in our research. If you do not wish your paper or review entered into a our peer review research programme, please let us know by emailing The BMJ's editorial office papersadmin@bmj.com as soon as possible.

v. Correspondence of the thesis article: Secondhand smoke risk perception and smoke-free rules in homes: a cross-sectional study in Barcelona (Spain)

Cover letter to the editor of BMJ Open

Barcelona, September 8th, 2016.

Dr. Trish Groves
Editor in Chief
British Medical Journal Open

Dear Dr. Groves,

Please find enclosed our manuscript "Secondhand smoke risk perception and smoke-free rules in homes: room for improvement" for your consideration in the British Medical Journal Open.

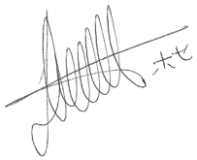
We observed that there are an association between the smoke-free homes adoption and the perceived risk of secondhand smoke exposure. Our data highlight the need to increase awareness of the health risks of tobacco passive exposure in private settings, especially among smokers. In this sense, warning campaigns about the harmful effects of secondhand smoke exposure at homes, especially in the presence of minors, should be promoted in Spain. Furthermore, it should also be reported by the media the health benefits of having a smoke-free home.

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. The authors declare there are no conflicts of interest.

We would of course be ready to provide further information about our data and methods you 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.

Yours sincerely,



Jose M Martínez-Sánchez, PhD, MPH, BSc

E-mail: jmmartinez@uic.es

Editor's response and comments from the BMJ Open reviewers

-----Mensaje original-----
De: onbehalfof+info.bmjopen+bmj.com@manuscriptcentral.com [mailto:onbehalfof+info.bmjopen+bmj.com@manuscriptcentral.com]
Enviado el: martes, 11 de octubre de 2016 14:36
Para: jmmartinez@uic.es
CC: clidon@uic.es; jmmartinez@uic.es; mfu@iconcologia.net; mballbe@iconcologia.net; jcmartin@uic.es; cmartinez@iconcologia.net; efernandez@iconcologia.net
Asunto: BMJ Open - Decision on Manuscript ID bmjopen-2016-014207

11-Oct-2016

Dear Dr. Martínez-Sánchez,

Manuscript ID bmjopen-2016-014207 entitled "Secondhand smoke risk perception and smoke-free rules in homes:
room for improvement" which you submitted to BMJ Open, has been reviewed. The comments of the reviewers are included at the bottom of this letter.

The reviewers have recommended revisions to your manuscript. Therefore, I invite you to respond to the reviewers' comments and revise your manuscript. Please remember that the reviewers' comments and the previous drafts of your manuscript will be published as supplementary information alongside the final version.

In addition to the above, please address the editorial requests towards the end of this letter.

To revise your manuscript, log into https://mc.manuscriptcentral.com/bmjopen and enter your Author Center, where you will find your manuscript title listed under "Manuscripts with Decisions." Under "Actions," click on "Create a Revision." Your manuscript number has been appended to denote a revision.

You may also click the below link to start the revision process (or continue the process if you have already started your revision) for your manuscript. If you use the below link you will not be required to login to ScholarOne Manuscripts.

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You will be unable to make your revisions on the originally submitted version of the manuscript. Instead, revise your manuscript using a word processing program and save it on your computer. Please also highlight the changes to your manuscript within the document by using the track changes mode in MS Word or by using bold or colored text.Once the revised manuscript is prepared, you can upload it and submit it through your Author Center.

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You will receive a proof if your article is accepted, but you will be unable to make substantial changes to your manuscript, please take this opportunity to check the revised submission carefully.

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Because we are trying to facilitate timely publication of manuscripts submitted to BMJ Open, your revised manuscript should be submitted within 28 days. If it is not possible for you to submit your revision by this date, we may have to consider your paper as a new submission.

Once again, thank you for submitting your manuscript to BMJ Open and I look forward to receiving your revision.

Sincerely,

Dr Edward Sucksmith
BMJ Open Managing Editor
esucksmith@bmj.com

Editorial Requests:

- Please revise your title so that it includes your study design and setting. This is the preferred format for the journal. Please also remove "room for improvement" - we ask authors to refrain from using declarative titles (i.e those that state the study's main finding(s)).

- Please re-write the 'Strengths and Limitations' section on page 3. Currently only the final bullet point is a strength or limitation of the study.

- The manuscript contains some typographical/ grammatical errors. Please thoroughly copy-edit the paper.

- Please include an ethics statement in the methods section of the manuscript.

Reviewers' Comments to Author:

Reviewer: 1
Reviewer Name: Giuseppe Gorini
Institution and Country: ISPO, Florence, Italy Competing Interests: None to declare

Most studies on household SHS exposure considered indoor household ban, for instance, studies on effects of SHS exposure on children. If smokers go outdoor SHS levels are very low.
Thus, in my opinion, it's important that there is an indoor ban, not an outdoor household ban. If smokers are allowed to smoke in terraces, patios and gardens, it's good. Instead, if smokers are allowed to smoke in one or more rooms, it's not good. So, I suggest to divide "partial ban" into two groups: " partial ban (only indoor is not allowed to smoke; about 70% of the 35% respondents in this group)" and "partial ban (it's allowed to smoke indoor in some areas; about 30% of the 35% respondents in partial ban group).
Then I will put together your categories "complete ban" plus the category " partial ban (only indoor is not allowed to smoke)", creating a new category "complete indoor ban". Moreover, I will put together "absent smoking rules" plus "partial ban (it's allowed to smoke indoor in some areas), creating a new category "partial or absent indoor ban" . Then, you have to run again the statistical analyses using these two new categories "complete indoor ban" and "partial or absent indoor ban"

Reviewer: 2
Reviewer Name: S Phani Veeranki
Institution and Country: Preventive Medicine and Community Health, University of Texas Medical Branch, Galveston, TX USA Competing Interests: None declared

In this study, the authors conducted a follow up of a previous cohort to investigate the prevalence of voluntary adoption of smoke free laws and identify factors associated with it. In addition, they also assessed the relationship between SHS risk perception and smoke-free rules in homes. This study has significant impact in the tobacco literature due to its investigation on voluntary smoke free laws. I commend the authors for their effort, however I have several reservations as highlighted below.

The introduction does not present the background rationale of importance of the study question. Why voluntary smoke-free laws are important? What are health effects associated with SHS exposure inside home to children and young adolescents? Why voluntary and not mandatory? What are the other venues for SHS exposure?

Data on US is out of context. I suggest the authors present a rationale in relation to venues of shs exposure and availability of smoking laws to cover these venues.

What is the rationale in conducting a follow up survey 3 years post implementation of comprehensive smoke free law?

Provide more details on the survey- administration, questionnaire, how sample was accessed, type of sampling procedure etc.

Did the original baseline survey include "<18 years"? Provide sufficient details about the original survey.

Approximately 28% of survey participants were either loss to follow up or died or refused to participate. How did you address this in the statistical models? How were these different from those who participated in the survey? Inclusion/exclusion of these participants will influence the estimates.

There are several other confounding variables that influence either voluntary adoption of smoke free laws or SHS risk perception other than age, sex and smoking status. For ex: occupation, employment, knowledge, access to tobacco products, tobacco industry advertising and promotions etc.

Please describe how weights were determined and incorporated.

It seems the authors purposefully presented results from unadjusted estimates, which is incorrect. You are supposed to present adjusted estimates. Please revise the results section. Also there is no information on variables at baseline and follow up survey.

The adjusted estimates in table 2 revealed no association between SHS risk perception and smoke-free laws. What might be the reason?

Reviewer: 3
Reviewer Name: Emilia Zainal Abidin
Institution and Country: Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, Malaysia
Competing Interests: None declared.

Paper is well-written. The following are a few suggestions regarding the need for modifications of some parts of the text to further increase the readability of this paper.

Abstract
1. line 23, secondhand instead of second; methods, first line consider revising sentence 2. "perceptions", suggestion: Briefly state the significant variables of risk perceptions; breathing tobacco smoke from smokers is harmful (PR: 1.50; 95% CI: 1.07-2.11), second-hand tobacco smoke is dangerous for adults (PR: 1.44; 95% CI: 1.04 - 2.00) and non-smokers (PR: 1.65; 95% CI: 1.12 - 2.44) were associated with the voluntary adoption of smoke-free home.
3. line 45-48, rephrase to make sentence clearer 4. Line 32-35, did the Euro-barometer consider smoking in outdoor areas at home as complete ban?

Strength & limitation
1. Suggest to revise the points regarding strength of the study,

Introduction
1. Acronym not defined; SHS and Line 7, since the introduction of...
2. Line 37. Reference for law missing
3. Line 48, consider revising
4. Justification for paper not included

Methods
Page 5
1. Line 12, 2014, instead of 1014. Add a brief sentence explaining the method of baseline data collection.
2. Line 26, add frequency in parentheses to explain percentages 3. Line 32, The final number of subject included in this study is 736 or 731? statement contradict with next paragraph.
Page 5
4. Line 6, 8, 11; request to standardise SHS term used 5. Reference for FCTD is missing 6. Please state language used and ethical approval statement

Results
1. In households with partial rules, outdoor areas as balconies, patios, terraces and gardens, were the most commonly designated places for smoking (70.0%). ---- is there a reason why outdoor smoking (balconies, patios, terraces and gardens) not considered as complete ban? Or does this follow the Euro-barometer?
2. This is an important point, suggest that author include data. ---> Besides, enclosed areas of the home were the least designated for smoking (data not shown).
3. For table 1 and 2, suggest to add * to indicate $p<0.05$, or bold, or whatever is easier

Discussions
1. Line 31, please state the percentages of adoption of smoke-free home adoption among never smokers and among those who lived with minor in these previous studies.
2. line 34, it is suggested to discuss why the adoption of smoke-free home was higher among never smoker and among those who lived with minors. Additional statistical analysis could be performed to confirm if there are significant differences of any kind of risk perceptions towards SHS exposure across smoking status and the presence of minors at home.
3. Line 29, 33 page 12 tobacco passive exposure, consider revising 4. Are there any link between the findings and the effectiveness of the last smoke-free legislation in Spain (Law 42/2010)? Please identify and add relevant information if any and references to further strengthen the discussions.

Response to the BMJ Open reviewer's comments

bmjopen-2016-014207
Secondhand smoke risk perception and smoke-free rules in homes: room for improvement

We thank the editor and the reviewers for their useful comments.

We enclose a point-by-point response and we have highlighted the changes in the text of the manuscript.

Editorial Requests:

- Please revise your title so that it includes your study design and setting. This is the preferred format for the journal. Please also remove "room for improvement" - we ask authors to refrain from using declarative titles (i.e those that state the study's main finding(s)).
As the editor suggests, we have changed the title as follows:

> "Secondhand smoke risk perception and smoke-free rules in homes: a cross-sectional study in Barcelona (Spain)"

- Please re-write the 'Strengths and Limitations' section on page 3. Currently only the final bullet point is a strength or limitation of the study.

We have re-written the 'Strengths and Limitations' section as follows:

> "• The main limitation of this study is the potential bias of participation due to the attrition of the cohort of participants. However, all analyses used weighted data to generate representative estimates of the city of Barcelona.
> • The study was conducted only in the city of Barcelona and generalization of the results to the rest of Spain should be cautious.
> • Another potential limitation is the cross-sectional nature of the data, which allow to establish associations but not to infer causality."

- The manuscript contains some typographical/ grammatical errors. Please thoroughly copy-edit the paper.
We have carefully revised the manuscript and edited the typographical and grammatical errors.

- Please include an ethics statement in the methods section of the manuscript.
This statement has been added in the page number 6 (last paragraph).

Reviewer: 1
Reviewer Name: Giuseppe Gorini
Institution and Country: ISPO, Florence, Italy
Competing Interests: None to declare

1. Most studies on household SHS exposure considered indoor household ban, for instance, studies on effects of SHS exposure on children. If smokers go outdoor SHS levels are very low. Thus, in my opinion, it's important that there is an indoor ban, not an outdoor household ban. If smokers are allowed to smoke in terraces, patios and gardens, it's good. Instead, if smokers are allowed to smoke in one or more rooms, it's not good. So, I suggest to divide "partial ban" into two groups: "partial ban (only indoor is not allowed to smoke; about 70% of the 35% respondents in this group)" and "partial ban (it's allowed to smoke indoor in some areas; about 30% of the 35% respondents in partial ban group). Then I will put together your categories "complete ban" plus the category" partial ban (only indoor is not allowed to smoke)", creating a new category "complete indoor ban". Moreover, I will put together "absent smoking rules" plus "partial ban (it's allowed to smoke indoor in some areas), creating a new category "partial or absent indoor ban". Then, you have to run again the statistical analyses using these two new categories "complete indoor ban" and "partial or absent indoor ban".

We thank the reviewer for the interesting comment. According to his suggestion, we have re-calculated all analyses using the proposed categorization about smoke-free rules at home ("complete indoor rules" and "partial or absent indoor rules"). The prevalence of the new categories are 57.4% for complete indoor rules and 42.6% for partial or absent indoor rules. We explain the new re-codification in the Methods section, have modified the tables, and have re-written the Results section accordingly.
Moreover, due to the new categorization, the log-binomial regression model adjusted for sex, age, and smoking status do not converge. For this reason, we have decided to remove the smoking status from the adjustment; thus, the models were adjusted for sex and age. We have clarified this in the methods section as follows:

> "We also fitted a log-binomial regression models to calculate the prevalence ratios, adjusted for sex and age (PRa)."

Reviewer: 2
Reviewer Name: S Phani Veeranki
Institution and Country: Preventive Medicine and Community Health, University of Texas Medical Branch, Galveston, TX USA
Competing Interests: None declared

In this study, the authors conducted a follow up of a previous cohort to investigate the prevalence of voluntary adoption of smoke free laws and identify factors associated with it. In addition, they also assessed the relationship between SHS risk perception and smoke-free rules in homes. This study has significant impact in the tobacco literature due to its investigation on voluntary smoke free laws. I commend the authors for their effort, however I have several reservations as highlighted below.
Thank you very much for the kind comment to our work.

1. The introduction does not present the background rationale of importance of the study question. Why voluntary smoke-free laws are important? What are health effects associated with SHS exposure inside home to children and young adolescents? Why voluntary and not mandatory? What are the other venues for SHS exposure?

We thank the reviewer for these insights. Following the reviewer's queries, we provide additional information in the Introduction section:

> "The health consequences of second-hand smoke (SHS) exposure on non-smoker's are well-known(1). Moreover, passive exposure could be due to different settings such as workplaces, public places (bars, restaurants, etc.), public transport, or private places. For this reason, since the introduction of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC), many countries have implemented smoke-free policies in public and workplaces to reduce the impact of SHS exposure in non-smoker's health; consequently there has been a reduction in SHS exposure after their implementation in workplaces and public places(2). However, private settings (mainly cars and homes) are never or rarely included in tobacco control policies. Nevertheless, the household is usually the main source of exposure to SHS in children(3,4). In addition, children are especially vulnerable to SHS exposure because they breathe more rapidly and inhale more pollutants per pound of body weight adults(5). In addition, SHS exposure is a risk for infant death syndrome, acute respiratory infections, ear problems, and mental disorders in children(6,7)."

And,

> "Currently, to our knowledge, there are no national descriptive studies about the adoption of smoke-free homes in Spain after the Spanish tobacco control legislations. Moreover, there is scarce evidence about the relationship between voluntary adoption of smoke-free homes and the risk perception of SHS exposure. Therefore, the objective of this study is to describe the voluntary adoption of smoke-free homes in Spain and to identify variables associated to its voluntary adoption, including risk perception towards SHS exposure."

_____

New references:

(1) U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. 2014. Available at: http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf

(5) Canadian Institute of Child Health. Environmental hazards: Protecting children. 1997. http://www.cich.ca/PDFFiles/EnvFactSheetsENG.pdf (accessed 20 October 2016).

(6) Padrón A, Galán I, Garcia-Esquinas E, et al. Exposure to secondhand smoke in the home and mental health in children: a population-based study. Tob Control 2015 25:307-12.

(7) Hahn EJ. Smokefree legislation: a review of health and economic outcomes research. Am J Prev Med 2010;39:S66-76.

2. Data on US is out of context. I suggest the authors present a rationale in relation to venues of shs exposure and availability of smoking laws to cover these venues.

We have removed the information about smoke-free homes in US. Moreover, as the reviewer suggested, we have added the following paragraph in the Introduction section:

> "The health consequences of second-hand smoke (SHS) exposure on non-smoker's are well-known(1). Moreover, passive exposure could be due to

different settings such as workplaces, public places (bars, restaurants, etc.), public transport, or private places. For this reason, since the introduction of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC), many countries have implemented smoke-free policies in public and workplaces to reduce the impact of SHS exposure in non-smoker's health; consequently there has been a reduction in SHS exposure after their implementation in workplaces and public places(2)."

3. What is the rationale in conducting a follow up survey 3 years post implementation of comprehensive smoke free law?

This work is part of a longitudinal study, aims to assess the impact of the Spanish smoking bans. The follow-up was conducted 3 years after the implementation of the current comprehensive smoke-free legislation. This work has used exclusively the follow-up data. We have clarified this issue in the Methods section (please see comments from 4 to 6 of reviewer #2). If the editor considers appropriate to provide detailed information of the study, we will be ready to include it.

4. Provide more details on the survey- administration, questionnaire, how sample was accessed, type of sampling procedure etc.

As the reviewer suggests, we have added more details on the baseline survey in the Methods section:

"We used the follow-up data of a cohort study from a representative sample of the adult population (≥16 years) of the city of Barcelona (Catalonia, Spain). The objective of the cohort study was to assess the impact of the Spanish smoking bans on tobacco consumption and SHS exposure. The baseline study was carried out during the years 2004-2005 through a representative random sample of the adult (≥ 16 years old) non-institutionalized population of Barcelona (Spain) (10,11)(n = 1,245). We obtained the personal data and addresses from the updated official Census, as provided by the Institute of Statistics of Barcelona. We sent a personal letter to introduce the study; afterwards trained interviewers administered a face-to-face questionnaire (in Spanish or Catalan) at the participant's home to gather information on socio-demographic data and active and passive smoking. The follow-up took place in 2013-2014.
For this study, we exclusively used the follow-up data."

5. Did the original baseline survey include "<18 years"? Provide sufficient details about the original survey.

The baseline study in 2004-2005 was carried out through a representative sample of the adult (≥ 16 years old) non-institutionalized population of Barcelona. However, we could not follow those under 18 years old, because they were not legally adults at that time and we did not ask them any consent to be re-contacted in the future. Moreover, the consent form signed by their parents was only for the study in 2004-05. As the reviewer suggested, we provide more details about the original survey as follows:

"From the baseline sample, we excluded 235 subjects; 150 after checking their data in the Insured Central Registry of Catalonia (101 had died and 49 had migrated out of the province of Barcelona) and another 85 did not give consent to be followed up or were <18 years old in 2004-2005, because they were not legally

> adults at that time and we did not ask to their parents any consent to be re-contacted."

In addition, as also recommended by the reviewer #2 (please see comment 4), we have added more details on the baseline survey and the cohort study in the Methods section.

6. Approximately 28% of survey participants were either loss to follow up or died or refused to participate. How did you address this in the statistical models? How were these different from those who participated in the survey? Inclusion/exclusion of these participants will influence the estimates.

We thank the reviewer for the useful comment. As the reviewer points, approximately 28% of the survey participants were lost in the follow-up. Moreover, the final sample was skewed as slightly older in comparison with the general population of Barcelona. For this reason, we have weighted the final sample by age to assure the representativeness of the sample. We now explain this and the weight method in the Methods section.

We agree with the reviewer about the importance of reporting the differences between the lost (n=509) and followed up participants (n=736). We have observed statistically significant differences according to age, educational level, and smoking status. We have added more information about the lost individuals in the Methods section as follows:

> "There were statistically significant differences between the follow-up sample and the participant lost in the follow-up according to age, level of education, and smoking status. Followed-up participants overestimate the young people and smokers in comparison with lost participants, for this reason, the increase of smoke-free homes could be higher among lost participants. On the other hand, the final sample overestimated the older people compared with the distribution observed in the population of Barcelona. Therefore we used inverse probability weights to balance our data according to age distribution of the city of Barcelona to maintain its representativeness of the sample."

7. There are several other confounding variables that influence either voluntary adoption of smoke free laws or SHS risk perception other than age, sex and smoking status. For ex: occupation, employment, knowledge, access to tobacco products, tobacco industry advertising and promotions etc.

We fully agree with the reviewer's comment. Unfortunately, the survey did not include such detailed information, because its objective was not focused only on smoke-free rules in private settings. Nevertheless, the survey gathered information about employment and access to tobacco products. We analyzed the smoke rules at home according to these variables and we have only found statistically significant differences according to the employment of the participants. For this reason, we have decided to include only the information of the latter variable to make the analysis simpler to the reader. If the editor considers better to include also the information about the access to tobacco products, we are ready to provide it.

8. Please describe how weights were determined and incorporated.

The weights are proportional to the inverse of the probability of being included in the sample, i.e., a *d_i* weight for individual *i* can be interpreted broadly, as the *i* individual represents *d_i* individuals in the sample population. Such weights are known as inverse probability weights. As the reviewer suggests, we have added this information to make this clear:

> "Therefore we used inverse probability weights to balance our data according to age distribution of the city of Barcelona to maintain its representativeness of the sample."

9. It seems the authors purposefully presented results from unadjusted estimates, which is incorrect. You are supposed to present adjusted estimates. Please revise the results section. Also there is no information on variables at baseline and follow up survey.

As the reviewer suggests, we have presented the results for adjusted estimates.
We had not provided information of the baseline survey because we have focused only in the follow-up data (cross-sectional study). In order to clarify the data we used, we have added more information about the variables at baseline and at follow-up (please, see comment from 4 to 6 of the reviewer #2).

10. The adjusted estimates in table 2 revealed no association between SHS risk perception and smoke-free laws. What might be the reason?

We thank the reviewer for the observation. The reason of that lack of association was the inclusion of the variable 'smoking status' in the adjustment. Following the reviewer #1's recommendation, we have recoded the variable 'smoke-free homes'. Moreover, the regression model did not converge due to the smoking status variable. For this reason, we re-run the models according to the new categories proposed by the reviewer 1 for the 'smoke-free homes' variable and we have decided to remove the 'smoking status' variable of the adjustment, based on these results. Currently, in the new version of the analysis, the statistical significance of these variables is the same in the adjusted and unadjusted models.

Reviewer: 3
Reviewer Name: Emilia Zainal Abidin
Institution and Country: Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, Malaysia
Competing Interests: None declared.

Paper is well-written. The following are a few suggestions regarding the need for modifications of some parts of the text to further increase the readability of this paper.

Thank you very much for the kind comment to our work.

Abstract

1. line 23, secondhand instead of second; methods, first line consider revising sentence

We have corrected the word in line 23 and changed the first line of the Methods section in the abstract as follows:

> "Cross-sectional study of a representative sample (n=731) of the adult population (>26 years) of Barcelona, Spain, in 2013-14."

2. "perceptions", suggestion: Briefly state the significant variables of risk perceptions; breathing tobacco smoke from smokers is harmful (PR: 1.50; 95% CI: 1.07-2.11), second-hand tobacco smoke is dangerous for adults (PR: 1.44; 95% CI: 1.04 - 2.00) and non-smokers (PR: 1.65; 95% CI: 1.12 -2.44) were associated with the voluntary adoption of smoke-free home.

As the reviewer suggests, we have stated the significant variables of risk perceptions as follows:

> "Believe that breathing tobacco smoke from smokers is dangerous for non-smokers (PRa: 1.77; 95% CI: 1.06-2.97) is associated with the voluntary adoption of complete indoor smoke-free home."

3. line 45-48, rephrase to make sentence clearer

We have rephrased the conclusions statement in the Abstract section as follows:

> "Risk perceptions of secondhand smoke exposure were associated with the voluntary adoption of indoor smoke-free homes."

4. Line 32-35, did the Euro-barometer consider smoking in outdoor areas at home as complete ban?

The Eurobarometer uses the same question to our study regarding smoke-free homes. The question used in the Eurobarometer is "Which of the following situations best describe the smoking rules in your house?" with three possible answers: 'Nobody can smoke', 'Smoking is allowed in some places' and 'Smoking is allowed everywhere'. However, the report of the Eurobarometer analyzes this question without differencing indoor and outdoor smoking. We have clarified this in the Discussion section as follows:

> "This prevalence is higher than that obtained in the Eurobarometer(8) (44%), maybe because the Eurobarometer considers as complete smoke-free homes those households where smoking is not allowed, without distinction between indoor and outdoor areas."

Strength & limitation

5. Suggest to revise the points regarding strength of the study.

We have re-written the 'Strengths and Limitations' section (please, see the editorial requests).

Introduction

6. Acronym not defined; SHS and Line 7, since the introduction of...

We have defined all acronyms.

7. Line 37. Reference for law missing

As the reviewer suggests, we have added the reference for the law

8. Line 48, consider revising

We have modified this line, following the recommendation by the reviewer #2 (see comment 2 of the reviewer #2).

9. Justification for paper not included

We have added the following justification before the objective of the study:

> "Currently, to our knowledge, there are no national descriptive studies about the adoption of smoke-free homes in Spain after the Spanish tobacco control legislations. Moreover, there is scarce evidence about the relationship between voluntary adoption of smoke-free homes and the risk perception of SHS exposure. Therefore, the objective of this study is to describe the voluntary adoption of smoke-free homes in Spain and to identify variables associated to its voluntary adoption, including risk perception towards SHS exposure."

Methods
10. Page 5, Line 12, 2014, instead of 1014. Add a brief sentence explaining the method of baseline data collection.

We edited the typographical error. Moreover, we have added more details on the baseline survey in the Methods section (see comment 4 of the reviewer #2).

11. Line 26, add frequency in parentheses to explain percentages

Done.

12. Line 32, The final number of subject included in this study is 736 or 731? statement contradict with next paragraph.

In this study we have available data from 731 individuals due to missing data in the variable of interest. We have clarified this in the Methods section as follows:

> "For this analysis, we have available data from 731 out of the 736 individuals, due to missing data in the variable of interest."

13. Page 6, Line 6, 8, 11; request to standardise SHS term used

As the reviewer suggests, we have standardized the SHS term across the manuscript.

14. Reference for FCTD is missing

As the reviewer suggests, we have added the following reference for FCTD.

_____

New references:

(12) Fagerström K. Determinants of tobacco use and renaming the FTND to the Fagerstrom Test for Cigarette Dependence. Nicotine Tob Res. 2012;14:75-8.

15. Please state language used and ethical approval statement

We have included an ethics statement in the Methods section (see editorial requests). Moreover, we have indicated the language of the survey (Spanish and Catalan) and the statistical software used.

Results

16. In households with partial rules, outdoor areas as balconies, patios, terraces and gardens, were the most commonly designated places for smoking (70.0%). ---- is there a reason why outdoor smoking (balconies, patios, terraces and gardens) not considered as complete ban? Or does this follow the Euro-barometer?

We thank the reviewer for the interesting comment. We have re-calculated all analyses using the new categories "complete indoor rules" and "partial or absent indoor rules", following the reviewer 1 suggestion (see comment 1 of the reviewer #1). Thus, we have finally considered smoking in outdoor areas of the households as complete rules.

17. This is an important point, suggest that author include data. ---> Besides, enclosed areas of the home were the least designated for smoking (data not shown).

We thank the reviewer for the comment. According to the reviewer #1, we have decided to re-calculate all analyses using the new categories "complete indoor rules" and "partial or absent indoor rules" (see comment 1 of the reviewer #1). Therefore, we have removed the information regarding to partial smoke-free home rules across the manuscript.

18. For table 1 and 2, suggest to add * to indicate p<0.05, or bold, or whatever is easier.

As the reviewer suggests, we have indicated when prevalence ratio are significant, to guide the reader, including the following symbols: * p-value <0.05, ** p-value<0.01, *** p-value<0.001. If the editor considers it appropriate, we can also provide the p-values.

Discussions

19. Line 31, please state the percentages of adoption of smoke-free home adoption among never smokers and among those who lived with minor in these previous studies.

We thank the reviewer for the comment. We agree with the importance to report more information about previous studies. However, the five articles cited reference eight countries, and three cities. In our opinion, it would be a lot of information to state. Moreover, not all of

the articles provide this information. Therefore, we have decided to include grouped information about Europe (UK), United States, Canada and Australia:

> "Moreover, as observed in previous studies(15-19), the adoption of smoke-free homes in our study was higher among never-smokers and among those who lived with a minor. The prevalence of adoption of smoke-free homes among households with non-smokers was 23.5% in UK, 39.2% in USA, 39.1% in Canada, and 44.3% in Australia(15). The prevalence of adoption of smoke-free home among households with infants and pre-primary children was 29 % and 26% in UK, 38.9% and 51.5% in USA, 41% and 48.8% in Canada, and 60.3% and 52.7% in Australia, respectively(15)."

However, if the editor considers appropriate to include information of more countries and cities, we are able to provide it.

20. line 34, it is suggested to discuss why the adoption of smoke-free home was higher among never smoker and among those who lived with minors. Additional statistical analysis could be performed to confirm if there are significant differences of any kind of risk perceptions towards SHS exposure across smoking status and the presence of minors at home.

We thank the interesting comment. As the reviewer suggests, we have performed additional statistical analysis to confirm if non-smokers and participants who lived with minors have higher percentage of perception of risk. According to the new analyses, the perception of risk of the five questions was always higher among non-smokers and those who lived with a minor. For this reason, there are higher adoption of smoke-free homes among never smokers and among those who lived with minors. We have included the following text in the Discussion section:

> "Our data show that the voluntary adoption of complete indoor smoke-free home rules is higher among never-smokers and among people who lived with minors. Never smokers present statistically significant higher risk perception of SHS exposure than smokers and former smokers (data not shown). This could be one reason why complete indoor smoke-free home rules are higher among never smokers. However, we found similar prevalence of SHS risk perception among people who lived with and without minors (data not shown). On the other hand, people who had some kind of risk perception of SHS exposure showed higher adoption of complete smoke-free homes rules. Similar results were obtained in a study in Italy about the support for tobacco regulation and consumption in private vehicles in the presence of minors(21)."

21. Line 29, 33 page 12 tobacco passive exposure, consider revising

As the reviewer suggests, we have changed this sentence as follows:

> "These results highlight the need to increase awareness of the health risks of SHS in private settings, especially among smokers."

22. Are there any link between the findings and the effectiveness of the last smoke-free legislation in Spain (Law 42/2010)? Please identify and add relevant information if any and references to further strengthen the discussions.

Even though the data analyzed were gathered after the last national smoking ban, it is not possible to determine any link between our findings and the effectiveness of the legislation, due to the cross-sectional nature of the study. The objective of this study is to update the descriptive information on the voluntary adoption of smoke-free homes in Spain according to sociodemographic variables and to the perception of risk of SHS exposure.

Letter of acceptance of BMJ Open journal

-----Mensaje original-----
De: onbehalfof+info.bmjopen+bmj.com@manuscriptcentral.com [mailto:onbehalfof+info.bmjopen+bmj.com@manuscriptcentral.com]
Enviado el: viernes, 02 de diciembre de 2016 12:09
Para: jmmartinez@uic.es
CC: clidon@uic.es; jmmartinez@uic.es; mfu@iconcologia.net; mballbe@iconcologia.net; jcmartin@uic.es; cmartinez@iconcologia.net; efernandez@iconcologia.net
Asunto: BMJ Open - Decision on Manuscript ID bmjopen-2016-014207.R1

02-Dec-2016

Dear Dr. Martínez-Sánchez:

It is a pleasure to inform you that your manuscript "Secondhand smoke risk perception and smoke-free rules in homes: A cross-sectional study in Barcelona (Spain)" has been accepted for publication in BMJ Open.

Please see the editorial comments towards the end of this letter.

To enable all research published in BMJ Open to be fully open access, an article-processing charge is levied. This charge supports the peer review process, production costs (typesetting, copy editing, etc.), and the costs of maintaining the content online and marketing it to readers.

Therefore, your payment of £1350 (excluding VAT) for manuscript bmjopen-2016-014207.R1 is now due.

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Please note, a number of institutions have taken out Open Access Memberships with BMJ, which either covers the cost of open access publishing for authors at participating institutes, or allows authors to receive a discount on the article-processing charge. Please visit our open access page to see a full list of participating institutions, find out if you are eligible and how to obtain your discount code - http://journals.bmj.com/site/authors/openaccess.xhtml#open-access-institutional-memberships.

All accepted papers are reviewed for their media potential by our PR office within two weeks of acceptance. If your paper is selected for press release by the journal, we will let you know within this timeframe.

Once your article is published online you will be able to keep track of usage. Each article published in BMJ Open has individual usage statistics which are updated daily and can be accessed from the Article Usage Statistics link in the Services section of the right hand column on each page of the article. In this column you can also sign up to be alerted about any e-letter responses to your article.

Thank you for your contribution, and we hope that you will continue to submit to the journal in future.

Sincerely,

Dr Edward Sucksmith
BMJ Open Managing Editor
esucksmith@bmj.com

**Editorial Comments:

When you receive the author proofs, please revise the second bullet point of the strengths and limitations section (page 3) to: "In this study we used a face-to-face questionnaire with trained interviewers that potentially increased the internal validity of our results as compared with internet and self-administered surveys."

Please also remember to carefully check the rest of the manuscript for typographical/ grammatical errors.

Reviewer Comments to Authors:

Reviewer: 2
Reviewer Name: S Phani Veeranki
Institution and Country: Preventive Medicine and Community Health, University of Texas Medical Branch, USA Competing Interests: None declared

I believe the authors have adequately addressed the queries. I have no further comments. I look forward to reading the paper in print.

Reviewer: 3
Reviewer Name: Emilia Zainal Abidin
Institution and Country: Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, Malaysia Competing Interests: None declared

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We are constantly trying to find ways of improving our peer review system and continually monitor processes and methods by including article submissions and reviewers' reports in our research. If you do not wish your paper or review entered into a our peer review research programme, please let us know by emailing The BMJ's editorial office papersadmin@bmj.com as soon as possible.

VI. Correspondence of the thesis article: Correlation between tobacco control policies, consumption of rolled tobacco and e-cigarettes, and intention to quit conventional tobacco, in Europe

Cover letter to the editor of Tobacco Control

Barcelona, May 25th, 2015.

Prof. Ruth Malone
Editor
Tobacco Control

Dear Prof. Malone,

Please find enclosed our manuscript "Correlation between tobacco control policies and consumption of rolling tobacco, electronic cigarette users, and intent to quit conventional tobacco in Europe" for your consideration in Tobacco Control as a *Research Paper*.

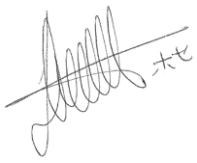
The level of smoke-free legislation among European countries is correlated with a decrease of prevalence of smoking of conventional cigarettes and an increase of intent to quit smoking. However, our study show there is positive correlation between the different levels of tobacco control policies implemented among European countries and the consumption of other tobacco products among former smokers of conventional cigarettes, particularly hand-rolled tobacco. Moreover, there is an indirect, but not statistically significant, correlation between the prevalence the prevalence of ever e-cigarette users and the levels of tobacco control policies implemented in Europe.

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. The authors declare there are no conflicts of interest.

We would of course be ready to provide further information about our data and methods you 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.

Yours sincerely,



Jose M Martínez-Sánchez, PhD, MPH, BSc

E-mail: jmmartinez@iconcologia.net

Editor's response and comments from the Tobacco Control reviewers

-----Mensaje original-----
De: onbehalfof+tobaccocontrol+bmj.com@manuscriptcentral.com [mailto:onbehalfof+tobaccocontrol+bmj.com@manuscriptcentral.com] En nombre de tobaccocontrol@bmj.com
Enviado el: miércoles, 05 de agosto de 2015 9:21
Para: jmmartinez@iconcologia.net
CC: clidon@uic.es; jcmartin@uic.es; patrickuic@uic.es; jan.graffelman@upc.edu; jmmartinez@iconcologia.net
Asunto: Tobacco Control - Decision on Manuscript ID tobaccocontrol-2015-052482

05-Aug-2015

Dear Dr. Martínez-Sánchez:

Thank you for submitting your manuscript ID tobaccocontrol-2015-052482 entitled "Correlation between tobacco control policies and consumption of rolling tobacco, electronic cigarette users, and intent to quit conventional tobacco in Europe". Please accept my apologies for the delay in responding to this submission. It has taken longer than we would have liked to receive reviews on this, but I'm pleased to let you know we have now done so and are able to make a decision on this.

The editorial team would like to invite you to revise and resubmit this manuscript as a brief report (http://tobaccocontrol.bmj.com/site/about/guidelines.xhtml#brief) of not more than 1,500 words with a single table.

In making these revisions, we feel it would be helpful to reference the previously published analysis (Martínez-Sánchez et al (2010) Smoking behaviour, involuntary smoking, attitudes towards smoke-free legislations, and tobacco control activities in the European Union. PLoS One doi: 10.1371/journal.pone.0013881) and to clarify how the objectives of this study differ from those of the previous analysis.

We will be happy to reconsider this manuscript after revision, providing you have responded to the comment above and those of the referees (see below).

Please note, by offering to reconsider a revised paper, we are making no commitment to publish a revised version.

Important: Please CUT AND PASTE THE REVIEW COMMENTS BELOW INTO A SEPARATE DOCUMENT. With spaces between each comment and your response, provide a specific reply to each reviewer comment, making it clear whether or not you have incorporated the changes as suggested and indicating where the relevant changes are now found in the text. If you elect not to follow reviewers' suggestions or respond to particular criticisms, please provide a response in each case so that the editors might consider your reasoning.

Tobacco Control is published six times per year, and because of the inherent delay in publication with this schedule, we are concerned to avoid overly lengthy periods between notifying authors that a paper needs revision and receipt of the revised version.

If you DO intend to resubmit a revised version, please inform us of the likely submission date.

If we do not hear from you within 4 weeks, we will assume that you do not intend to resubmit and will withdraw your paper. If you need to request an extension of this deadline, please contact us as soon as possible.

To revise your manuscript, log into https://mc.manuscriptcentral.com/tobaccocontrol and enter your Author Center, where you will find your manuscript title listed under "Manuscripts with Decisions." Under "Actions," click on "Create a Revision." Your manuscript number has been appended to denote a revision.

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When submitting your revised manuscript, you will be able to respond to the comments made by the reviewer(s) in the space provided. You can use this space to document any changes you make to the original manuscript. In order to expedite the processing of the revised manuscript, please be as specific as possible in your response to the reviewer(s).

You will receive a proof if your article is accepted, but you will be unable to make substantial changes to your manuscript, please take this opportunity to check the revised submission carefully.

IMPORTANT: Your original files are available to you when you upload your revised manuscript. Please delete any redundant files before completing the submission.

Because we are trying to facilitate timely publication of manuscripts submitted to Tobacco Control, your revised manuscript should be submitted before 04-Oct-2015. Your option to submit a revision expires on that date. If it is not possible for you to submit your revision by this date, we may have to consider your paper as a new submission.

We also ask that in addition to the revised paper you provide a point by point response to the reviewer comments, and upload a marked copy of your paper highlighting the changes you have made - preferably 'tracked changes' if using Microsoft word. Please upload this as a supplemental file and label it 'Marked Copy' (your paper will not be able to be processed without this).

All material submitted is assumed to be submitted exclusively to the journal unless the contrary is stated. Submissions may be returned to the author for amendment if presented in the incorrect format.

Please note that only the article text (from first word of main text to the last word in reference list) will be used to typeset your article.

All other data (known as the metadata), such as article title, author names and addresses, abstract, funding (etc) statements will be taken from the fields you have filled in at submission, so you must ensure that these are up to date and accurate.

I hope you will find the comments useful.

Respectfully,

Dr Sarah Hill PhD MBChB
Senior Lecturer, Global Public Health Unit Social Policy, School of Social & Political Science University of Edinburgh 15a George Square Edinburgh UK EH8 9LD Telephone +44 (0)131 650 3884 s.e.hill@ed.ac.uk, Tobacco Control tobaccocontrol@bmj.com

Reviewer(s)' Comments to Author:

Reviewer: 1

Comments to the Author
The present manuscript shows the results of an ecological study aimed at analyzing the correlation between the implementation of tobacco control policies (measured through the Tobacco Control Scale) and smoking habits, including consumption of cigarettes and other tobacco products, intention to quit smoking and exposure to second-hand smoke, in 27 EU countries. Authors should consider

the following points:

1) Authors identify current smokers with intention to quit smoking through the question: “Have you ever tried to quit smoking?”. However, this question identifies previous quit attempts and not intention to quit. Thus, authors should use the appropriate question to give the prevalence of current smokers with intention to quit (if available in the Eurobarometer survey). Otherwise, authors should change the interpretation of results and conclusions to correctly interpret the correlation between TCS and quit attempts.

2) The description of other variables derived from the Eurobarometer survey is not clear (Methods section).For example:
a. the first question investigates cigarette consumption: “regarding smoking cigarettes, cigars or pipe, which of the following applies to you?”. Which were the possible answers to this question? Was this a single or a multiple choice answer? Cigarette users were defined as ever or current smokers?
b. Regarding the second question, in the methods section authors report that the use of other tobacco products was “differentiated between smokers and non-smokers”, while in table 1 users of other tobacco products appeared to be categorized in smokers and former smokers. Which was the correct categorization?
c. Was the use of water pipe, snus and e-cigarettes investigated only among cigarette smoking or also in never smokers?
These points must be clarified and fixed in order to allow the reader to understand which measures were correlated with the TCS.

3) Besides analyzing the correlation between the use of different tobacco products (and other smoking-related variables) and overall TCS, authors also consider correlations with the 6 specific components of the TCS. However, these findings are not reported in tables or in the results sections. Since the manuscript includes only one table, I suggest author to add a table providing the correlations with each single component of the TCS, describing corresponding main results. This would put in evidence which are the strategies highly correlated with the various tobacco variables, and would also allow authors to show whether the price-component is more or less related to the use of cheaper tobacco products.

4) Authors analyze the correlation between TCS and the use of other tobacco products also among former smokers. However, among former smokers, a huge proportion of individuals likely quitted smoking several years before the implementation of specific control tobacco policies. Therefore, the fact that they smoked hand-rolled cigarettes or cigars or pipe may have been a choice rather than a consequence of, for example, the increase in conventional cigarettes price. Since it is not possible to restrict this analysis to former smokers who quitted smoking after the implementation of a tobacco control measure, I strongly suggest author to delete all the analyses on former smokers from the present paper.

5) In the Discussion section, authors state that “the two years gap of time between the measure of TCS and the Eurobarometer survey allows seeing the effect of the application of the tobacco policies in different countries”. I suggest to delete this from the strengths of the study. Otherwise authors should add to the limitations of their study that their choice did not allow them to detect the effect of measures adopted over the last two years (between 2010 and 2012).

6) Authors should cite in the Introduction or in the Discussion section two similar papers on this issue (Ferketich et al., 2014 Tob Control, PMID: 25335901; Martinez-Sanchez et al., 2010 PLoS One, PMID: 21079729).

7) The English language in the manuscript needs to be revised. A native English speaker with editorial experience should read the manuscript and make appropriate changes.

8) In table 1 the heading of the second column is wrong: please, substitute TCS with rsp.

Reviewer: 2

Comments to the Author
This is a well written manuscript of intermediate interest/priority.

Response to the Tobacco Control reviewer's comments

Tobaccocontrol-2012-050877
Do smoke-free policies in work and public places increase smoking in private venues?

Response to the Reviewers' comments

We thank the editor and the reviewers' comments for the useful comments.

Reviewer #1

This is an important topic and the regional size of the study (Europe) is great. However, I believe the conclusion of the paper is not reflective of what the study measured. As I read the paper, the variable used was strength of tobacco control (tobacco control score) and not passage of smoking bans. In addition, the data on smoking behavior is taken at one time so it is impossible to know if changes in work and public place bans lead to increases in private venues.

We agree with the reviewer that TCS covers more than smoking bans –it is a scale including several components of tobacco control. We had already explained this in the "Tobacco control policies" section of the Methods. Moreover, the TCS also includes the level of implementation of smoke-free bans at work and public places (score between 0 and 22). Then, we focused mainly in this policy because this is the most relevant one to answer the debate raised about whether banning smoking in public places can move tobacco consumption to private settings.

According to this comment we have included the following sentence in the results of the abstract:

> "A similar lack of association was observed between the TCS score of specific bans at work and in public places and smoking rules inside houses and cars."

The objective of our study was not to measure changes in smoking behavior. We aimed to evaluate the correlation between the level of tobacco control (as measured by the TCS) and prevalence of smoking behavior in private venues after the policies were implemented. We also tried to measure any possible correlation between level of smoke-free bans and tobacco consumption in private settings. Consequently, the ecological design of our study allowed us to analyze this correlation.

Instead, the study showed that in those countries with strong tobacco control, non-smoking behaviors extended to private locations. Problem is that in countries with weaker overall tobacco control - did these same benefits not transfer or perhaps was there increasing private exposure in those countries. You still a valuable brief but the overall claim of what the data shows could be sharpened.

Our results showed there is no correlation between TCS, smoke-free bans, and smoking in private venues. If the restriction of smoking in public places would displace tobacco consumption to private venues, as the tobacco industry and the hospitality sector argued, this correlation would have been positive. Moreover, our data also showed a positive correlation, although statistically non significant, between TCS and the prevalence of smoke-free houses.

We have included the following sentence in the discussion to clarify our results:

> "If the hypothesis argued by the tobacco industry and hospitality sector were true this relationship would have been positive."

Reviewer #2

1. Page 2 line 48. Conclusion of abstract. 'and thus is not increasing the prevalence of second-hand smoke exposure...' The data do not tell us anything about the intensity of exposure - it is entirely possible that in those houses and cars where people continue to smoke that they are now smoking more (due to their inability to smoke in public spaces). So while the prevalence is not increasing, those smokers who continue could, possibly be smoking more.

We agree with the reviewer's comment. We deleted this sentence in the conclusion of the abstract.

2. Page 3 Line 32. it would be useful to mention the Akhtar study in the introduction. This study showed no evidence of displacement of smoking activity to homes after the introduction of smoke-free legislation in Scotland in 2006.

We included in the Introduction a sentence on the Akhtar and other studies, providing the relevant reference:

> "To our knowledge, only one study,[9] conducted in US, supports this hypothesis, whilst other studies show no displacement of smoking prevalence to home after the implementation of smoking ban. [2;10;11]"

3. Page 3 line 39. Again in the study objective I would recommend making it clear that it is to look at smoking prevalence in private venues.

We have changed the sentence according to the suggestion of the reviewer.

4. Page 4. Line 41 and 53. 'Tobacco consumption'. The data do not provide information aout consumption (i.e. there is no consideration of volume or frequency of smoking) and so I would recommend calling these two variables 'Tobacco use inside the house/car'.

Done.

5. Page 5. Line 29. Typo '...indicating full implementation...'

Done.

6. Results. I think it would be useful to give a table with data including the TCS scores and public ban scores for each country.

We agree with the reviewer on the utility of such a table. However, we do not have the possibility to include it; given the rules of the journal for brief reports (only one table is allowed). This information, moreover, is available in the TCS report (references 12 and 13, which can be accessed on the internet).

7. Page 6. Line 53. The first sentence of the discussion again makes the mistake of saying that there is no relationship between smoke-free laws and exposure to SHS in private venues. What it should say is prevalence - we have no data on intensity of exposure among those who continue to be exposed.

We changed it.

8. Page 7/8. the discussion acknowledges the weakness of an ecological study. It may be useful here to explicitly acknowledge that at an individual level those who continue to be exposed may be exposed more often.

We agree with the reviewer's comment and we have included this limitation in the discussion section as follows:

> "We have no information about the intensity of SHS exposure[19] at the individual level in the house where smoking continues to be allowed."

9. Page 8. Line 13. Wrong use of the word 'exposure' again: suggest correct with 'the prevalence of exposure'

Done.

10. The authors may wish to consider that this evidence may suggest that TC policies have little effect on private space prevalence of exposure and so have little effect on the de-normalisation of smoking. Some consideration of why Finland has 95% smoke-free homes (and yet only a 58 point TCS score) may be useful.

We agree with the reviewer's comment. It is true that there is a sort of paradox with the Finnish data: high prevalence of smoke-free homes (and cars) whilst a "relatively" low TCS score (Finland ranks sixth among the 27 EU states). Perhaps there are other non-controlled factors, in addition to our primary focus – the TCS. Actually, Finland stands in the 4th stage (final stage) of the Lopez's tobacco epidemic model, and has a relatively low smoking prevalence (and the country). This is also related to the prevalence of smoke-free homes. As suggested by the reviewer we have included a comment on this point:

> "Another potential limitation derives of the lack of information about the stage of the tobacco epidemic among different countries[21]. Countries at late stages have low prevalence of smokers and hence the likelihood of smoke-free homes is higher, even in the absence of strong

tobacco control policies. Data from Finland and Sweden illustrate this possible paradox."

Reviewer: 3

• In terms of background information, it would be very useful to document any changes in country-level policies between 2007 and 2009 (your data collection points).

We compared the TCS of 2007 and 2010 to document potential changes in the policy on smoking restriction in our period of data-collection. We did not find substantial changes (average of +2 points in the score) during this period. As suggested by the reviewer, we included a sentence in the discussion section to address this topic:

> "Moreover, the score of the policy on smoking bans in public and work places of the TCS in the period of our study, between 2007 and 2010, did not show appreciable changes: the score increased in 14 countries, did not change in 9 countries, and decreased in 5 countries. [22]"

• I would suggest that public place bans do not just protect non-smokers from SHS but also smokers.

We agree with the reviewer's comment as explained in the second sentence in the first paragraph of the introduction section. Moreover, we specified the protection of SHS among smokers as follows:

> "The implementation of comprehensive smoke-free policies decreases SHS exposure and associated health hazards for non-smokers and smokers as well"

• You mention "exposure" in both your introduction and discussion section and suggest that your findings can inform us about exposure to SHS, however I do not believe that you can, at the end of the day, the questions from the Eurobarometer survey do not address exposure to SHS but just places where smoking is permitted. I might smoke only in the living room but if that is where everyone is sitting then they will be exposured more to SHS than me smoking only in the kitchen and bedroom that are not used as much. Thus you cannot claim in any way that you are contributing to understand the influence of policy on SHS exposure. You can only see if there is or isn't an association between tobacco control policy and extent to which smoking is restricted in shared private places such as homes and cars. This is less of interest to researchers in the field.

We agree with the reviewer's comment, as also pointed out by reviewer #2 (see comment #3). We have changed "exposure to SHS" by "prevalence of smoking" in the whole manuscript. Moreover, as the example cited by the reviewer illustrates, we have no information about the intensity of exposure from the Eurobarometer (see also comment #8, reviewer #2).

• It makes less sense to me to look at the overall tobacco control score, you don't make a clear case in your introduction, why you would expect total amount of tobacco control to influence where smoking is permitted. I think that these two variables are so distal and it would be unlikely to find any effect even if a case was made.

All the initiatives for tobacco control, particularly smoke-free bans, have generated intense debate in the media among different actors according with their own interests (i.e.: the tobacco industry and hospitality representatives argued that this policy can move tobacco consumption from public to private places). Countries with high level of tobacco control have banned tobacco advertising and launched more frequently media campaigns (TV, radio, newspapers, etc.) about the adverse effects of exposure to SHS on non-smokers health. This information could partially explain the increased support to smoke-free bans and denormalisation of smoking (Fong et al. Tob Control 2006; Fichtenberg et al. BMJ. 2002; Martinez-Sanchez et al. PLoS ONE. 2010; Willemsen et al. BMC Public Health. 2012). The increased support to smoking bans and the denormalisation of tobacco consumption could influence in the voluntary extension of smoke-free regulation to private venues.

We have included the following sentence in the introduction section:

> "Moreover, the increase of the overall tobacco control measures may improve the support to smoking bans in public venues and to the denormalisation of tobacco consumption[4;5;7;8] ; this could help the adoption of voluntary smoke-free homes and cars."

• Finally in terms of the prior results mentioned in your discussion, I would not say that your results are consistent as you didn't find any effects and furthermore the studies discussed focus on more specific relationships and thus it is hard to compare your research with the prior research that you discuss.

According to the reviewer comment, we have modified the sentence:

> "<u>The results from this ecological analysis are in the line</u> with those of other studies carried out with data at the individual level before and after national smoke-free bans at workplaces and in public places."

Letter of acceptance of Tobacco Control journal

-----Mensaje original-----
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CC: clidon@uic.es; jcmartin@uic.es; patrickuic@uic.es; jan.graffelman@upc.edu; jmmartinez@iconcologia.net
Asunto: Tobacco Control - Decision on Manuscript ID tobaccocontrol-2015-052482.R1

06-Jan-2016

Dear Dr. Martínez-Sánchez:

Manuscript ID tobaccocontrol-2015-052482.R1 entitled "Correlation between tobacco control policies and consumption of rolling tobacco, electronic cigarette users, and intent to quit conventional tobacco in Europe" which you submitted to Tobacco Control, has been reviewed.

After considering your manuscript, we would be pleased to accept it for publication, providing you attend to the following minor changes:

1. The title of the paper is slightly confusing (and doesn't clearly map onto the study aim). Suggest revising this to: 'Correlation between tobacco control policies, consumption of non-conventional tobacco and nicotine products, and intention to quit conventional tobacco in Europe' OR 'Correlation between tobacco control policies, consumption of rolled tobacco and e-cigarettes, and intention to quit conventional tobacco in Europe'
2. The abstract and text refer to use of non-conventional tobacco products among 'former smokers' – but these aren't former smokers if they are still using smoked tobacco. Suggest replacing 'former smokers' with 'former cigarette smokers' in all relevant places.
3. The inclusion of the word 'previous' in your stated objective is somewhat confusing (presumably you were aiming to examine the correlation of TCS with actual intention to quit, though of course you're limited to the specific measure included in the Eurobarometer survey – ie intention to quit in the last 12 months). I suggest you remove the word 'previous' from this sentence.

To revise your manuscript, log into https://mc.manuscriptcentral.com/tobaccocontrol and enter your Author Center, where you will find your manuscript title listed under "Manuscripts with Decisions." Under "Actions," click on "Create a Revision." Your manuscript number has been appended to denote a revision.

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I hope you will find the comments useful.

Respectfully,

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