

Evaluation of tobacco control policy implementation in European and Latin-American countries

Ariadna Feliu Josa

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Evaluation of tobacco control policy implementation in European and Latin-American countries

Ariadna Feliu Josa Doctoral dissertation 2020-2021

Evaluation of tobacco control policy implementation in European and Latin-American countries

Doctoral thesis presented by **ARIADNA FELIU JOSA**

To obtain the PhD degree under the direction of

Prof. Esteve Fernández Muñoz Dr. Cristina Martínez Martínez

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Amb la present, els doctors **Esteve Fernández Muñoz** i **Cristina Martínez Martínez**, directors de la tesis de la doctoranda **Ariadna Feliu Josa** donen el seu vistiplau a la versió definitiva de la tesis doctoral *Evaluation of tobacco control policy implementation in European and Latin American countries* i n'autoritzen el dipòsit i la defensa sempre i que la Comissió de Doctorat així ho aprovi.

I, perquè consti i tingui els efectes que corresponguin, signen la present.

Ariadna Feliu Josa Doctoranda

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Thesis presentation

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Thesis presentation

This doctoral thesis is the result of the three-year research I have conducted at the Institut Català d'Oncologia, that is a WHO Collaborating Centre for Tobacco Control.

This thesis is a compilation of five manuscripts, three of them have been published in high-impact peer-review international journals and the other two are currently under review. All these publications are directed to evaluate the impact of tobacco control policy implementation in European and Latin American countries. Especially, by monitoring country-level tobacco control policy implementation, understanding the socioeconomic factors associated to countries' implementation of these policies, and assessing the effect that these policies have had on several tobaccorelated indicators.

This PhD thesis has been written in English and structured into the following sections: introduction, justification and implications for public health, hypothesis and objectives, methods, results, discussion, conclusions, and bibliographic references. The annexes include the approval of the Ethical Committee from Hospital Universitari de Bellvitge, the supplementary tables of the papers, other publications and websites launched related to this thesis, and the *curriculum vitae* of the PhD candidate.

List of abreviations

DALY: Disability-Adjusted Life Year

EC: European Commission

EU: European Union

FCTC: Framework Convention on Tobacco Control

GATS: Global Adult Tobacco Survey

GBD: Global Burden of Disease

GDP: Gross-Domestic Product

GYTS: Global Youth Tobacco Survey

JATC: Joint Action for Tobacco Control

LA: Latin America

MS: Member States

NCD: Non-Communicable Disease

PAHO: Pan-American Health Organization

SDG: Sustainable Development Goals

SES: Socioeconomic status

SHS: Second-hand smoke

TAPS: Tobacco Advertising Promotion and Sponsorship

TCS: Tobacco Control Scale

TPD: Tobacco Products Directive

UK: United Kingdom

WHO: World Health Organization

YLL: Years of Life Lost

Abstract

Abstract (in English)

Introduction. Smoking is one of the major public health problems of our times, killing eight-million people a year from direct tobacco-related diseases. Active smoking has been associated with an increased risk of lung cancer and several other cancers, cardiovascular diseases, including ischaemic heart disease, bronchitis and emphysema, and ante- and perinatal mortality. Non-smokers exposed to second-hand smoke (SHS) are also at an increased risk for developing lung cancer and ischemic heart disease.

Many efforts have been made globally to prevent and control tobacco use. Actions, however, have been accelerated by the WHO Framework Convention on Tobacco Control (FCTC) and the MPOWER package, which includes six cost-effective policies to fight the tobacco epidemic. Effective tobacco control policies denormalise smoking, result in a decrease of smoking prevalence and, in a reduction of tobacco-attributable morbidity and mortality. However, adoption of tobacco control policies and their implementation process has varied widely across countries. Hence, monitoring tobacco control policies, describing socio-political and economical drivers of their implementation and evaluating policies' effectiveness and impact on tobacco-related indicators is key to continue to reduce the tobacco epidemic and move forward a tobacco-free world.

Objectives. The main aim of this PhD thesis is to evaluate the impact of tobacco control policy implementation in Europe and Latin America (LA). The specific objectives are: **a**) to assess the use of the Tobacco Control Scale (TCS) as a research tool through a literature review; **b**) to evaluate the association between country-level implementation of tobacco control policies and smoking prevalence and quit ratios in the European Union (EU) over time; **c**) to assess the association between country-level socioeconomic factors (SES) and tobacco control policy implementation in Europe; **d**) to evaluate whether the hardening hypothesis can be confirmed at the in the EU and to analyse the determinants of hardcore and light smoking with a multilevel approach; and, finally, **e**) to monitor tobacco control policies in LA countries by developing and adapting the TCS to the region context.

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Methods. This PhD thesis by articles consists of four studies. All studies have an observational design with either ecological (with countries as the unit of analysis) or multilevel (with individual data as first-level unit and country-related data as second-level unit of aggregated information) data. Additionally, a literature review on the topic is included.

Results. Our findings suggest that the TCS is a commonly used tool to measure country-level tobacco control policy implementation in research, and to explain potential variation of tobacco-related outcomes (i.e., smoking or exposure to SHS) in association with tobacco control policies. Indeed, our results show that higher TCS score(s) in 2007 are associated with both lower smoking prevalence ($r_{r_{e}} = -0.444$; p=0.02) and higher quit ratios (r_{sp} =0.373; p=0.06) in 2014. Also, we observed that higher TCS score(s) in 2007 were associated with higher relative decreases in smoking prevalence (r_{cn} =-0.415; p=0.03) between 2006-2014 in EU Member States (MS). Moreover, our results suggest a softening of the population of smokers in this region, since the hardcore smoking prevalence among adult smokers has increased by 0.55 (0.14–0.96) per each additional percentage point in the overall smoking prevalence. The odds of being a hardcore smoker increased over time and were higher in middle-aged men, people with financial difficulties and citizens of countries with lower country-levels of tobacco control policy implementation. However, no associations were found between the selected direct indicators of countries' SES factors and their implementation level of tobacco control policies according to TCS scores, except for public spending on tobacco control. Crosscountry differences in tobacco control efforts in Europe may partly be explained by their male-to-female ratio (used as a proxy of the stage of the epidemic at which countries are) and a geographical component as Western countries scored 15.69 points (pts) less on average in the total TCS than Northern countries (p=0.01).

Finally, Panama with 70 pts and Uruguay with 68 pts are the countries that exhibit higher tobacco control policies according to the TCS-LA; while Guatemala (32 pts), Bolivia (30 pts) and Dominican Republic (29 pts) have implemented a lower number of tobacco control policies. Eight countries have implemented at least half of the tobacco control policies measured by the TCS-LA (with a score of 50 pts or more).

Conclusion. Our findings show that tobacco control policies in Europe have had a positive effect on reducing the smoking prevalence and increasing the quit ratios, which have led to a softening of the population smokers. However, our results also suggest that tobacco control policies could have a differential impact on countries at different stages of the tobacco epidemic and on most vulnerable groups, increasing health inequalities. Hence, further research is needed to better understand the long-term effects of tobacco control policies on tobacco-related outcomes.

Abstract (in Spanish)

Introducción. El tabaco es uno de los mayores problemas de salud pública de nuestros tiempos, que mata a ocho millones de personas cada año por enfermedades directas relacionadas con su consumo. El consumo activo de tabaco se ha asociado con un mayor riesgo de padecer cáncer de pulmón y otros tipos de cáncer, enfermedades cardiovasculares, incluidas las cardiopatías isquémicas, la bronquitis y el enfisema, y la mortalidad ante- y perinatal. Las personas no fumadoras expuestas al humo ambiental del tabaco (HAT) también tienen mayor riesgo de cáncer de pulmón y cardiopatía isquémica.

En los últimos años, se han realizado muchos esfuerzos a nivel mundial para prevenir y controlar el consumo de tabaco. Sin embargo, las medidas se han acelerado gracias al Convenio Marco de la OMS para el Control del Tabaco (CMCT) y al conjunto de medidas MPOWER, que incluye seis medidas costo-efectivas para luchar contra la epidemia del tabaco. Las políticas de control del tabaco eficaces desnormalizan su consumo y en consecuencia, producen una disminución de la prevalencia de consumo y una reducción de la morbi-mortalidad atribuibles al tabaco. No obstante, la adopción de políticas de control del tabaco y su proceso de aplicación varía mucho entre países. Por tanto, la monitorización de estas políticas, la descripción de los factores sociopolíticos y económicos que impulsan su aplicación y la evaluación de su eficacia y de su impacto en los indicadores relacionados con el consumo de tabaco son fundamentales para seguir reduciendo la epidemia del tabaco y avanzar hacia un mundo sin tabaco.

Objetivos. La finalidad de esta tesis es evaluar el impacto de la implementación de las políticas de control del tabaco en Europa y América Latina. Los objetivos específicos son: **a**) evaluar el uso de la Tobacco Control Scale (TCS) como herramienta de investigación mediante una revisión bibliográfica; **b**) evaluar la asociación entre la implementación de políticas de control de tabaco a nivel nacional y la prevalencia de consumo de tabaco y la razón de abandono en la Unión Europea (UE) a lo largo del tiempo; **c**) evaluar la asociación entre los factores socioeconómicos (SES) a nivel de país y la implementación de políticas de control de tabaco en Europa; **d**) evaluar si la hipótesis del *hardening* puede confirmarse en la UE y analizar los determinantes de

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las personas fumadoras recalcitrantes (*hardcore smokers*) y sociales (*light smokers*) con un enfoque multinivel; y, por último, **e**) monitorizar las políticas de control del tabaco en los países de América Latina mediante la elaboración y adaptación de la TCS al contexto de la región.

Métodos. Esta tesis doctoral por compilación de artículos consta de cuatro estudios. Todos los estudios tienen un diseño observacional con datos ecológicos (con los países como unidad de análisis) o multinivel (con los datos individuales como unidad de primer nivel y los datos relativos a los países como unidad de segundo nivel de información agregada). Además, se incluye una revisión de la literatura sobre el tema.

Resultados. Los resultados sugieren que la TCS es una herramienta de uso común para medir el nivel de implementación de las políticas de control del tabaco a nivel nacional en el ámbito de la investigación y para explicar la variación potencial de los indicadores relacionados con el tabaco (p. ej. la prevalencia de tabaco o la exposición al HAT) como consecuencia de la aprobación de políticas de control del tabaco. De hecho, nuestros resultados muestran que la(s) puntuación(es) más alta(s) de la TCS en 2007 está(n) asociada(s) tanto con una reducción de la prevalencia de consumo de tabaco (r_{sn}=-0,444; p=0,02) como con un incremento de la razón de abandono del tabaco (r_==0,373; p=0,06) en 2014. Además, las puntuaciones altas en la TCS se asocian con una mayor disminución relativa en la prevalencia del tabaco (r_{sn}=-0,415; p=0,03) entre 2006 y 2014 en los Estados Miembros de la UE. Además, nuestros resultados sugieren un softening, es decir, una mitigación de la adicción de la población de fumadores en UE, puesto que la prevalencia de fumadores hardcore entre los fumadores adultos aumentó en 0,55 (0,14-0,96) por cada punto porcentual adicional en la prevalencia general del tabaco. Las probabilidades de ser un fumador hardcore aumentan con el tiempo y son mayores en los hombres de mediana edad, las personas con dificultades financieras y los ciudadanos de países con un nivel más bajo de implementación de políticas de control del tabaco. No obstante, no se encontraron asociaciones entre los indicadores directos de los factores SES de los países y su nivel de implementación de políticas de control del tabaco en función de su puntuación en la TCS, excepto para el gasto público en control del tabaco. Las diferencias entre países en cuanto a los esfuerzos de control del tabaco en Europa pueden explicarse en parte por la razón de prevalencia hombre/mujer (utilizada como indicador de la etapa de la epidemia de tabaco en la que se encuentran los países) y un componente geográfico, ya que los países de Europa Occidental obtuvieron una puntuación media de 15,69 puntos menos en la TCS total que los países del Norte de Europa (p=0,01).

Finalmente, en LA, Panamá con 70 puntos y Uruguay con 68 puntos son los países que presentan mayores políticas de control de tabaco según la TCS-LA; mientras que Guatemala (32 puntos), Bolivia (30 puntos) y República Dominicana (29 puntos) son los países que han implementado un número menor de políticas de control de tabaco. Ocho países han implementado como mínimo la mitad de las políticas de control del tabaco medidas por el TCS-LA (con una puntuación de 50 puntos o más).

Conclusión. Los resultados muestran que las políticas de control del tabaco en Europa han tenido un efecto positivo en la reducción de la prevalencia de consumo del tabaco y el aumento de la razón de abandono, lo que ha dado lugar a un softening de la población de fumadores. Sin embargo, nuestros resultados también sugieren que las políticas de control del tabaco podrían tener un impacto diferencial en los países en función de las diferentes etapas de la epidemia de tabaco en la que se encuentran y en los grupos más vulnerables, aumentando las desigualdades en materia de salud. Por consiguiente, es necesario seguir investigando para comprender mejor los efectos a largo plazo de las políticas de control del tabaco en los resultados relacionados con el tabaco.

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Abstract (in Catalan)

Introducció. El tabac és un dels majors problemes de salut pública dels nostres temps, que mata a vuit milions de persones a l'any per malalties directament relacionades amb el seu consum. El tabaquisme actiu s'ha associat amb un major risc de patir càncer de pulmó i varis altres tipus de càncer, malalties cardiovasculars, incloses les cardiopaties isquèmiques, la bronquitis i l'emfisema, i la mortalitat antei perinatal. Les persones no fumadores exposades al fum ambiental del tabac (FAT) també tenen major risc de càncer de pulmó i cardiopatia isquèmica.

En els últims anys, s'han realitzat molts esforços a nivell mundial per prevenir i controlar el consum de tabac. No obstant això, les mesures s'han accelerat gràcies al Conveni Marc de la OMS de Control del Tabac (CMCT) i al conjunt de mesures MPOWER, que inclou sis mesures cost-efectives per a lluitar contra l'epidèmia del tabac. Les polítiques eficaces de control del tabac desnormalitzen el consum de tabac, cosa que comporta una disminució de la prevalença de consum i, en conseqüència, produeixen una reducció de la morbi-mortalitat atribuïbles al consum de tabac. No obstant això, l'adopció de polítiques de control del tabac i el seu procés d'implementació varia molt entre els països. Per tant, el monitoratge d'aquestes polítiques, la descripció dels factors sociopolítics i econòmics que impulsen la seva implementació i l'avaluació de l'eficàcia de les polítiques i el seu impacte en els indicadors relacionats amb el consum de tabac són fonamentals per a continuar reduint l'epidèmia del tabac i avançar cap a un món sense tabac.

Objectius. L'objectiu d'aquesta tesis és avaluar l'impacte de la implementació de les polítiques de control del tabac a Europa i Amèrica Llatina (LA). Els objectius específics són: **a**) avaluar l'ús de la Tobacco Control Scale (TCS) com a eina de recerca mitjançant una revisió bibliogràfica; **b**) avaluar l'associació entre la implementació de polítiques de control de tabac a nivell nacional i la prevalença de consum de tabac i la raó d'abandó a la Unió Europea (UE) al llarg del temps; **c**) avaluar l'associació entre els factors socioeconòmics (SES) a nivell de país i la implementació de polítiques de control de tabac a Europa; **d**) avaluar si la hipòtesi del *hardening* pot confirmar-se a la UE i analitzar els determinants de les persones fumadores recalcitrants (*hardcore smokers*) i socials (*light smokers*) amb un enfocament multinivell; i, finalment,

e) monitoritzar les polítiques de control del tabac als països de LA mitjançant l'elaboració i adaptació de la TCS al context de la regió.

Mètodes. Aquesta tesi doctoral, que es presenta per compilació d'articles, consta de quatre estudis. Tots els estudis tenen un disseny observacional amb dades ecològiques (amb els països com a unitat d'anàlisi) o multinivell (amb les dades individuals com a unitat de primer nivell i les dades relatives als països com a unitat de segon nivell d'informació agregada). A més, s'inclou una revisió de la literatura sobre el tema.

Resultats. Els resultats suggereixen que la TCS és una eina d'ús comú per a mesurar la implementació de polítiques de control del tabac a nivell nacional en recerca, i per a explicar la variació potencial dels indicadors relacionats amb el tabac (p. ex. la prevalenca de consum del tabac o l'exposició al FAT) en associació amb les polítiques de control del tabac. De fet, els nostres resultats mostren que la(es) puntuació(ns) més alta(es) de la TCS l'any 2007 està(n) associada(es) tant amb una menor prevalença de fumadors ($r_{r_{e}}$ =-0,444; p=0,02) com amb majors raons d'abandó (r_{sn}=0,373; p=0,06) el 2014. I, també, amb majors disminucions relatives en la prevalença de fumadors (r_{sn}=-0,415; p=0,03) entre 2006 i 2014 en els Estats Membres de la UE. A més a més, els nostres resultats suggereixen un softening de la població de fumadors a Europa, donat que la prevalença de tabaquisme hardcore entre els fumadors adults augmenta en un 0,55 (0,14-0,96) per cada punt percentual addicional en la prevalença general de fumadors. Les probabilitats de ser un fumador hardcore augmenten amb el temps i son majors en els homes de mitjana edat, les persones amb dificultats financeres i els ciutadans de països amb nivells més baixos d'implementació de polítiques de control del tabac. No obstant això, no es troben associacions entre els indicadors directes dels factors SES dels països i el seu nivell d'implementació de polítiques de control del tabac en funció de la seva puntuació a la TCS, excepte per a la despesa pública en control del tabac. Les diferències entre països quant als esforços de control del tabac a Europa poden explicar-se en part per la raó de prevalença home/dona (utilitzada com un indicador de l'etapa de l'epidèmia en la qual es troben els països) i un component geogràfic, ja que els països de l'Europa Occidental obtenen una puntuació mitjana de 15,69 punts menys en la TCS total que els països del Nord d'Europa (p=0,01).

Finalment, Panamà (70 punts) i l'Uruguai (68 punts) són els països que exhibeixen majors polítiques de control de tabac segons la TCS-LA; mentre que Guatemala (32 punts), Bolívia (30 punts) i República Dominicana (29 punts) han implementat un nombre menor de polítiques de control de tabac. Vuit països han implementat com a mínim la meitat de les polítiques de control del tabac previstes a la TCS-LA (amb una puntuació de 50 punts o més).

Conclusió. Els resultats mostren que les polítiques de control del tabac a Europa han tingut un efecte positiu en la reducció de la prevalença de fumadors i l'augment de la raó de cessació, la qual cosa ha donat lloc a un *softening* de la població de fumadors. No obstant això, els nostres resultats també suggereixen que les polítiques de control del tabac podrien tenir un impacte diferencial d'acord amb

TOBACCO CONTROL IN EUROPE AND LATIN AMERICA

ABSTRACT

les diferents etapes de l'epidèmia de tabac en que es troben els països i en els grups més vulnerables, augmentant les desigualtats en salut. Per consegüent, és necessari continuar investigant per a comprendre millor els efectes a llarg termini de les polítiques de control del tabac en els resultats relacionats amb el tabac.

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Introduction

1. Tobacco consumption

1.1. Smoking worldwide

Tobacco use is one of the major public health problems of our times. There are over 1.4 billion tobacco users aged 15 years and above worldwide -1.07 billion smokers and 367 million smokeless tobacco users[1] –and, among them, up to half will die from tobacco-related diseases[2]. According to the Global Burden of Disease (GBD) study, the global age-standardized prevalence of current smoking among individuals aged \geq 15 years in 2017 was 20.1%. Smoking prevalence among males is on average five times higher than among females in all age groups (33.5% vs. 6.7%) (Figure 1)[3].

In 2017, around eight million people died from direct tobacco-related disease[4] as tobacco is a risk factor for six of the eight leading causes of death[2]. Smoking is the second leading risk factor globally and is responsible for 7.3% of total Disability-Adjusted Life Years (DALYs)[5]. Tobacco use can also be deadly for non-smokers since exposure to second-hand smoke (SHS) causes significant morbidity and mortality[6], causing an additional 1.2 million deaths annually worldwide to those caused from direct tobacco use, representing 2.2% of the total deaths with the majority of the burden concentrated in women and children[5].

The World Health Organization (WHO) estimates that mortality attributed specifically to tobacco is 12%[7]. The health consequences of active smoking on smokers and non-smokers are well known since smoking has been associated with an increased risk of not only several different cancers, including lung, bladder and a dozen of other cancers, but also cardiovascular diseases, ischaemic heart disease, bronchitis and emphysema, and increased antenatal and perinatal mortality[8].

The economic cost of smoking globally amounts to nearly 2 trillion dollars (in 2016 Power Purchase Parity) each year, equivalent to almost 2% of the world's total economic output. Most of the total economic cost of smoking is the lost human capital and productivity that results from tobacco-attributable morbidity and mortality and the healthcare-related expenses of treating smoking-attributable diseases[9].



Over the past decade, countries have made substantial progress in establishing evidence-based and cost-effective tobacco control measures contributing to decrease smoking rates from 22.5% to 19.2% worldwide, showing a relative reduction of 15% over 10 years (2007–2017)[1]. Tobacco smoking prevalence within a population depends on initiation rates, smoking cessation, and smoking-related mortality[10]. However, not all regions are trending in the same direction because countries are at different stages of the tobacco epidemic and have implemented different tobacco control measures[4].

Lopez *et al.* (1994) suggested a four-stage model to describe the effects on mortality of the cigarette epidemic in economically developed countries, updated by Thun *et al.* in 2012 [11,12]. According to this model, countries in early stages of the epidemic experiment increases in their smoking rates from a low level whilst smoking attributable-deaths increase steadily, those at stages 2–3 are beyond their peak rate and their prevalence is starting to decline whilst smoking attributable-mortality starts to increase, and those at a later stage of the epidemic are entering to a stage of low smoking and initiation rates after experiencing declines for some years; however, tobacco consumption attributable deaths reach their highest level (Figure 2)[4,12].

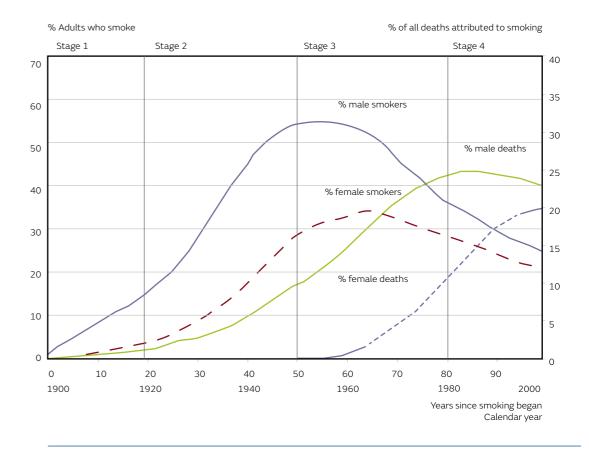


Figure 2. The four stages of the tobacco epidemic based on the comparative levels of smoking prevalence and smoking-attributed mortality in men and women.

Adapted from Thun M, Peto R, Boreham J, et al. Stages of the cigarette epidemic on entering its second century. *Tob Control.* 2012;21:96-101[12].

INTRODUCTION

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Age-standardized prevalenc [0 - 10%[[10 - 20%[[20 - 30%[[30 - 40 %[[40 - 50%[≥ 50%] No data

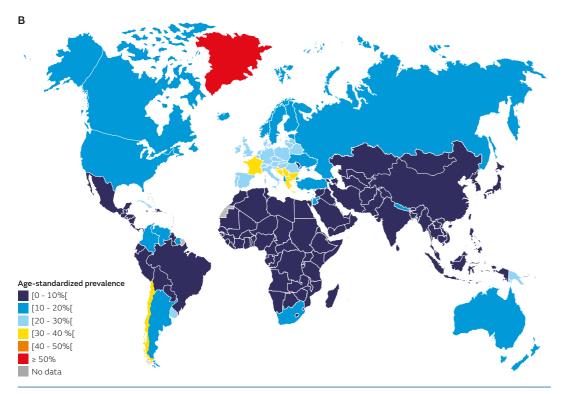


Figure 1. Prevalence of current smoking for men (A) and women (B) aged 15 and older (age-standardized) in 2017.

Adapted from Flor LS, Reitsma MB, Gupta V, Ng M, Gakidou E. The effects of tobacco control policies on global smoking prevalence. *Nat Med.* 2021.[3].

However, it should be noted that this model was designed for cigarette use only as at the time of its launching (1994-2012) new tobacco products such as e-cigarettes or heated tobacco were not yet on the market. Thereby, this model has some limitations to fully explain the current global tobacco epidemic.

Trends in tobacco initiation among youth and young adults have also decreased over time[13]. However, according to the WHO, still 12.1% of adolescents aged 13-17 years report using one or more types of tobacco product (GYTS, 2008-2018)[4]. Early tobacco exposure is particularly damaging, as individuals are more vulnerable to tobacco effects in growth stages than when organ systems are fully developed since young adolescents are particularly susceptible to nicotine addiction. Emerging evidence suggests that tobacco use at an early age may have an impact on health across generations[10] as it predicts greater likelihood of future daily and heavy smoking, lower likelihood of quitting, and higher risk of lung cancer[13].

Tobacco control efforts have contributed not only to a reduction in smoking initiation among youth, but also to a decrease in tobacco products' demand and an increase in the intention to quit and quit attempts of tobacco users[1]. According to the Global Adults Tobacco Survey (GATS) from 2008 to 2013, including 22 countries (mostly low- and middle-income countries), reports that over 60% of current smokers are interested in quitting and 40% had attempted to quit in the last 12 months[14]. Quitting smoking results in significant improvements in health and life expectancy, reducing the health care costs associated with long-term tobacco-related illness and increasing the years of economically and socially productive lives, benefiting economies[1]. According to Pirie *et al.*, quitting smoking before the age 40 years (and preferably well before) avoids more than 90% of the excess mortality caused by continuing smoking[15]. Therefore, the quit ratio (the percentage of former smokers among ever smokers) is an important indicator to measure the impact of tobacco control policies and programs[14].

1.2. Smoking in Europe

1.2.1. WHO European Region

The WHO European Region has the highest prevalence of tobacco smoking among adults over 15 years old 28% (31% males, 22% females; year 2017) and some of the highest prevalence of tobacco use by adolescents[16]. The average rate of current tobacco use in the WHO European region shows a relatively slow rate of decline, currently tracking towards an 18% relative reduction between 2010 and 2025[4].

The WHO European Region has one of the highest proportions of deaths attributable to tobacco use. According to the GBD, over 1.4 million people died from direct tobacco smoking and 162,554 from exposure to SHS in 2017 alone. Tobacco-related non-communicable diseases (NCDs) attributed mortality in Europe is 17.7% (25.8% in males, 9.4% in females), accounting for 14.6% of total DALYs[5].

Hence, almost one in every five premature deaths caused by NCDs could be avoided eliminating tobacco use from the Region[16].

Tobacco-smoking prevalence is decreasing overall among adults. Estimated prevalence decreased in European countries from 34.2% to 27.4% between 2000 and 2015, with a median decline of about 19.9% in that period[4]. The pattern of decrease; however, is different between sexes as prevalence among women is expected to remain high and even increase in a few countries in contrast with estimated-male trends[16].

Decreasing trends in some countries over time and across all ages are encouraging, but are not enough to reach the overall target of a 30% reduction of tobacco-use prevalence among the adult population in the WHO European Region[16].

1.2.2. European Union

Tobacco consumption is responsible for 700,000 deaths each year in the European Union (EU) that are responsible for 14.3% of total DALYs[5,17]. Despite considerable progress made in recent years, the number of current smokers in the EU is still high 26.5% of the overall population aged 15 years and older. From them, around 50% will die prematurely, resulting in the loss of an average of 14 years of life that account for 18.9% of total Years of Life Lost (YLL) (23.2% in male, 13.2% in female). However, there are important differences in consumption across the EU with persistently higher rates of smoking in Southern Europe (Figure 3)[17].

Former smokers represent 20% of the overall adult population over 15 years old in the EU and are most prevalent in the Member States (MS) of Northern Europe, i.e. in the Netherlands (32%) and Denmark (33%)[17]. Over the last decade, data from the Eurobarometer surveys (2006-2017) indicate that the quit ratios have increased by a 21.1% (20.4% male, 16.0% female) in the EU27.

1.3. Smoking in Latin America

1.3.1. WHO Region of the Americas

Tobacco consumption in the Americas is also high, despite falling from 22.1% to 17.4% (4.7 percentage points) between 2007 and 2015, being close to the world average. In terms of the distribution of prevalence by sex, however, the Americas follows Europe as the region with the second-largest prevalence of female smokers. Overall, the highest prevalence is in Chile (38.7%), while Ecuador (7.4%) and Panama (6.5%) have the lowest prevalence rates (Figure 4)[18].

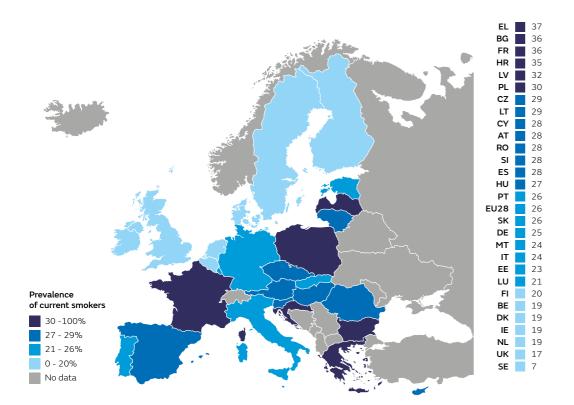
According to the WHO, the average prevalence of current tobacco use in the Americas region is expected to fall from around 23% in 2010 to 15% in 2025, assuming tobacco control efforts in the countries of the Region are maintained at current levels[4].

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In the Americas, although there is a downward trend in smoking prevalence, tobacco is responsible for nearly 1 million deaths per year that are responsible for 8.9% of total DALYs[5,18]. According to the GBD, all causes attributed mortality to tobacco use, including both tobacco smoking and exposure to SHS, is 13.7% (15.8% in males, 11.4% in female) in the Americas[5].



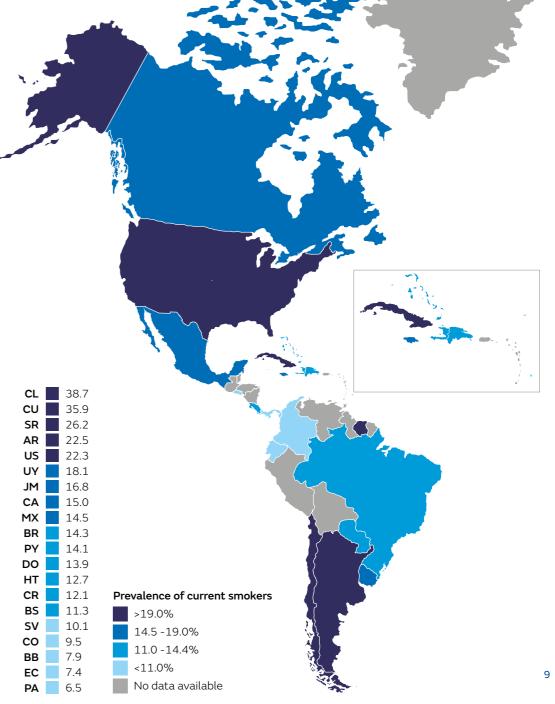


Figure 3. Prevalence of adult (≥15 years) current smokers in the 28 EU Member States in 2017. Austria (AT), Belgium (BE), Bulgaria (BG), Croatia (HR), Cyprus (CY), Czechia (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Ireland (IE), Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Malta (MT), Netherlands (NL), Poland (PO), Portugal (PT), Romania (RO), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE), United Kingdom (UK).

Adapted from European Commission. Special Eurobarometer 458. Attitudes of Europeans towards tobacco and electronic cigarettes. European Commission: Brussels, 2018[17].

Figure 4. Prevalence of adult (≥15 years) current smokers in the Americas in 2015. Argentina (AR), Bahamas (BS), Barbados (BB), Brazil (BR), Canada (CA), Chile (CL), Colombia (CO), Costa Rica (CR), Cuba (CU), Dominican Rep. (DO), Ecuador (EC), El Salvador (SV), Haiti (HT), Jamaica (JM), Mexico (MX), Panama (PA), Paraguay (PY), Suriname (SR), United States (US), Uruguay (UY).

Adapted from the Pan American Health Organization. Report on Tobacco Control in the Region of the Americas, 2018. Washington, DC: PAHO, 2019[18].

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In Latin America and the Caribbean, the prevalence of tobacco use among adults 15 years and older is 15.3% (21.2% male, 9.4% female; year 2016). Tobacco consumption decreased over the period 2013-2016 in 12.4 percentage points, showing a similar trend in both male and females[19].

According to the GBD, more than 390,000 people die every year in this region as a direct consequence of tobacco smoking, which represents almost 9 million years of life lost to avoidable premature death or disability[5]. Moreover, each year tobacco use takes up almost US\$ 34 billion of the health budgets of the countries of Latin America. This represents a total loss of 0.7% of the Gross Domestic Product (GDP) and 8.3% of health expenditures[20].

Tobacco control is key to achieve the global goal of reducing prevalence of current tobacco use in persons aged over 15 years old in a 30% by 2020, but also reducing premature mortality from non-communicable diseases in a 25% by 2025, agreed upon by the World Health Assembly in 2013[21].

2. The WHO Framework Convention on Tobacco Control

Effective tobacco control policies denormalise smoking, result in a decrease of smoking prevalence[22]; and, consequently, in a reduction of tobacco-attributable morbidity and mortality[23].

Over the last decades, many efforts have been made to prevent and control tobacco use, culminating in the WHO Framework Convention on Tobacco Control (FCTC) in response to the pervasive consequences of tobacco use and the complex economic and political issues involved in implementing tobacco control effective policies. The WHO FCTC became the first global legally binding international treaty on public health, adopted by the United Nations' World Health Assembly in May 2003[24].

The objective of the WHO FCTC is "[...] to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke." (Article 3)[24].

To achieve this objective, countries need to tackle the causes of the tobacco epidemic; which spread is facilitated through a several complex factors with crossborder effects; including trade liberalization and direct foreign investment. Other factors as global marketing, transnational tobacco advertising, promotion and sponsorship have also contributed to the explosive increase in tobacco use[2,24].

In 2005, the WHO FCTC came into force in recognition of the smoking tobacco pandemic[25], to establish tobacco control as a public health priority, and provide basic tools for countries to enact comprehensive tobacco control legislation[26] since effective action against tobacco requires countries to understand the magnitude of the adverse effects of smoking on their populations[27].

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2.1. Parties to the WHO FCTC

The responsibilities outlined in this agreement have become the source of guiding principles for tobacco control in the 181 Parties that, as May 2020, are signatories to the Treaty[28], covering more than 90% of the world population. Parties to the WHO FCTC have committed to protect their population from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by joining the fight against the tobacco epidemic[24]. However, large differences still exist in implementation levels among the countries that ratified the WHO FCTC ten years after it came into effect[29].

2.1.1. Parties in Europe

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Fifty one out of the 53 countries of the WHO European Region have, as May 2020, ratified the WHO FCTC, except for Monaco and Switzerland [28]. The latter, however, did sign the treaty, which is a sign of preliminary support to the Convention although it does not establish a legally binding obligation.

Moreover, the treaty counts with the ratification of the EU, since 2005, as it is competent to adopt measures, which complement the national policies of its MS, directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health related to tobacco consumption[28].

2.1.2. Parties in Latin America

Similarly, in Latin America, 16 out of 20 countries, as May 2020, have ratified the WHO FCTC, except for Argentina, Cuba, Dominican Republic and Haiti[28]. The Dominican Republic is the sole country that has not at least signed the Convention.

2.2. The Convention

The Convention is divided into sections, including the objectives, guiding principles and general obligations (Articles 3-5); measures relating to the reduction of demand for tobacco (Articles 6-14); measures relating to the reduction of supply of tobacco (Articles 15–17); protection of the environment (Article 18); liability (Article 19); scientific and technical cooperation and communication of information (Article 20-22); institutional arrangements and financial resources (Articles 23-26); and settlement of disputes and development of the Convention (Article 27-29). The main tobacco control provisions are regulated; however, across Articles 6 to 17.

2.2.1. Measures relating to tobacco demand (Articles 6–14)

Measures relating to the reduction of demand for tobacco include price and tax measures (Article 6); non-price measures (Article 7); effective measures to provide protection from exposure to tobacco SHS (Article 8); regulation of the contents TOBACCO CONTROL IN EUROPE AND LATIN AMERICA

2.2.2. Measures relating to tobacco supply (Articles 15 - 17)

Measures relating to the reduction of supply of tobacco products include the commitment of Parties to eliminate all forms of illicit trade of tobacco products (Article 15); measures to prohibit the sales of tobacco products to or by persons underage (Article 16); and the provision of support for economically viable alternative activities to reduce all tobacco products supply (Article 17).

WHO FCTC Parties have also adopted, by consensus after intergovernmental processes guidelines for implementation of key provisions of the WHO FCTC, which help them meet their legal obligations through recommended actions that elaborate on the provisions[1]. Moreover, to assist states to fulfil their obligations with the WHO FCTC with a focus on cost-effectiveness, practicality and impact, in 2008, the WHO introduced a package of six evidence-based tobacco control demand reduction multifaceted interventions that have proven to reduce tobacco use: the MPOWER strategy[2].

3. The MPOWER strategy

The MPOWER package measures reflect one or more provisions of the WHO FCTC. This evidence-based policy package focuses on six essential policy areas: Monitoring tobacco use and prevention policies (Article 20); Protecting people from tobacco smoke (Article 8); Offering help to quit tobacco use (Article 14); Warning about the dangers of tobacco (Article 11 and 12); Enforcing bans on tobacco advertising, promotion and sponsorship (Article 13); and Raising taxes on tobacco (Article 6) [24,30].

The MPOWER policy package pretends to reverse tobacco epidemic and prevent millions of tobacco-related deaths by reducing prevalence rates, by lowering initiation rates and encouraging quit rates among use.

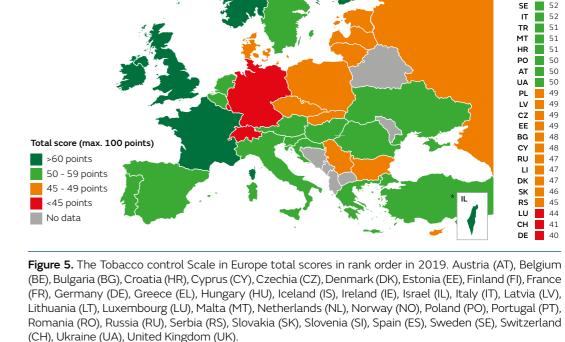
Five billion people, about 65% of the world's population, are covered by at least one MPOWER measure at the highest level of achievement. This number has more than quadrupled since 2007 when only 1 billion people, 15% of the world's population, were protected by at least one MPOWER measure[1].

Below, there is a full description of each of the MPOWER measures providing a special focus on their situation in the European and Latin American region.

3.1. Monitoring tobacco use and prevention policies

Monitoring tobacco use indicators, including tobacco smoking, smokeless tobacco and other tobacco products or related is crucial to understand the progress of the tobacco epidemic and to assess the effect of prevention policies[31]. These indicators are usually assessed by nationally representative surveys as the GATS, the GYTS or the Special Eurobarometer on Tobacco, which is conducted in all EU MS. However, monitoring should also cover the impact of tobacco control policy interventions and tobacco industry activities[1]. Comprehensive monitoring informs governmental leaders and civil society about tobacco negative effects, helps them allocate tobacco control resources towards populations major necessities, enables appropriate policy implementation, and adjustment of the strategies as needed. Therefore, strong monitoring is key to increase the likelihood of success of the other five policy interventions from the MPOWER package[2,32].

According to the WHO, there are 2.8 billion people in 74 countries, or 38% of the world's population, protected by strong monitoring systems that include recent, representative, and periodic surveys for both adults and youth. Most of these countries (59.5%) are high-income countries. By contrast, low-income countries are not monitoring at best practice level, even though monitoring can be made more affordable if thoughtfully integrated with health systems strengthening activities[1]. In Europe, there are 38 out of 53 countries (71.7%) monitoring at best practice level, including all EU MS; while in the Americas only 11 out of 35 countries do (31.4%). In Latin America there are 7 countries monitoring tobacco use at best practice: Brazil, Chile, Costa Rica, Ecuador, Panama, Peru, and Uruguay.



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Adapted from Joossens L., Feliu A., Fernández E. The Tobacco Control Scale 2019 in Europe. Brussels: Association of European Cancer Leagues, Catalan Institute of Oncology; 2020[34].

Moreover, in European countries another monitoring tool prior to the MPOWER strategy was developed by Joossens and Raw in 2006, the Tobacco Control Scale (TCS). This scale is based in six cost-effective measures that should be prioritized in comprehensive tobacco control policies, according to the World Bank[33]. These measures have been adapted to tobacco control needs across years. The last edition includes the following: 1) price of cigarettes, 2) smoke-free bans in public and workplaces, 3) public spending on information campaigns, 4) comprehensive bans on the advertising and promotion, 5) health warnings, 6) treatment to help smokers quit, 7) illicit tobacco trade, and 8) tobacco industry interference. According to Joossens *et al.*, the United Kingdom is leading, and Germany remains the country with the lowest level of implementation of tobacco control policies in Europe (Figure 5). Moreover, there are three countries (Slovenia, Greece and Austria) that have remarkedly improved their tobacco control policies implementation over the last triennial (2016-2019)[34].

3.2. Protecting people from tobacco smoke

Involuntary smoking affects children and adults' health causing substantial mortality and morbidity, as exposure to SHS can lead to severe and fatal diseases including cardiovascular disease, respiratory disease and cancer[1]. The inhalation of this mixture of irritant, toxic particles, and gases has respiratory effects, and on other organ systems[35]; and therefore, avoiding exposure to SHS has become a high priority for public health policy and practice[36] as there is no safe level of exposure to SHS[1].

Smoke-free laws are highly effective in decreasing exposure and enhancing indoor air quality for both smokers and non-smokers; however, to be enough, they must be comprehensive as the only intervention that has shown to fully protect from SHS is a smoke-free environment that permits no exceptions. Moreover, smoke-free laws denormalise smoking, encouraging healthier behaviours and that smokers reduce their tobacco use[1].

According to WHO, to date, comprehensive smoke-free legislation is in place for over 1.6 billion people in 62 countries, covering 22% of the world's population. In Europe, 14 out of 53 countries (26.6%) have implemented smoke-free policies at the highest level, meaning that all public places completely smoke-free or at least 90% of their population is covered by complete subnational smoke-free legislation. Only seven EU MS, including Bulgaria, Greece, Ireland, Malta, Romania, Spain and the United Kingdom, have achieved this milestone with a high or moderate level of adherence to the legislation[1].

By contrast, in the Americas 20 out of 35 countries (57.1%) have achieved to protect at the highest level 90% of their population from SHS. From them, 13 countries are in Latin America, including Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Honduras, Panama, Peru, Uruguay, and Venezuela. Most of these countries show a high or moderate compliance with the smoke-free legislations[1].

3.3. Offering help to quit tobacco use

Three out of four smokers who are aware of the health hazards of tobacco consumption want to quit[2]; however, without cessation assistance only 4% of quit attempts succeed[1]. The chance of successfully quitting smoking could be doubled with proven cessation medications and professional support[1]. Thus, all smokers wanting to stop should be advised and provided with information about the treatment choices to help them to do so[31].

Countries' health-care systems hold the primary responsibility for treating tobacco dependence[2]. Integrating brief advice into existing primary health care systems is one of the first actions countries can take to develop tobacco cessation support[1], as provision of advice to quit smoking is among the most cost-effective interventions in medicine[31]. Every country, therefore, should use their existing systems and resources to ensure that tobacco users at least receive brief advice[1].

Tobacco cessation has shown to have an optimal effect when it is implemented in conjunction with other demand-reduction tobacco control policies, since such tobacco control measures promote tobacco cessation by encouraging quitting and creating a supportive environment[1].

Comprehensive tobacco cessation services have been implemented in 23 countries, covering 2.4 billion people or 32% of the population worldwide. Despite comprehensive tobacco cessation measures are lagging behind the other MPOWER measures, the number of countries adopting best-practice cessation services has increased from 10 countries (5% of the world's population) in 2007 to 23 countries in 2018[1,2].

In Europe, eight out of 53 countries provide smoking cessation services at the highest level of adoption, including a national quit line, and cost-covered nicotine replacement therapy and other cessation services by the government. From them, all are EU MS (Czechia, Denmark, Ireland, Luxembourg, Slovakia, and Sweden); except for Turkey. Similarly, in the Americas six out of 35 countries have achieved best cessation practices, including Brazil, El Salvador and Mexico[1].

3.4. Warning about the dangers of tobacco

Health warnings on tobacco packs and mass media campaigns, according to the evidence, have proved to be powerful effective methods to motivate attempts to stop smoking, prevent relapse, and reduce smoking prevalence[31].

3.4.1. Health warning labels

Consumers have the right to be warned about the health impacts of the products they purchase and consume, including sufficient and accurate information regarding

the risks of tobacco use[1]. Health warnings on tobacco packages are an important medium for communicating the health risks of tobacco use to consumers[37].

Large graphic warnings on tobacco packages are an effective means of increasing health knowledge among smokers, which may also help to reduce the disparities in health by providing low-income smokers with regular access to health information[38]. Moreover, prominent warnings have shown to prompt tobacco users to think about quitting, resulting in decreased tobacco use[1]. Thus, health warnings on tobacco packages are an ideal population-level intervention as they have broad reach, low cost to implement and are sustainable over time[37].

According to the WHO, strong graphic pack warnings are in place for almost 3.9 billion people in 91 countries, covering over half of the world's population (52%). More people is protected by this measure than any other, with 47% of countries implementing graphic pack warning requirements at the highest level. Countries with large graphic pack warnings on cigarettes has increased from 9 to 91 over the last decade, as in 2007 only 5% of the world's population accomplished comprehensive graphic pack warning requirements[1].

In Europe, 38 out of 53 countries have implemented health warnings at the highest level, meaning large warnings covering on average 50% of front and back of the package. All EU MS have achieved this milestone. Meanwhile, in the Americas 20 out of 35 countries have adopted health warnings labels best practices, and from them, 13 are located in Latin America[1].

3.4.2. Mass media anti-tobacco campaigns

Mass media campaigns are proven to reduce tobacco use among youth and adults increasing quit attempts, lower youth initiation rates and reduce SHS exposure. Anti-tobacco campaigns are effective in changing smoking behaviours by raising awareness and informing the population about the harms of tobacco use and SHS. However, the intensity and duration of mass media campaigns may influence their effectiveness[39,40], since sustained campaigns are more likely to have a longer-term impact on tobacco use behaviour. Therefore, governments should develop and deliver sustained messages designed to educate current and potential tobacco users about the dangers of tobacco influence attitudes and beliefs about tobacco use[1].

According to the WHO, less than 25% of the population worldwide (1.7 billion people), live in a country that has aired at least one national comprehensive anti-tobacco mass media campaign in the past 2 years. Low-income countries are the least exposed to anti-tobacco mass media as over 60% of their population have not been exposed to any kind of campaign in this period.

Few European countries run campaigns that sustain this level of population reach and intensity. According to the WHO, in 2018, only 16 European countries met the WHO recommendations[1]; and, thus, mass media campaigns are a much underexploited opportunity for smoking prevention in Europe[31]. Similarly, in the Americas only six out of 35 ran an anti-tobacco campaign during that time, three in Latin America[1].

3.5. Enforcing bans on tobacco advertising, promotion, and sponsorship

Enforcing bans on tobacco advertising, promotion and sponsorship (TAPS) has proven to be an effective tobacco control measure, as substantial evidence exists on the harmful consequences of unregulated advertising on smoking behaviour[41]. Comprehensive advertising bans are crucial to denormalise tobacco use, especially among youth[42]. However, the scope of advertising restrictions and their enforcement are a critical factors in their effectiveness, as comprehensive bans have a greater effect on reducing tobacco use than limited bans[41].

In the EU, the Tobacco Advertising Directive (2003/33/EC) progressively prohibited advertising through print media, radio broadcasting, and the internet and, finally, sponsorship of sports or events involving at least one EU MS. However, this Directive does not apply to national advertising within MS[43]. Most EU countries have enforced laws banning billboard advertising, except for Germany, although advertising in social media continues[31].

According to the WHO, banning TAPS remains an under-adopted measure inasmuch as only 48 countries –18% of the world's population –have implemented a comprehensive ban; and there are still 44 countries that have not adopted any TAPS bans to date. Over the years, the adoption of complete TAPS ban has steadily increased from seven countries in 2007 to 48 countries in 2018, meaning that nowadays 1.3 billion people (one in four) is covered by these measures at best-practice level[1].

From the 48 countries that have banned on all forms of direct and indirect advertising, seven are in Europe (none being an EU MS), and seven in the Americas, including Brazil, Colombia, Panama, and Uruguay.

3.6. Raising taxes on tobacco

Retail price of cigarettes is a crucial determinant of cigarette consumption[44] and; thus, price and tax measures are an effective and important means of reducing tobacco use by leading some current users to quit, preventing potential users from initiating use, and reducing consumption among current users[24]. Increasing of tobacco prices through taxes is one of the most effective and cost-effective tobacco control measures[44], especially for young people and others from low incomes[31]. On average a 10% price increase reduces consumption by 5% in low- and middle-income countries, and by about 4% in high-income countries[44]. However, the

effects of price increases, however, are substantially reduced by the availability of lower-price options, including roll-your-own tobacco, and illicit tobacco[31].

Moreover, raising taxes on tobacco is effective not only reducing tobacco consumption and improving health, but also generating more government revenues[44]. According to the WHO, additional funding should be used for launching tobacco control programmes as using tax revenues in this manner could further increase public support for higher taxes[1].

Increasing the price of tobacco products through tobacco taxes, despite being the most effective and efficient measure to reduce tobacco use, is the least-achieved MPOWER measure with only 38 countries with sufficiently high taxes, covering scarcely 14% of the population worldwide. Most of the countries that have adopted such high taxes are high-income countries, including 24 European countries from which 18 are EU MS, and 5 American countries (Argentina, Brazil, Chile, and Colombia). Finally, only 15 countries do not levy an excise tax on tobacco products[1].

4. The progress and impact of tobacco control policies

The development process of tobacco control policies worldwide has been accelerated by the WHO FCTC. Over the last decade, there has been a significant increase in the proportion of countries that implemented each of the five key measures of the treaty at the highest level that has been associated with significantly greater reductions in the prevalence of smoking[45]. Moreover, Levy et *al.* estimated that nearly 22 million future premature smoking-attributable deaths worldwide were averted as a result of strong implementation of demand-reduction measures adopted by countries in a seven-year period[46].

According to Gravely *et al.*, Northern Europe, South America and Australia are the subregions that have had a greater engagement in strong WHO FCTC implementation[45]. Despite the WHO FCTC has generally had a positive impact on tobacco control, there are still several ongoing challenges to the effective implementation of the treaty, including tobacco industry interference, ineffective implementation of existing guidelines, insufficient capacity and lack of financial support, and poor enforcement[47].

Thereupon, the impact of tobacco control policies; however, is proven to be amplified when a package of comprehensive policies is implemented[48]. According to Flor et al., if MPOWER measures had been adopted at their maximum level and cigarette prices had been raised, resulting in reduced affordability levels; adult prevalence (aged 15 years and older) in 2017 would have reduced by 10.6% among men and by 12% among women worldwide. These numbers translate to approximately 100 million fewer smokers across 155 countries. Hence, these findings highlight missed opportunities in tobacco control and indicate that even though much progress has been achieved, efforts need to be strengthened and accelerated so it can lead to additional gains in global health[3]. The importance of strengthening tobacco control globally was recognized with the inclusion of the topic in the United Nations' Sustainable Development Goals (SDGs)[49].

5. Tobacco control efforts in the European Union

Despite considerable progress made in recent years, the smoking prevalence in the overall population in the EU is still high (26.5%, in 2017)[17]. To tackle this situation, the EU and national governments have taken various tobacco control measures, including regulating tobacco products, implementing advertising and promotion restrictions, creating smoke-free environments, raising taxes and persecuting activities against illicit trade; in the form of legislation, recommendations, and information campaigns. These initiatives are directed to protect EU citizens from the adverse effects of tobacco consumption. Hereafter are explained the different initiatives the EU has undertaken to fight the tobacco epidemic.

5.1. Public opinion

The European Commission regularly carries out public opinion representative polls to monitor current tobacco consumption indicators and attitudes to tobacco control policies of European citizens towards tobacco-related issues[17]. This Special Eurobarometer on tobacco control has been carried out since 2003 and, although the questionnaire has changed over time to tackle concrete needs in each year, its main objectives have remained unchanged. These are mapping the current tobacco products consumption, understanding motivations behind smoking and attitudes underlying smoking behaviour, and identifying measures to reduce the number of Europeans who smoke[50].

5.2. Tobacco products regulation

5.2.1. The Tobacco Products Directive

Tobacco control policies in Europe have been driven also by the EU as it has introduced several directives concerning labelling of tobacco products and taxation[51]. Among them, one of the most representative is the Tobacco Product Directive (TPD).

The first EU TPD which regulated aspects such as manufacture, sale and presentation of tobacco products was approved in 2001 (Directive 2001/37/EC). Over a decade later, under the pressure of the public health community, and the entry into force of the WHO FCTC in 2005, the European Commission decided to review the TDP[23].

The revised EU TPD (2014/40/EU) aims to improve the functioning of the internal market for tobacco and related products, while ensuring a high level of health protection for European citizens. The TPD prohibits the sale of cigarettes and roll-your-own tobacco with characterising flavours (such as menthol, vanilla, etc.), requires the tobacco industry to report to EU MS on the ingredients used in tobacco products, and requires health warnings on tobacco and related products. In addition, in terms of labelling, regulates that EU MS should:

- apply combined (picture, text, and information on how to stop) health warnings by covering 65% of the front and back of cigarette and roll-your-own tobacco packages;
- set minimum dimensions for warnings and prohibits small packages for certain tobacco products, bans promotional and misleading elements on tobacco products, e-cigarettes, and herbal products for smoking;
- introduce EU-wide tracking and tracing to combat the illicit trade of tobacco products, allows EU countries to prohibit internet sales of tobacco and related products; and
- set out safety, quality and notification requirements for electronic cigarettes, and obliges manufacturers and importers to notify EU countries about novel tobacco products before placing them on the EU market[52].

The revised EU TPD, which is based on the proposal of the European Commission, entered into the force on the 19th of May 2014 and became applicable in the EU MS on 20 May 2016. The TDP, being an EU Directive, will have to be transposed by EU MS onto their national legislation. As March 2020, EU MS have totally or partially transposed the TDP[53].

5.2.2. The Joint Actions on Tobacco Control

One of the key aspects of the TPD is developing an EU common reporting format for submission of ingredients data contained in tobacco and related products and disclosure of the collected data to the public. In this context, the European Commission together with the EU MS launched the Joint Action on Tobacco Control (JATC) in October 2017 that is a comprehensive EU funded project that aims to provide support for implementing the TPD throughout the 28 EU MS, by tackling tobacco product monitoring at an EU-wide level. Specifically, this collaborative action aims at

- improving the protection of EU Public Health by facilitating access to the data collected through the EU Common Entry Gate;
- monitoring and providing support to the tasks of tobacco and e-cigarette products regulation;

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- assisting collaborations between laboratories for tobacco products and e-cigarettes evaluation;
- offering support to EU MS in the process of monitoring and updating priority additives; and
- integrating results into national policies to improve evidence-based tobacco control policies at the national, regional or European level[54].
- 24 The European Commission has launched the Call for the new Joint Action (2021-2023) with the following overall aims: to facilitate the exchange of good practices between MS to improve implementation of the TPD, to ensure greater consistency in the application of the TPD, and to promote activities consistent with the objectives of the WHO FCTC.

5.3. Smoke-free environments

Protection from exposure to tobacco smoke has improved in the EU, following the *Council Recommendation on Smoke-Free Environments (2009/C296/02)*, which was adopted on November 2009, that called on EU MS to adopt and implement laws to fully protect their citizens from exposure to SHS in enclosed public places, workplaces and public transport[55]. According to the last European Commission implementation report (2013), 17 EU MS had comprehensive smoke-free legislation in place, and among these, Bulgaria, Greece, Hungary, Ireland, Malta and Spain had a complete ban on smoking in indoor public places, workplaces and on public transports[56]. Nevertheless, from then on, other EU MS have also implemented more stringent smoke-free policies as exposure to SHS in bars and restaurants has decreased 5% and 3%, respectively[17].

5.4. Advertising, promotion, and sponsorship

Tobacco advertising, promotion and sponsorship is restricted in the EU by the *Tobacco Advertising Directive (2003/33/EC)*, the *Audio-visual Media Services Directive (2010/13/EU)* and the *Council Recommendation (2003/54/EC)* on the prevention of smoking in initiatives to improve tobacco control.

The Tobacco Advertising Directive is aimed to eliminate direct and indirect effects of promoting any tobacco product by banning on cross-border tobacco advertising and sponsorship in the media other than television, covering print media, radio, internet and sponsorship of events involving more than an EU MS together with free distribution of any tobacco product in such events[43]. Moreover, to ensure its full-compliance, the European Commission has acted against non-compliant MS to the European Court of Justice for failing to correctly transpose the sponsorship.

Tobacco advertising and sponsorship on television was banned by the *Television* without Frontiers Directive (89/552/EEC) in 1989 and has been replaced by the

Audio-visual Media Services Directive (2010/13/EU) that extended the prohibition to all forms of audio-visual commercial communications, including product placement [57]. Moreover, other forms of tobacco promotion are regulated by the *Council Recommendation on the Prevention of Smoking and on Initiatives to improve tobacco control* that recommends to MS to ban the use of promotional items and tobacco samples, use and communication of sales promotion, use of billboards, posters, and other indoor and outdoor advertising and in cinemas. However, unlike previous legislations, its content is not legally binding as it only suggests to MS the adoption of appropriate and/or administrative measures to ban all forms of advertising and promotion[58].

5.5. Other EU activities

The European Commission has also implemented a Council Directive (2011/64/ EU) that regulates the structure and rates of excise duty applied to manufactured tobacco; and the European Anti-Fraud Office that investigates illegal tobacco trading. Finally, the EU has also contributed to raise awareness of the health consequences of tobacco use fostering EU-wide campaigns addressed to reduce its burden across Europe.

6. The future of tobacco control: Endgame strategies

Tobacco consumption has considerably decreased in high-income countries over the last decades due to population-level strategies implementation such as comprehensive tobacco control policies. Consequently, there is growing interest in 'endgame strategies', following the full implementation of these existing measures[59]. Major tobacco control successes suggest that changing what tobacco use and the tobacco industry means is foundational to ending the global pandemic[60].

The tobacco 'endgame' is 'the final stage of the process of ending tobacco use' and suggests moving beyond tobacco control toward a tobacco-free future[61,62], resulting in a paradigm shift in this field[62]. Tobacco control endgame strategies, although there is not a unified definition, could be described as initiatives designed to change and/or eliminate permanently the structural, political and social dynamics that sustain the tobacco epidemic to end it within a specific time[61]. Hence, an endgame strategy addresses tobacco as a systems issue, rather than an individual behaviour, addresses health and political implications, reframes strategic debates, advances social justice and is fundamentally transformative in changing how tobacco use and the tobacco industry are regarded[63].

Endgame strategies are most feasible to be implemented in jurisdictions with low prevalence and/or relatively rapid reductions in prevalence since as smoking becomes increasingly unacceptable it is easier to regulate against it. Therefore, one of the main requirements is the need for strong political will as the tobacco control problem at its core is a political problem[60,64]. According to Thomson et *al.*, less than 15% tobacco use in adults could provide situations where tobacco is sufficiently socially denormalised for governments to plan for a predicted end to tobacco use[62].

Public policy commitment to achieve a true endgame ought to be driven by strong public support to reach an endpoint. In European countries, despite such support still appears to be distant, according to Gallus *et al.*, one in three adults (and one in

four smokers) supports a tobacco endgame strategy[64]. Several countries have already developed plans to achieve their respective tobacco endgames by 2025, including Sweden and Ireland. The Netherlands and Finland have also envisioned an endpoint by 2035[65] and 2040 respectively; although the latter has taken forward this initiative despite having a relatively low public support[66]. Therefore, to shorten the pathway towards a tobacco-free society, the tobacco control movement should initiate a public conversation in order to help the public understand its benefits[64].

According to van der Deen et al., tobacco endgame strategies could accelerate the progress towards reducing smoking prevalence to minimum levels (\geq 5%) and result in large health gains and cost savings to the health system. Endgame strategies could reduce health inequalities associated with the tobacco-related disease burden[67]. However, the implications of an endgame and the goals adopted may vary according to circumstances and context[62].

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7. Justification and implications for public health

According to the WHO, despite the global efforts to reduce the tobacco epidemic, large differences still exist in tobacco control policy implementation and enforcement across Europe and the Americas[1,45]. Moving forward with effective tobacco control policies to reduce differences across countries requires monitoring data on tobacco use patterns and trends and exposure to tobacco smoke. These sources of information are particularly important for making comparisons between countries, and in some cases can be used to demonstrate the impact of policies[68]. However, to understand progress in tobacco control policies and evaluating their effectiveness since they are both key to sustaining tobacco control progress[32].

Tobacco control policies are of interest because of their potential to affect large number of people, in some cases entire populations and; therefore, it is important to evaluate whether such policies have achieved their objectives and are cost-effective[68]. This information together with their impact on tobacco-related indicators is useful for raising awareness, motivating decision makers and stakeholders to adopt new measures or intensify existing ones, and mobilizing greater resources to control the tobacco epidemic[32]. Hence, as more countries move towards adoption and implementation of effective tobacco control measures, consolidating their evidence-based effectiveness becomes even more critical and timely. Better understanding of the impact of these policies on smoking prevalence and other indicators could contribute to tailoring specific recommendations on tobacco control legislation at the country-level[3]. Evaluation allows the most effective interventions to be implemented and maintained (and perhaps improved further) while less effective interventions are either improved or de-implemented[68,69].

Moreover, adoption of tobacco control policies and their implementation process has varied widely across countries. According to Bosdriesz et *al.*, in Europe, such variation has been observed in terms of both strength of policies and the timing of implementation[70]. Evidence on which factors influence governments to enact tobacco control policies and drivers behind this process is needed to predict policy development and understand why differences between countries still exist. In conclusion, monitoring tobacco control policies, describing socio-political and economical drivers of their implementation; and evaluating their effectiveness and its impact on tobacco-related indicators (i.e., smoking prevalence, cessation rates, etc.), is key to reduce the tobacco epidemic and move forward to a tobacco-free world that would have a great impact on public health as eliminating tobacco would reduce millions of premature deaths a year.

As reported, over the last decade several tobacco control regulations –such as the WHO FCTC, TPD, among others –have been enforced worldwide, including in the European and Latin American regions. Moreover, several tools and surveys have been developed over this period to monitor both tobacco control policies and other smoking indicators in different countries, especially in the EU. Given the conjunction of both elements, this thesis has addressed several research questions regarding the evaluation of tobacco control policies in Europe and Latin America.

Hypothesis

Hypothesis

- H1: The Tobacco Control Scale has been commonly used in research as a proxy to assess tobacco control policy implementation at a country-level in Europe.
- H2: A higher level of implementation of tobacco control policies correlates with both lower smoking prevalence and higher smoking cessation rates.
- H3: European countries with a lower socioeconomic status have a lower level of tobacco control policy implementation.
- H4: Smokers in those EU countries where smoking prevalence has declined are softening rather than hardening.
- H5: The TCS can be adapted to the Latin American context and used in these countries to systematically monitor tobacco control policy implementation.

Objectives

The main aim of this PhD thesis is to evaluate tobacco control policy implementation impact in Europe and Latin America.

1. General objectives

The main objectives (O) of the PhD thesis are:

- 1. to assess the use of the TCS as a research tool through a literature review;
- 2. to evaluate the association between country-level implementation of tobacco control policies and smoking prevalence and quit ratios in the EU over time;
- 3. to assess the association between country-level socioeconomic factors and tobacco control policy implementation in Europe;
- 4. to evaluate whether the hardening hypothesis can be confirmed in the EU and to analyse the determinants of hardcore and light smoking with a multilevel approach; and, finally,
- 5. to monitor tobacco control policies in Latin American countries by developing and adapting the TCS to the region context.

2. Specific objectives

The specific objectives for each of the main objectives stated are:

O1. To assess the use of the TCS as a research tool through a literature review

- a. to describe to what purpose reviewed publications have included the TCS as a variable;
- b. to report on its limitations and strengths as a proxy to tobacco control policies implementation; and
- c. to critically assess its use as a research instrument in tobacco control.

O2. To evaluate the association between the country-level implementation of tobacco control policies and smoking prevalence and quit ratios in the EU over time

- a. to geographically represent changes in smoking indicators between 2006 2014 in EU countries;
- b. to calculate the relative changes in smoking prevalence and quit ratios across this period; and
- c. to assess the correlation between tobacco control policies implementation and smoking prevalence and quit ratios at country-level stratified by age and sex.

O3. To assess the association between country-level socioeconomic factors and tobacco control policy implementation in Europe

a. to conduct a review of the literature to understand the key indicators that are used in ecological designs to assess countries' socioeconomic status;

- b. to assess the correlation between socioeconomic status indicators and implementation of tobacco control policies at a country-level; and
- c. to determine which socioeconomic status indicators are associated to a higher implementation level in different policy domains (i.e., price, smoke-free bans, spending in public campaigns, etc.).

O4. To evaluate whether the hardening hypothesis can be confirmed in the EU and to analyse the determinants of hardcore and light smoking with a multilevel approach

- a. to describe and graphically represent the smoking prevalence trends in the general population and hardcore and light smokers in the EU Member states globally and by country;
- b. to assess the association between the relative change in the prevalence of hardcore or light smokers among current smokers and the relative change in smoking prevalence from 2009 to 2017;
- c. to investigate the changes in hardcore and light smoking prevalence per each additional percentage point in smoking prevalence; and
- d. to analyse the determinants of hardcore and light smoking considering both individual and contextual country-level characteristics.

O5. To monitor tobacco control policies in Latin American countries by developing and adapting the TCS

- a. to develop and adapt the Tobacco Control Scale for Latin American and the Spanish-speaking Caribbean countries by engaging stakeholders in the adaptation of the tool;
- b. to translate the scale's questionnaire into Spanish and Portuguese from Brazil to collect the data through an online platform; and
- c. to quantify the level of implementation and reported level of compliance of tobacco control policies in countries in Latin America and Spanish-speaking Caribbean and to report initial results.

Methods

1. Study design

This thesis dissertation consists of four studies. All of them have an observational design with either ecological (with countries as the unit of analysis) or multilevel (with individual data as first-level unit and country-related data as second-level unit of aggregated information) data; and also includes a literature review.

2. Data sources

Data sources in our project are mainly secondary-data from surveys, reports or open-access database; including the Tobacco Control Scale, the Eurobarometer, the Eurostat, the World Bank's Global Health Observatory Data Repository, the Human Development Reports, and the WHO Reports on the global tobacco epidemic, among others. Among them, the TCS and the Eurobarometer have a highlighted importance because of their transversal use across the different studies in this work.

2.1. The Tobacco Control Scale

The TCS was developed by Joossens and Raw in 2006 together with an experts' working group from the European Network for Smoking Prevention (ENSP) to monitor the implementation of tobacco control policies systematically at country-level across Europe by means of a questionnaire sent to the ENSP correspondents within the countries[33].

The scale is based on the six cost-effective interventions described by the World Bank which, according to the evidence, should be prioritised since it is suggested that, despite price increases is the most effective tobacco control measure, best results are achieved when a comprehensive set of measures is implemented together. These measures are:

- Price increase through higher taxes on cigarettes and other tobacco products.
- Bans and restrictions on smoking in public and workplaces.
- Better consumer information, including public information campaigns, media coverage, and publishing research findings.
- Comprehensive bans on the advertising promotion of all tobacco products, logos and brands names.
- Large and direct health warning labels on cigarette boxes and other tobacco products.
- Treatment to help dependent smokers quit smoking, including increased access to medications.

The TCS assigns a score to each European country based on tobacco control policy implementation of each policy domain and ranks countries according to their total score[33]. The results of the TCS are published every three years, except for the second edition, and there have been six-editions so far (2005, 2007, 2010, 2013, 2016, and 2019). The policy domains and corresponding score(s) have varied across consecutive editions, although the total maximum score has maintained the same. The main changes have been done between editions of 2007 and 2010; and 2016 and 2019[71].

The policy domains and their corresponding score(s), according to the last published report, are: price (30 points); bans and restrictions on smoking in public and workplaces (22 points); spending on public information campaigns, media coverage, and publicising of research findings (10 points); comprehensive bans on tobacco advertising, promotion and sponsorship (13 points); large direct health warning labels on tobacco products (10 points); treatment to help smokers quit (10 points); illicit tobacco trade (3 points); and tobacco industry interference (2 points). This score increases with the strength of tobacco control policies up to a possible maximum score of 100 points, indicating a full implementation for all strategies considered[34]. The score(s) attributed to each policy domain is weighted by its reported evidence-based effectiveness on tobacco control[33].

2.2. The Special Eurobarometer on Tobacco

Data on smoking prevalence in EU MS is available through the Special Eurobarometer on Tobacco N° 458 (wave EB87.1), which had fieldwork data conducted in March 2017[17]; and other precedent reports[50,72–75]. The EU, since 2003, regularly performs public opinion polls to monitor Europeans' attitudes to a range of tobacco-related issues. The aims of these cross-sectional surveys are to assess the prevalence of tobacco use and exposure to tobacco smoke in public places, to explore the motivations for smoking, and to help identify measures to reduce the number of smokers in the EU.

The current survey explores the prevalence of consumption in the EU of both tobacco and e-cigarettes; the age at which Europeans started using tobacco and e-cigarettes and their frequency of use; the type of tobacco products consumed; issues related to starting and quitting smoking; factors that influence the choice of cigarettes or e-cigarettes; exposure to tobacco smoke at work and in public places; exposure to advertising for e-cigarettes; perception of harm from e-cigarettes; and attitudes to tobacco and e-cigarette control policies.

The latest survey was conducted by TNS Opinion & Social network in the 28 EU MS between the 18^{th} and 27^{th} March by interviewing 27,901 men and women aged ≥ 15 years from different social and demographic groups. The interview was conducted face-to-face at home in their mother tongue on behalf of the Directorate-General for Health and Food Safety[17].

Each wave covers the population of the respective nationalities of the EU MS, resident in each of the 28 MS and aged 15 years and over (about 1,000 respondents in each country[17]. The Eurobarometer sampling methods and size are consistent in all EU countries and in the different waves used, ensuring that tobacco smoking indicators estimates do not differ between countries and/or years[76].

Results

Results

Hereunder are summarized the five publications presented in this PhD thesis, three of which have been published in high-impact international journals (Table 1).

Table 1. Summary of publications: Impact factor (2019), category and journal rank of the publications presented in this PhD thesis.

Authors and title	Journal and reference	Impact Factor	Category, Journal rank	Citations
Feliu A, Fernández E, Baena A, Joossens L, Peruga A, Fu M, Martínez C. The Tobacco Control Scale as a research tool to measure country-level tobacco control policy implementation	Tob Ind Diseases 2020;18:91	1.434	Public, environmental, and occupational health, 144/193 Q3	0
Feliu A, Filippidis FT, Joossens L, Fong GT, Vardavas CI, Baena A, Castellano Y, Martínez C, Fernández E. Impact of tobacco control policies on smoking prevalence and quit ratios in 27 European Union countries from 2006 to 2014	Tob Control 2019; 28:101-109	6.726	Substance abuse, 1/20 Q1 (D1)	44

Feliu A, Filippidis FT, Joossens L, Amalia B, Tigova O, Martínez C, Fernández E. The association between tobacco control policy implementation and country-level socioeconomic factors in 31 European countries	Sci Rep, under review	3.998	Multidisciplinary sciences, 17/71 Q1	-
Feliu A, Fernández E, Martínez C, Filippidis FT. Are smokers "hardening" or rather "softening"? An ecological and multilevel analysis across 28 European Union countries	Eur Resp J 2019; 54:1900596	12.339	Respiratory system, 4/64 Q1 (D1)	4
Feliu A, Martínez C, Peruga A, Joossens L, Bianco E, Cornejo M, Nogueira SO, Fernández E. A tool to monitor tobacco control policies' implementation: The Tobacco Control Scale in Latin America. Adaptation process and pilot study	Tob Control, under review	6.726	Substance abuse, 1/20 Q1 (D1)	-

*Citations source: Web of Science (9th Feb, 2021)

Paper I

The Tobacco Control Scale as a research tool to measure country-level tobacco control policy implementation

Ariadna Feliu, Esteve Fernández, Antoni Baena, Luk Joossens, Armando Peruga, Marcela Fu, Cristina Martínez

Tob Ind Diseases 2020;18:91

Research Paper

Tobacco Induced Diseases

The Tobacco Control Scale as a research tool to measure country-level tobacco control policy implementation

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ABSTRACT

INTRODUCTION The Tobacco Control Scale (TCS) was designed for advocacy purposes but has also been used as a research tool. In the present study, we characterized TCS use, its limitations and strengths, and critically assessed its use as a research instrument.

METHODS We conducted an extensive search of the biomedical databases PubMed and Web of Science for the keyword 'tobacco control scale' in all fields. The search was limited to studies published in the period March 2006 to December 2019. Out of 69 hits, 32 studies met the inclusion criteria. Two reviewers independently extracted information from each publication regarding their general characteristics, publication and research aspects, and the characteristics of the use of the TCS.

RESULTS We found that researchers have used the TCS as a tool to monitor tobacco control policies mainly in cross-sectional observational studies with ecological and multilevel designs directed to advocacy and the promotion of further research. Different outcomes, such as smoking prevalence and quit ratios, have been associated with tobacco control policy scores. The main reported limitations of the TCS were a low variance across countries and a failure to express enforcement and to incorporate the most recent legislation.

CONCLUSIONS The TCS has been commonly used to assess differences in outcomes according to tobacco control policies. However, there are still areas for improvement in its use in research regarding the lack of comparability of TCS scores across time. The lessons that have been learned should be used to adapt and expand the TCS overseas.



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KEYWORDS

tobacco, tobacco control policies, epidemiology, research

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INTRODUCTION

smoking, decrease smoking prevalence¹, and reduce Effective tobacco control policies help denormalize morbimortality attributable to tobacco². Many efforts

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epidemic³, stimulated by the enforcement of the identify publications that have used the TCS score(s) Framework Convention on Tobacco Control. In the European Union (EU), the Tobacco Products Directive has driven the application of stringent tobacco control policies to reduce tobacco use and its negative consequences on health. However, the implementation and enforcement of tobacco control policies still vary greatly across Europe⁴.

Among the initiatives to monitor the implementation of tobacco control policies in Europe, Joossens and Raw⁵ developed the Tobacco Control Scale (TCS) in 2006. The TCS score is determined by a questionnaire based on six cost-effective policy interventions that should be prioritized according to the World Bank. These measures include taxation, smoke-free policies, public spending in information campaigns, advertising bans, health warnings, and treatment. The score assigned to each of these components is weighted by its reported evidence-based effectiveness. Therefore, the score attributed to each country increases with the strength of tobacco control policies up to a maximum of 100 points, indicating full implementation⁵.

monitor the progress in tobacco control in Europe at a national level by comparing the performance of countries by their ranking⁵ and to inform the agenda by highlighting the policy components for which progress is lacking, as well as the countries or regions most affected by such delays6. Since 2006, the TCS has been updated every three years (available at www. tobaccocontrolscale.org).

Evaluating the impact of tobacco control policies among the population has become an important research area; thus, the TCS has been used as a research tool to measure the implementation of tobacco control policies, though it was not designed for such purposes. However, little is known about the use of the TCS by the tobacco control research community and its advantages and disadvantages as a research tool. Therefore, our aim was to characterize the use of the TCS by researchers and its main limitations and strengths as a research tool in order to critically assess its use as a research instrument.

METHODS

Data sources

have been made globally to tackle the tobacco online databases PubMed and Web of Science to as an independent or dependent variable from 27 March 2006, when the first TCS was published, until 1 December 2019. The search was conducted using 'tobacco control scale' as the keyword in all fields without any other restrictions to ensure a very sensitive search. The Ethics and Clinical Research Committee of the Hospital Universitari de Bellvitge approved this study (PR247/18).

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Study selection

We identified 69 publications (32 duplicated in both databases). After removing duplicates, two researchers (AF and AB) screened the titles and abstracts, obtaining 32 studies. The inclusion criteria were quantitative research and inclusion of the TCS score(s) (as dependent or independent variable) in the analysis. We found 27 eligible publications (Figure 1). We completed our search by manually reviewing the reference lists of the selected papers and by conducting the same search in Google Scholar (www.scholar.google.com; with search terms in At its inception, the aim of the TCS was to English). These additional searches provided five new publications that met the inclusion criteria and the full-texts were reviewed.

> Therefore, we finally included 32 publications that used the TCS score(s) as a dependent or independent variable.

Data extraction

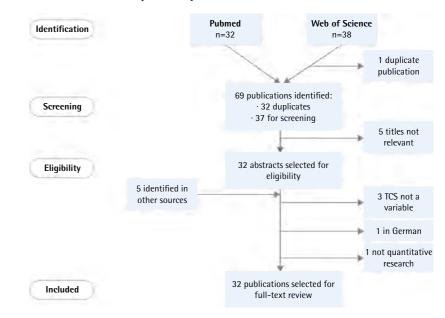
A detailed protocol and Microsoft Access® database were designed to extract and register the information from each publication. The evaluation protocol was developed by three researchers who are experts in tobacco control (AF, CM, and EF). The protocol describing the main objectives, information sources, search strategy and eligibility criteria, and the data collection was reviewed and approved by all researchers. All variables for which data were described in the publications' Methods sections were listed

Two reviewers independently extracted the data according to the protocol (AF and AB). If any discrepancies emerged, the reviewers discussed the papers until agreement was reached and, when no consensus was met, divergences were solved by We performed an extensive literature search in the discussing them with a third reviewer (CM). The



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Figure 1. Flowchart of the selection process of publications for full-text review



evaluation process was conducted in January 2020. The extracted information included general characteristics, publication characteristics, research characteristics, and characteristics of the use of the TCS (Table 1).

RESULTS

The 32 publications were published between 2008 and 2019. More than two-thirds (n=23; 71.9%) were published by research groups from the Netherlands (n=8), Spain (n=9), and the United Kingdom (n=6). Almost all (n=30; 93.8%) were original articles published in peer-reviewed journals, 12 of which were Open Access (37.5%). In addition, almost all declared no conflicts of interest (n=29; 90.6%) and were financially supported (n=26; 81.3%) with public funds (n=19; 73.1%), both public and private funds (n=5; 19.2%), or private funds (n=2; 7.7%).

Most of the publications (n=31) were observational studies; 16 used ecological data (50%) with the country as the unit of analysis and 16 used multilevel data (50%) with individual data from surveys as the first-level unit and TCS score by country as second-level aggregated information. Regarding

the study design, 23 of the publications were crosssectional studies (78.6%). Most of the articles (n=24; 75%) (Table 2) included the TCS score(s) as an independent variable from primary reports, whereas 10 publications (31.3%) (Table 3) used the scores from secondary sources that calculated a new score based on the TCS methodology. Overall, 87.5% (n=28) of the publications used the overall TCS score by country and 65.6% (n=21) used the individual policy component scores.

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Twelve out of 21 articles (60%) using individual TCS scores included all six policy components in the analysis. The most frequently used policy components were the individual score on bans in public places (n=20; 95.2%) and advertising bans (n=16; 76.2%). In contrast, the least used were data on public spending on information campaigns (n=12; 57.1%). The publications included data from between 1 and 31 countries; only one publication used scores from all of the countries included in the TCS report, including >30 EU and non-EU countries7; however, 46.9% of publications included scores from all EU Member states except Croatia because it was first included in 2013.

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Table 1. Summary of the information extracted (variables and categories) from each publication

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General	Author surname and initials, institutional affiliation, and country of affiliation of the first author	
	Funding	Yes, no, or not declared; and if yes, private, public, or both
	Conflicts of interest	Yes, no, or not declared
Publication	Type of publication	Research paper, brief paper, review, letter to the editor, editorial, comment, or other
	Publication year	
	Journal	
	Open Access	Yes or no
Research	Objective of the study	
	Type of design	Observational or experimental; cross-sectional or longitudinal
	Type of study data	Individual, ecological, or multilevel, with individual data from surveys as first level unit with TCS score by country as second level of aggregated data
	Main results	(literals)
	Limitations (specifically, those related to the use of the TCS as a tool to monitor tobacco control policy implementation)	(literals)
	Main conclusions and their purpose	For advocacy (when directly addressed to stakeholders and policymakers), to undertake further research on the topic, or both
Use of the Tobacco	Type of variable	Dependent, independent, or both
ontrol Scale (TCS)	Year of the TCS report	
	Source of the TCS score(s)	Primary source, when publications included the TCS score(s) from the original reports; or secondary source, when publications included TCS data from other publications in which case the alternative data source was recorded
	Total score	Yes or no
	Individual components score(s)	Yes or no; and if yes, which components were included
	Countries from the original TCS report(s)	Yes or no; and if not, we recorded the number of countries included

Half (n=16) of the publications were directed studies aimed to address the relationship between towards policymakers with the aim of urging tobacco control policies and several outcomes, such as governments to implement more stringent tobacco the prevalence of preterm births and low birthweight⁷, control policies, 6 publications aimed to foster further of hard-core and light smokers⁸, and of smoking in research on this topic (18.8%), and the conclusions of adolescents^{9,10}; smoking prevalence and quit ratios^{4,11}; 10 papers (31.3%) addressed both aims.

Articles using TCS scores from primary reports Almost all of the studies that used the TCS reports as a self-reported exposure to secondhand smoke (SHS)¹⁵⁻ primary source (n=22) (Table 2), were observational in nature (n=21; 95.5%) and 19 were cross-sectional restrictions¹⁸⁻²¹. (86.4%). According to the type of unit of analysis,

consumption of rolling tobacco, e-cigarettes, and readiness to quit in adults¹²; and risk of lung cancer¹³. Other indicators were smoking in private venues^{1,14}, ¹⁷, and attitudes towards smoking and tobacco product

Other publications were focused on exploring the half were ecological studies and half multilevel. These association between the price of tobacco products

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Feliu et al. ⁸ 2019, Spain	To empirically evaluate whether the hardening hypothesis can be confirmed at the population level in the 28 EU member states, and to analyze the determinants of hard- core and light smoking considering both individual and contextual country-level characteristics	Observational, multilevel, time-trends	Independent variable, original data, only total score	Hardening smoking is not increasing in EU member states where smoking prevalence is decreasing. Odds of being a hard-core smoker are higher among middle-aged men of lower class and lower in countries with higher TCS scores	No limitations reported about Advocacy the TCS as a variable	Advocacy
González- Marrón et al. ¹³ 2019, Spain		Observational, multilevel, cross-sectional	Independent variable, original data, only total score	Significant inverse correlation between TCS 2010 and the proportion of former and ever smokers at high risk of lung cancer according to NELSON criteria	The cross-sectional design of TCS limits the validity of the study to establish causation	Advocacy and research
Feliu et al. ⁴ 2019, Spain	To assess the midterm association of tobacco control policies on smoking prevalence and quit ratios among 27 EU countries	Observational, ecological, and cross-sectional	Independent variable, original data, total score and by components	In EU27, countries with higher scores in the TCS has lower prevalence of smokers, higher quit ratios, and higher relative decreases in their prevalence of smokers over the last decade	The TCS does not score the level of enforcement except for smoke-free policies and the score may not fully reflect tobacco control policies implemented in subsequent years. The ranking of countries according to TCS scores has been relatively consistent across different editions	Advocacy and research
Diez-Izquierdo et al. ⁷ 2018, Spain	To evaluate the correlation between tobacco control policies and the prevalence of preterm births and low birthweight in the European countries	Observational, ecological, and cross-sectional	Independent variable, original data, total score and by components	The TCS score negatively correlated with the prevalence of preterm births for <37 weeks and <32 weeks and the prevalence of low birthweight (<2500 g) in European countries in 2010	No limitations reported about Advocacy the TCS as a variable	Advocacy
Lidón-Moyano et al. ¹⁸ 2018, Spain	To describe the acceptability of some tobacco product regulations and to explore their relationship with tobacco control legislation levels in Europe	Observational, ecological, and cross-sectional	Dependent and independent variable, original data, total score and by components	Strong support for tobacco product regulations was observed. A positive relationship was found between TCS scores and support for tobacco product regulations at both the ecological and individual level	No limitations reported about the TCS as a variable	Research

Table 2. Continued

	t Advocacy	t Research	t Advocacy	Advocacy
	No limitations reported about Advocacy the TCS as a variable	No limitations reported about the TCS as a variable	No limitations reported about Advocacy the TCS as a variable	The 2-year gap between the measure of the TCS and the Eurobarometres survey does not allow detection of the effect of measures adopted between 2010 and 2012
Main results	Larger differences between median and minimum cigarette prices were associated with increased rates of infant mortality. Median price intreases during the study period were associated with 9208 fewer infant deaths, but a further 3195 infant deaths could have been avoided if no price difference was observed between minimum- priced and median-priced cigarettes	40.0% and 41.5% of respondents reported seeing any e-cigarette and tobacco product advertisement within the past year. Smokers, males, younger respondents, those with financial difficulties, people who had tried e-cigarettes, and daily internet users were more likely to report it. Respondents in countries with more comprehensive advertising bans were less likely to self- report exposure to any tobacco, but not to e-cigarette advertisements	No decrease in smoking in countries that introduced sales restrictions for minors (2007–2011) compared to countries that introduced these restrictions earlier before 2020). Sales restrictions were associated with a stronger decrease in perceived ease of the obtainability of cigarettes. The results were similar for adolescents of high and low socio-economic position	An inverse correlation between TCS score and prevalence of smoking of conventional cigarettes and a positive correlation with the intent to quit smoking within the past 12 months. The correlation between TCS and secondhand smoke (SHS) exposure at work was negative. Significant negative correlation between TCS score and the prevalence of having ever tried a waterpipe
Lse of TCS (Type of variable, original data, total and components score)	Independent variable, original data, only by components score	Independent variable, original data, only by components score	Independent variable, original data, total score by components	Independent variable, original data, total score and by components
	Observational, ecological, and longitudinal	Observational, multilevel, and cross-sectional	Experimental, multilevel, and cross-sectional	Observational, ecological, and cross-sectional
Objective	To examine associations between median cigarette prices, price differentials between cigarette brands, and infant mortality	To explore factors associated with self-reported exposure of the EU population to tobacco products and electronic cigarette advertising	To estimate the impact of introducing Experimental, Independent sales restriction laws in European multilevel, and variable, orig settings and to test whether the cross-sectional data, total sc impact of the laws differed between components adolescents of high and low socio-	Lidón-Moyano To analyze the correlation between et al. ¹² the implementation of tobacco 2017, Spain control policies and tobacco consumption, particularly rolling tobacco and e-cigarettes, and the intent to quit smoking in 27 countries of the EU
Reference, location	Filippidis et al. ²² 2017, UK	Filippidis et al. ²⁴ 2017, UK	Kuipers et al. ²³ 2017, the Netherlands	Lidón-Moyano et al. ¹² 2017, Spain

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Table 2. Continued

Allen et al. ³⁵ 2016, UK	To evaluate the potential effectiveness of maximizing the TCS score for the UK using a model artified by a scoio-economic circumstances and to illustrate health improvements associated with reduced smoking prevalence	Observational, ecological, and longitudinal	Independent variable, not original data, only total score	Improvements in tobacco control policies towards maximum TCS score could substantially reduce smoking prevalence and reduce health-related inequalities	Implementation was not considered	Advocacy
Ferketich et al. ¹ 2016, USA	To determine the relationship between the TCS score and the prevalence of in-home smoking bans and beliefs on other tobacco control policies	Observational, multilevel, and cross-sectional	Independent variable, original data, total score and by components	The TCS score was correlated with the prevalence of in- home smoking bans. Four of the individual contributions to the TCS scale (price, public campaigns, smoking bans and health warnings) were significantly related to in- home smoking bans	No limitations involving the use of TCS	Advocacy and research
Pförtner et al. ¹⁰ 2016, Germany	To address to what extent different measures of the TCS are associated with smoking in adolescence in 29 European countries and how the association between tobacco control policies and smoking varies by family affluence	Observational, multilevel, and cross-sectional	Independent variable, original data, only by components score	Tobacco control policies did not strongly interact with Family Affluence Scale (FAS) predicting adolescent smoking. For boys, prevalence of smoking decreased with higher tobacco price regardless of the socio-economic background. For girls, no difference was found in smoking prevalence by FAS	a. The limited number of observations at country level and the low variance of some tobacco policies aeross countries may reduce the robustness of parameter estimates; b. Analyzed data from the TCS has changed since 2006	Advocacy and research
Filippidis et al. ¹⁵ 2016, UK	To explore whether exposure to SHS among non-smokers in the EU showed any association with sociodemographic factors and/or the extent of national tobacco control policies	Observational, Independent multilevel, and variable, orig cross-sectional data, total sc and by comp	Independent variable, original data, total score and by components	29.0% of non-smoking participants reported being exposed to SHS in indoor areas. Males and individuals with difficulties paying bills had significantly greater odds of being exposed. For every unit increase of a country's score on the Smoke-free Component of the TCS, the probability of reporting exposure to SHS increased in bars, restaurants, and workplaces	No limitations reported about Advocacy the TCS as a variable	Advocacy

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Table 2. Continued

Conclusions	Advocacy and research	Advocacy	Advocacy	Advocacy and research	Advocacy
	No limitations reported about Advocacy the TCS as a variable and resea	No limitations reported about Advocacy the TCS as a variable	No limitations reported about Advocacy the TCS as a variable	No limitations reported about Advocacy the TCS as a variable and resea	No limitations reported about Advocacy the TCS as a variable
	No correlation was found between the implementation of smoke-free legislation at work and in public places and an increase in prevalence of smoking in private venues in the EU. More developed smoke-free policies positively correlated with a high prevalence of smoke-free houses	Light smokers are less likely to have houses and cars in which smoking is allowed, to have visited drinking or eating establishments that allow smoking, and to be systematically exposed to tobacco smoke in the workplace	Eastern European parents were about twice as likely to smoke near their children as those in Western Europe. Current maternal smoking prevalence was similar. A strong relationship was observed between parental education, tobacco control policies, and smoking near the child	Smokers in EU countries with higher TCS scores are more concerned about the effect of smoking. Support for tobacco policies is higher in countries with more concerned smokers	Dependent variable, Smoking prevalence was significantly higher in countries original data, with higher scores for corruption, material deprivation, total score and by and gender inequality, and lower in countries with higher gross domestic product per capita, social spending, life satisfaction, and human development scores
	Observational, Independent ecological, and variable, original cross-sectional data, total score and by components	Observational, Independent multilevel, and variable, original cross-sectional data, only total score	Independent variable, original data, only total score	Observational, Dependent and ecological, and independent cross-sectional variable, original data, only total score	
	Observational, ecological, and cross-sectional	Observational, Independent multilevel, and variable, orig cross-sectional data, only to score	Observational, multilevel, and cross-sectional	Observational, Dependent ar ecological, and independent cross-sectional variable, origi data, only tot score	Observational, ecological, and cross-sectional
	To evaluate the correlation between the implementation of tobacco control policies and smoking prevalence in private venues in the 27 countries of the EU	To investigate the relationship between the number of cigarettes smoked daily and habits and beliefs concerning passive smoking	To ascertain patterns of parental smoking in the vicinity of children in Eastern and Western Europe and their relation to TCS scores	To examine how a country's level of tobacco control is associated with markers of denormalization of smoking, smoking prevalence, and societal support for tobacco control	To test the hypothesis that smoking prevalence is higher in countries with high levels of public sector corruption and explore the ecological association between smoking prevalence and a range of other national characteristics in current EU Member States
Reference, location	Martínez- Sánchez et al. ¹⁴ 2014, Spain	Rughinis et al. ¹⁹ 2014, Romania	Kovess et al. ¹⁶ 2013, France	Willemsen et al. ²⁰ 2012, the Netherlands	Bogdanovica et al. ²⁵ 2011, UK

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Table 2. Continued

Objective Study design Use of TCS (Type of variable, original data, total and components score)
To describe the correlation between Observational, Independent the TCS and smoking prevalence, ecological, and variable, original self-reported exposure to SHS, cross-sectional data, total score and attitudes towards smoking and attitudes towards smoking the EU
To explore the relationship between Observational, Dependent variable, The Carbone monoxide concentration decreased with the SHS exposure and the strength multilevel, and original, data only strength of tobacco control policies, as scored by the TCS of national-level tobacco control cross-sectional total score in a large non-smoker European population policies
To investigate smoking policies in 29 Observational, Independent European countries in relation to the multilevel, and variable, original national smoking prevalence among cross-sectional data, total score young people and by components
To examine the extent to which Observational, Independent tobacco control policies correlate ecological, and variable, original with smoking cessation cross-sectional data, total score and by components

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Table 3. Main characteristics of the studies that used the TCS from a secondary source and estimated the scores of the countries using TCS methodology (N=10)

	No limitations reported about Research the TCS as a variable	No limitations involving the Research use of TCS	No limitations involving the Advocacy use of TCS	No limitations reported about Advocacy the TCS as a variable and research
	f ant		~	uit ed
	ta, only	Independent A 10-point increase in the TCS score was associated with variable, not a drop in the probability of smoking by 1.1 percentage original data, points (not significant). Pricing and smoke-free policies total score and by were significantly associated with smoking components	Independent An association was found between tobacco control variable, not policies and smoking cessation among higher educated original data, smokers. In middle- and high-educated smokers, policies total score and by were also associated with a decrease in smoking intensity components	Independent Progress in tobacco control policy in the Netherlands variable, not was significantly associated with an increase in the quit original data, only ratios (2001–2011) but were not significantly associated
Study design L (Typ ori total total	Observational, Independer multitevel, and variable, nc longitudinal original da total score	Observational, Indep multilevel, and variat longitudinal origin total : comp	Observational, Indep multilevel, and variat longitudinal origin total: comp	Observational, Indep multilevel, and variat longitudinal origin
	To describe changes in smoking prevalence over time within EU member states from 2009–2017; to describe how within-country and between-country variations in the implementation of tobacco control policies are associated with current smoking in individuals; and to describe how these variations affect individuals of different socio- economic positions.	To evaluate the impact of tobacco control policies on smoking among older adults in Europe from 2004– 2013	To assess whether tobacco control policy was associated with socio- economic inequalities in smoking across the EU in the period 2006– 2012	To assess whether developments in tobacco control policy in the Netherlands were associated with
Reference, location	So et al. ²⁶ 2019, UK	Serrano- Alarcón et al. ²⁷ 2019, Portugal	Bosdriesz et al. ³¹ 2016, the Netherlands	Bosdriesz et al. ³² 2015, the

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Table 3. Continued

	Research	Research
	 a. TCS score sometimes fails to express the degree to which policies are enforced; b. some policy areas could not be quantified readily; c. not able to include each separate measure of the TCS in its own right 	No limitations reported about Research the TCS as a variable
	ations in the progress of Observational, Dependent variable, Progress in tobacco control policy development in Europe a. TCS score sometimes fails of policy development ecological, and not original, only by was not uniform. Consistent progress was observed to express the degree to to identify whether the longitudinal components score in several areas but was lacking in tobacco prices and which policies are enforced; to identify whether the longitudinal components score in several areas but was lacking in tobacco prices and which policies are enforced; to edecomposed into be quantified readily; c. not able to include each separate measure of the TCS in its own right	Great progress in the development of tobacco control policy has been achieved in Lithuania. This progress was associated with an increase in smoking cessation. This
stury uesign Cocent Los (Type of variable, original data, total score and/or components)	Dependent variable, not original, only by components score	Independent variable, not original data,
	Observational, ecological, and longitudinal	Observational, ecological, and longitudinal
	ations in the progress of ol policy development to identify whether the or de decomposed into rns or components	te association between Observational, Independent ol policies and trends ecological, and variable, not ssation in Lithuania in longitudinal original data,

Reso	Rese	Adv and	Adv	Adv and	
 a. TCS score sometimes fails to express the degree to which policies are enforced; b. some policy areas could not be quantified readily; c. not able to include each separate measure of the TCS in its own right 	No limitations reported about the TCS as a variable	The TCS used in the current study contains five domains of tobacco control, not all of which may be as likely to affect adolescent smoking	The TCS contains little information on their enforcement in practice	 Potential measurement error; b. inadequate accuracy and conparability of data; c. the estimates could have been affected by exchange rate fluctuations 	
Observational, Dependent variable, Progress in tobacco control policy development in Europe ecological, and not original, only by was not uniform. Consistent progress was observed longitudinal components score in several areas but was lacking in tobacco prices and smoking cessation support	Great progress in the development of tobacco control policy has been achieved in Lithuania. This progress was associated with an increase in smoking cessation. This association was stronger among younger than older people	Adolescent smoking prevalence rates were higher among low-SES respondents than their high-SES peers. Stronger national-level tobacco control policies were associated with lower odds of daily smoking	An association was found between left-wing government and TCS over the period 1996–2003, but not over the whole studied period (1996–2010). The association between povernment effectiveness and TCS was significant and negative over the whole period, but positive between 2001 and 2005	The estimated TCS score for Armenia for smoke-free public places, advertising ban, health warnings, and treatment are below the European average (2005-2007). However, the score estimate for price and public spending are above average	
Dependent variable, not original, only by components score	Independent variable, not original data, total score and by components	Independent variable, not original data, only total score	Dependent variable, not original, total score and by components	Dependent variable, not original, total score and by components	
	Observational, ecological, and longitudinal	Observational, multilevel, and cross-sectional	Observational, ecological, and longitudinal	Observational, ecological, and cross-sectional	
To assess variations in the progress of tobacco control policy development in Europe and to identify whether the variations can be decomposed into specific patterns or components	To evaluate the association between tobacco control policies and trends in smoking cessation in Lithuania in 1994–2010	To examine the association between tobacco control policies and adolescent smoking, and to investigate the differences in this association between adolescents of high and low socio-economic status (SES)	To provide insight into the role of political factors in the development of tobacco control policy over time	To measure the 5-year progress in the implementation of FCTC in Armenia	
Bosdriesz et al ³⁰ 2015, the Netherlands	Klumbiene et al. ²⁹ 2015, Lithuania	Kuipers et al. ²⁸ 2015, the Netherlands	Bosdriesz et al. ⁶ 2015, the Netherlands	Movsisyan et al. ³³ 2014, Armenia	

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and infant mortality²², the effects of sales restriction laws on adolescents²³, and the factors associated with exposure to tobacco and e-cigarette advertising²⁴. One study assessed the association between smoking prevalence and public sector corruption and other national characteristics²⁵. The main characteristics and results of each article are given in Table 2.

Articles using TCS methodology to compute new scores As shown in Table 3, ten studies calculated new scores to measure tobacco control policies at a country level in a particular year using the TCS rationale and methodology instead of the original TCS. Most of these studies used data from European countries with a longitudinal design aimed at assessing the association between tobacco control policies and smoking^{6,26,27} and socio-economic inequalities outcomes in adolescents²⁸ or adults over time²⁹⁻³¹, or to examine political factors that drive tobacco control policy development³². According to the type of data, these publications were half ecological and half multilevel studies.

Two publications computed scores for non-European countries to monitor their tobacco control policy implementation by using the same rationale and methodology. These publications were aimed at measuring the progress after implementation of the WHO-FCTC in Armenia³³ and providing an overview and comparing the tobacco control progress in Eastern Mediterranean countries³⁴. The main characteristics and results of each study are shown in Table 3.

Main limitations of the TCS mentioned by the studies Only 11 (34.4%) of all publications included comments on the limitations of using the TCS score as a tool to assess tobacco control policies. The main limitations reported by the studies were that they failed to express the degree to which legislative policies are enforced^{6,32,35}, except for the smoke-free policies⁴. Another limitation is that the countries' rankings have only slightly changed over the years (i.e. the UK has remained in the top position from 2007 to $2016)^4$. This low variance across countries may reduce the robustness of the results of the studies¹⁰. Moreover, some studies reported that the information described by the TCS score(s) does not incorporate the most recent national legislation on tobacco control due to its cross-sectional design¹³, potentially underestimating the impact of such countries and/or over time. Notably, Joossens and

policies when using the TCS¹¹.

Finally, among the studies not using data from the original TCS reports, the main limitations were that some policy areas could not be quantified accurately and that some of the policy components assessed by the TCS could not be included³⁴ because of potential error in the measurement of their estimates, and inadequate accuracy and comparability of the data³³.

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DISCUSSION

Our results reveal that the TCS has been used mostly in observational, cross-sectional studies with either ecological (country as the unit of analysis) or multilevel data (individual data from surveys as the first-level unit and TCS score by country as secondlevel aggregated information). The TCS score has been mainly used as an independent variable to explain the potential variation in outcomes (i.e. tobacco product use, exposure to SHS, attitudes towards legislation, etc.), and mostly employed in European countries, as these countries were the target of the TCS when it was created.

Interpretation of the results

This is the first attempt to assess all of the available publications that have used the TCS as a means to measure tobacco control policy implementation since it was developed in 2006. In addition, this is the first study to map out the characteristics of the use of the TCS in scientific research, to understand how this tool has been applied despite its original design as a means to advocate for comprehensive tobacco control policies. Therefore, our findings suggest that the TCS has commonly been used as an indicator of the state of tobacco control policies in Europe

Almost all of the studies assessed tobacco control policies through the total TCS score, and most have used the policy components scores from the primary published reports. The policy components most commonly studied were public smoking bans and tobacco product advertising bans, possibly because they are two of the measures that have been most frequently regulated in Europe since the WHO-FCTC came into force in 2005³⁶.

Another important issue to address is the crosssectional and temporal comparability of the TCS because most of the studies make comparisons across

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across each report. However, these scores are not comparable across years because these standards have changed over time (i.e. the weighted average price for cigarettes was $\in 8.5$ in 2013 and $\in 10$ in 2016, considering the EU average Purchasing Power Standard)^{37,38}; on the other hand, the scale (i.e. Eurostat) and the Civil Society. methodology and scoring system changed between 2007 and 2010³⁹. Consequently, longitudinal studies to ensure temporal comparability between and within countries require adjusting scores to the highest standards by an escalation process and re-calculating major limitations, including difficulties in assessing scores from the 2005 and 2007 reports using the newest scoring system and methodology.

Raw⁵ designed the scale to compare tobacco control

policies across countries at a particular time point.

Thus, the reference values for scores are sustained

Importantly, most of the studies with a longitudinal design conducted in Europe have adapted the scale rationale and methods to estimate the level of implementation of tobacco control policies to ensure the temporal comparability and include data about years for which the TCS had not been published^{26,27,29,31,32}. Few non-European countries have adapted the scale as a proxy to monitor the status of tobacco control policies in non-European countries^{33,34}. Unfortunately, most of these studies did not clearly explain how they adapted the TCS to estimate new score(s) for each policy component. Therefore, new studies should provide a full description of their adaptation process and the potential limitations and strengths not only to ensure its replication, but also to further develop strategies to adapt the TCS to other contexts overseas.

These results highlight that the TCS, regardless of its limitations, has been applied as an objective indicator to measure the strength of the implementation of tobacco control policies at the country level. Other been commonly used in Europe over the last studies have used a total score obtained from summing the scores (from 1 to 5) assigned to each MPOWER policy dimension in the WHO's Reports on the Global Tobacco Epidemic^{40,41}. MPOWER's composite score has some clear advantages over the TCS total score because it is available for all countries, not only the tobacco control research field. This is supported European countries, and is comparable over time. by the fact that the publications conducted by these However, this proxy also has some disadvantages three research groups have received a higher number for research purposes. First, it assigns the same weight to each of the six individual MPOWER scores without taking into consideration that some MPOWER measures have been proven to be more effective than

other measures (i.e. taxation). Second, MPOWER's composite score has a narrower score range than the TCS score (6-29 vs 0-100, respectively), which limits variation across countries and may make it difficult to address variability between countries. Finally, unlike the MPOWER composite score, the TCS score is not affected by the government's political agenda, as the TCS is built on information from objective databases

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More than 65% of the reviewed publications did not report any limitation of the TCS as a proxy for measuring tobacco control policies. Nonetheless, Joossens and Raw⁵ already reported some of its enforcement versus implementation and its critical dependence on tobacco control experts' judgement when scoring⁵. Therefore, such underreporting of limitations makes it difficult to fully describe the limitations that researchers encounter, which is indispensable to moving forward in the field. Among the articles reporting limitations, most of them highlighted the fact that the TCS score(s) did not measure the enforcement of policies except smokefree policies. In this sense, no previous studies have examined the disparity between the implementation and enforcement of tobacco control policies; however, the TCS being predictive of so many outcomes suggests that the implementation of these policies is a good proxy of enforcement. In addition, some studies have questioned the ability of the TCS to incorporate new policies, such as smoke-free outdoor policies, indicating that the authors of the TCS should discuss how to incorporate these new tobacco control policies and which weight they should have in the scale.

Moreover, our study shows that the TCS has decade, but three research groups from Spain, the Netherlands, and the UK account for more than half of the publications using the TCS for research purposes. This suggests that these groups have led and consolidated the use of this monitoring tool in of citations, including a paper¹³ with 54 citations and another paper²³ with 103 citations (in Web of Science) up to December 2019.

More than half of all publications directed their

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conclusions towards advocacy for improving tobacco control policies. Therefore, most authors find the TCS useful for linking data to policy action, even though the TCS has been commonly used for research purposes. Therefore, the TCS has not lost its intended original purpose for advocacy, as it was developed to detect areas of improvement within each country and to establish comparisons among countries through a ranking, in order to motivate governments to strengthen their weakest polices⁵.

Our results indicate that, despite its potential limitations and lack of a formal validity assessment, the TCS is a good proxy of the strength of tobacco control policies implementation, or at least the best approximation developed so far. However, the TCS has been used at face-value. No attempts have been made to formally validate the scale. Construct validity of the TCS is a complex issue given the composite structure of the TCS itself, though some dimensions are based on objective data (i.e. price and SHS exposure) from population-based surveys and reports of the European Commission: others are based on the answers of one or two informants to an ad hoc questionnaire (i.e. cessation budget at national level)⁵.

Limitations and strengths

Publication bias is a potential source of error when the units of the investigation are published papers⁴². We searched the available literature in PubMed, the main biomedical database, as well as Web of Science and Google Scholar, and checked all references to identify other articles not published in academic journals. However, the possibility that unpublished manuscripts or other documents addressing the topic of interest may have been missed cannot be ruled out, but it was an *a priori* decision made by the experienced research team that was composed of tobacco control and policy experts, including the author of the TCS. Under these circumstances, selection (publication) bias seems unlikely to have affected the study.

Other potential limitations of our study are linked to the fact that a high number of the publications analyzed here did not include any comment about the limitations and strengths of using TCS scores as a variable to monitor tobacco control policy implementation in research. This missed reporting has hindered the identification of the main limitations and strengths of this tool for different types of study

designs, outcomes, or statistical analysis; therefore, our study may have some missing information.

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However, our study is the first to assess all published articles using the TCS as an indicator of tobacco control policy implementation and to characterize its use in tobacco control research, giving a full and comprehensive overview of how and for which purposes the TCS has been employed in previous studies. This study also presents information on how to best use the TCS as described by the authors in the Limitations sections of the publications. Thus, our study presents the lessons learned from previous research, creating an opportunity for researchers to plan to use the TCS to improve the quality of future studies.

CONCLUSIONS

This study shows that the TCS has been commonly used in observational, mostly ecological, studies to assess variations in a concrete outcome according to the policies instituted in Europe as a proxy of tobacco control implementation. In addition, the TCS has been employed to detect changes in individual and population outcomes (i.e. smoking prevalence or cessation) and establish conclusions about how policies have an effect in specific populations.

Our recommendations to researchers and policymakers planning to use the TCS in their future research are as follows. First, the TCS scoring methodology needs to be fully understood, as comparability is not ensured among countries across years. Second, researchers should consider a certain time gap between measuring the TCS score and the outcomes, as the TCS may not include the most recently adopted policies and policies need time to have an effect. Third, knowing the limitations of the TCS in measuring implementation (vs enforcement) of tobacco control policies is important. Fourth, researchers need to take into account the low variance of some tobacco control policies across countries, which may also reduce the robustness of the estimates.

A logical next step for future applications of the TCS in research would be to study the impact of tobacco control policy enforcement in terms of several indicators, such as prevalence, SHS, and tobacco sales, and to assess the impact of these policies at the population level. To achieve this goal, more extensive cross-country population-based surveys are needed to include new enforcement measures in future editions

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of the TCS (i.e. about compliance with smoke-free bans in public places differently than workplaces and hospitality venues, or about advertising, promotion, and sponsorship bans).

Finally, to gain a broader perspective of tobacco control as a public health need and build a stronger tool for tobacco research, we suggest adapting and extending the TCS to other countries of the WHO European Region, and to the reality of other regions of the globe, such as Latin America or Asia, incorporating local and cultural characteristics of these regions while preserving the comparability among countries worldwide.

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CONFLICTS OF INTEREST

The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none was reported.

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AUTHORS' CONTRIBUTIONS

Study design: AF, AB, CM, and EF. Collected data and prepared database for analysis: AF and AB. Contributed to strategy of analysis: AF, AB, CM, and EF. Analyzed data: AF. Interpreted data results: AF, AB, CM, LJ, MF, AP, and EF. Drafted manuscript: AF. Critically revised manuscript: All authors. Approved final manuscript version: All authors. Guarantors: EF and CM.

PROVENANCE AND PEER REVIEW

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Paper II

Impact of tobacco control policies on smoking prevalence and quit ratios in 27 European Union countries from 2006 to 2014

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6 **OPEN ACCESS**

Impact of tobacco control policies on smoking prevalence and guit ratios in 27 European Union countries from 2006 to 2014

Ariadna Feliu, ^{1,2,3} Filippos T Filippidis, ⁴ Luk Joossens, ⁵ Geoffrey T Fong, ^{6,7} Constantine I Vardavas, ^{8,9} Antoni Baena, ^{1,3} Yolanda Castellano, ^{1,3} Cristina Martínez, ^{1,3,10} Esteve Fernández^{1,2,3}

ABSTRACT Background Tobacco use is still highly prevalent in

European countries

models.

Europe, despite the tobacco control efforts made by

policies varies substantially across countries. The

the governments. The development of tobacco control

Tobacco Control Scale (TCS) was introduced to quantify

Objective To assess the midterm association of tobacco

control policies on smoking prevalence and guit ratios

among 27 European Union (EU) Member States (EU27).

Methods Ecological study. We used the TCS in EU27 in

2007 and the prevalence of tobacco and guit ratios data

2014 (n=26793)). We analysed the relationship between

from the Eurobarometer survey (2006 (n=27585) and

the TCS scores and smoking prevalence and guit ratios

and their relative changes (between 2006 and 2014)

Results In EU27, countries with higher scores in the

TCS, which indicates higher tobacco control efforts.

have lower prevalence of smokers, higher guit ratios

and higher relative decreases in their prevalence rates of

smokers over the last decade. The correlation between

P=0.02) and between the relative changes in smoking

correlation was observed between TCS scores and guit

ratios (r_=0.373; P=0.06). The percentage of smoking

comprehensive tobacco control policies as they are key

for reducing the prevalence of smoking and an increase

Tobacco remains the largest preventable health

hazard in European Union (EU), and it is respon-

sible for 700000 deaths a year.¹ Europe, despite

the decline of tobacco smoking prevalence over

the past decades,² has one of the highest smoking

prevalence among adults (28%).³ Comprehensive

tobacco control policies have shown to have an

The EU as a whole and its Member States (MS)

Conclusion EU27 should continue implementing

tobacco cessation rates in their population.

INTRODUCTION

prevalence explained by all TCS components was 28.9%.

prevalence (r_=-0.415; P=0.03) was negative. A positive

TCS scores and smoking prevalence ($r_{-}=-0.444$;

by means of scatter plots and multiple linear regression

the implementation of tobacco control policies across

published online only. To view please visit the journal online (http://dx doi.org/10 1136/ tobaccocontrol-2017-054119). For numbered affiliations see

Additional material is

end of article.

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EU MS.^{9 10} Thus, a variation in the extent to which smoking prevalence is decreasing in EU MS could be an indicator of commitment to tobacco control

Six cost-effective measures should be prioritised in comprehensive tobacco control programmes⁵ including taxes, smoke-free laws, public information, advertising bans, direct health warnings and access to treatment.¹¹ Increasing taxation on tobacco products is the most effective measure¹²; however, the evidence suggests that the best result is achieved when a comprehensive tobacco control policy is implemented.⁵ In a recent global study of 126 countries, analysing WHO data from 126 countries, the number of key demand-reduction WHO FCTC policies (MPOWER policies) implemented at the highest level was strongly associated with reductions in smoking prevalence from 2005 to 2015, the first decade of the treaty. Thus, there is promising evidence on the power of tobacco Similar results were found by Ngo et al,¹⁴ who examined the relationship between MPOWER scores and smoking prevalence changes reported by

This article assesses the relationship between the strength of key tobacco control policies and reductions in smoking prevalence using a different method, focusing specifically on that relationship across the EU MS. The Tobacco Control Scale (TCS), developed by Joossens and Raw to systematically monitor the implementation of tobacco control policies at country-level across Europe, has been used to chart overall progress in national-level tobacco control.¹⁵¹⁶ Previous studies in Europe have associated the implementation of tobacco control policies with attitudes towards smoke-free legislations, smoking behaviours and involuntary exposure to secondhand smoke.8 17 18 Those studies, however, did not examine the relationship between country-level tobacco control policies and the smoking prevalence and quit ratios considering adequate time-lag or the impact of the policies in the change of prevalence or quit ratios. Therefore, the objective of the present study was to evaluate the association between the implementation of tobacco control policies and smoking prevalence and quit ratios in 27 EU MS over time (2006-2014).

mented the recommended key tobacco control

impact on reducing smoking prevalence.4-6



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policies⁸ but with considerable differences across at the national level.¹⁰

control policies to reduce smoking prevalence.¹³ Euromonitor from 2007 to 2014.

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METHODS

Research paper

This is an ecological study with the EU MS as the unit of analysis. We used data from tobacco control activities, measured by the TCS proposed by Joossens and Raw.⁵ We used data from the 27 EU MS included in the 2007 TCS report (all current EU MS, except Croatia).¹⁹ The TCS provides a score for each country based on their national-level implementation of tobacco control policies according to the six most cost-effective policies.²⁰ Smoking status information was obtained from waves 66.2 and 82.4 of the Eurobarometer survey from 2006 and 2014, respectively.^{21 22} The Eurobarometer is a cross-sectional study of a representative sample of the adult population (≥ 15 years old) conducted by the European Commission in all the EU. The fieldwork was conducted in October-November 2006 and in November-December 2014 and included 27584 and 26793 respondents, respectively. The final samples were representative of the population aged 15 years and above in each country (about 1000 persons in each country except for Cyprus, Luxembourg and Malta, with approximately 500 respondents). The sample was weighted for sociodemographic variables. The Eurobarometer sampling methods and sampling size are consistent in all EU countries and in the different waves used ensuring that tobacco smoking indicators estimates do not differ between countries or years.²

Variables

Tobacco consumption

Smoking prevalence in 2014 was obtained from adult respondents answering 'I currently smoke' to the question 'Regarding smoking cigarettes, cigarillos, cigars or a pipe which of the following applies to you?' in wave 82.4.¹ Smoking prevalence in 2006 was obtained from the proportion of respondents who gave any of the answers 'You smoke packed cigarettes', 'You smoke roll-up cigarettes' or 'You smoke cigars or a pipe' to the question 'Which of the following applies to you?' in wave 66.2.²⁴

Tobacco cessation

Quit ratios were calculated as the ratio of former smokers divided by the number of ever-smokers (current and former smokers). Former smokers were respondents answering 'I used to smoke but now I have stopped' to the question 'Regarding smoking cigarettes, cigars, cigarillos or a pipe, which of the following answers applies to you?' Total ever-smokers were former smokers and respondents answering 'I currently smoke' at the preceding question from the Eurobarometer.

Tobacco control policies

TCS scores were used to assess the national-level implementation of tobacco control policies, using a scoring system developed by a panel of experts. The scale was developed by means of a questionnaire sent to European Network for Smoking and Tobacco Prevention correspondents in the participant EU MS. Hence, the six components of the TCS and their corresponding score are: price (30 points), public place bans (22 points), public information campaigns spending (15 points), advertising bans (13 points), health warnings (10 points) and treatment (10 points). This score increases with the strength of tobacco control policies up to a possible maximum of 100 points, indicating a full implementation for all strategies considered. The score of each of the six cost-effective policies was weighted by its reported effectiveness, judged by scientific evidence on tobacco control.^{5 20}

To eliminate missing values in public information campaign spending, we used the score from the previous TCS (2005) for

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this component assuming no change between 2005 and 2007 as 85% of the countries having values for both years only showed a ± 1 point variation in their score.

Statistical analysis

Age-standardised and sex-standardised smoking prevalence rates and quit ratios were calculated for each country by means of the direct method of standardisation using the European population of 2013 as the standard.

We graphically described the distribution of the prevalence rates, quit ratios and TCS scores across the EU MS. We analysed the association between the TCS score in 2007 (overall and by its six components) as independent variables and smoking prevalence rates and quit ratios in 2014 as dependent variables by means of scatter plots and Spearman rank correlation coefficients ($r_{\rm sp}$) and the corresponding 95% CIs. We considered this time-lag of 7 years sufficient to observe any impact of the tobacco control policies on prevalence. We also analysed the correlation between the relative changes in smoking prevalence rates and quit ratios from 2006 to 2014. The relative change expresses the absolute change as a percentage of the indicator in the earlier period. We used relative and not absolute change because baseline values of both indicators were different for each EU MS.

Finally, we performed a linear regression analysis to examine the association between each component of the TCS from 2007 (independent variables) and the smoking prevalence and quit ratios in 2014 and both smoking indicators relative changes from 2006 to 2014 (dependent variables). We also fitted a multivariable linear regression model adjusting for all component scores to assess their independent effect.

Diagnostic tests showed that the linear regression model was appropriate for the analysis with respect to the assumptions of linearity and normality of percentage point change in smoking prevalence in 2014 but not for homoscedasticity. We performed a logarithmic transformation of the data, but the model continued to not fulfil the assumption of homoscedasticity. However, we decided to fit the model assuming our model limitations as a result of the small sample size. For quit ratios, none of the linear regression conditions were met. We performed a logarithmic transformation, but the model continued unfulfilling the assumptions. Thus, we decided not to perform the linear regression model for quit ratios as the dependent variable. The analyses were performed separately for men and women and for six age groups (15-24, 25-34, 35-44, 45-54, 55-64 and ≥ 65 years) since tobacco control policies have shown a differential effect on smoking prevalence by sex and age in previous studies.¹⁵ ¹⁸ All tests of statistical significance were two sided, and P values less than 0.05 were considered statistically significant. Analyses were performed with Stata V.13.0 and SPSS V.20, incorporating the weights provided in the Eurobarometer dataset to account for the complex survey design.

RESULTS

In 2014, the prevalence of smokers was 25.4% (95% CI 23.3% to 27.6%) in EU27, varying from 12.6% in Sweden to 37.9% in Bulgaria (figure 1A). The prevalence of smokers in EU27 decreased by 13.9% (95% CI 7.3% to 20.6%) from 2006 to 2014, varying from a relative decrease of 48.9% in Sweden to 0.3% in Bulgaria. Three EU27 countries (France, Portugal and Slovenia) have however increased their prevalence of smokers during the last decade (figure 1B). In 2014, the quit ratio was 44.2% (95% CI 40.3% to 48.1%) in the EU27, varying from 73.2% in Sweden to 29.9% in Hungary (figure 1C). The quit

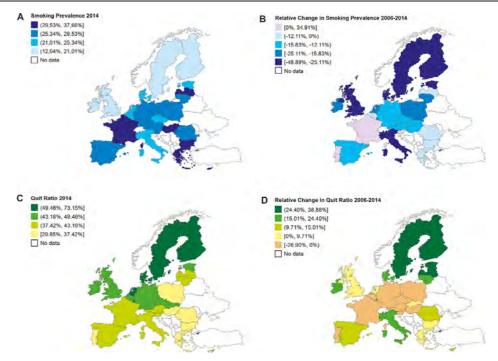


Figure 1 (A) Smoking prevalence in 2014, (B) relative change of the smoking prevalence from 2006 to 2014, (C) quit ratio in 2014 and (D) relative change of quit ratios between 2006 and 2014 in 27 European Union countries (EU27). For relative changes, intervals have been determined by quartiles from 0%.

ratio in EU27 has increased by 8.5% (94% CI 2.2% to 14.9%) from 2006 to 2014, varying from 38.9% in Latvia to 2.9% in Bulgaria. Some countries have decreased their quit ratio during the last decade (figure 1D), with the greatest decrease in Slovenia (26.9%).

In 2007, Austria was the EU MS with the lowest score in TCS (35), while the UK had the highest one (93) (figure 2). The EU MS that had higher scores in the TCS (UK, Malta and Sweden; scores ≥ 60) showed relatively low smoking prevalence (less than 12.5%) and higher quit ratios (over 49%). Those with lower scores in the TCS (Germany, Greece and Luxembourg; scores ≤ 40) had relatively high smoking prevalence (between 20.9% and 37.9%) and the quit ratios were relatively low (between 51.6% and 33.4%).

There was a moderate inverse association between TCS score and the prevalence of smokers in 2014 ($r_{r_{e}} = -0.444$, 95% CI -0.71 to -0.08; P=0.02; figure 3A; table 1) and a moderate direct association between TCS scores and the relative change in smokers' prevalence in EU27 from 2006 to 2014 (r_=0.415, 95% CI 0.04 to 0.69; P=0.03; online supplementary table S1) (figure 3A). Higher TCS scores in 2007 correlated with lower prevalence of smokers in 2014, being stronger among men (r = -0.512; P < 0.01), adults aged 25-34 years-old (r = -0.414;P=0.03). By the individual TCS components, higher scores on public places bans ($r_{ee} = -0.439$; P=0.02) and health warnings ($r_{p} = -0.414$; P=0.03) were the ones better correlated with the smoking prevalence in 2014 (table 1) in EU27. Price was the component with the lowest correlation ($r_{1} = -0.181$; P=0.37) (table 1). TCS scores and higher changes on tobacco smoking rates were highly correlated among men ($r_{m}=0.399$;

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P=0.04) and among adults aged >65 years old (r_{sp} =0.551; P<0.01). By components, higher TCS scores on public places bans (r_{sp} =0.502; P<0.01) and treatment (r_{sp} =0.564; P<0.01) correlated with higher changes in 2006–2014 on smoking prevalence (online supplementary table S1) in EU27.

There was a moderate non-significant direct association between TCS scores and quit ratios in 2014 (r = 0.373, 95% CI -0.01 to 0.66; P=0.06; figure 3B, online supplementary table S2) and a low non-significant direct association between TCS scores and changes in the quit ratios in 2006-2014 (r = 0.278, 95% CI -0.11 to 0.60; P=0.16; figure 3B, online supplementary table S3). Higher overall TCS scores correlated with higher quit ratios in 2014. This correlation was higher among men (r = 0.524; P<0.01) and among adults aged > 65 years old $(r_{p}=0.501; P<0.01)$. By TCS components, scores on public place bans ($r_{en}=0.364$; P=0.06) and health warnings ($r_{en}=0.377$; P=0.05) were those better correlating with higher quit ratios; however, both associations were non-significant (online supplementary table S2). TCS scores and higher changes on quit ratios were highly correlated among adults aged >65 years old $(r_{-}=0.398; P=0.04)$ and, by TCS components, scores on public place bans ($r_{p} = 0.505$; P<0.01) were those better correlating with higher relative changes in quit ratios from 2006 to 2014 (online supplementary table S3).

The unadjusted linear regression models for each TCS component showed that none of them explained more than 20% of the smoking prevalence in 2014 in Europe. As shown in table 2, in the linear regression model simultaneously adjusted for all TCS components, none of the components was statistically significantly associated with the smoking prevalence in 2014. The

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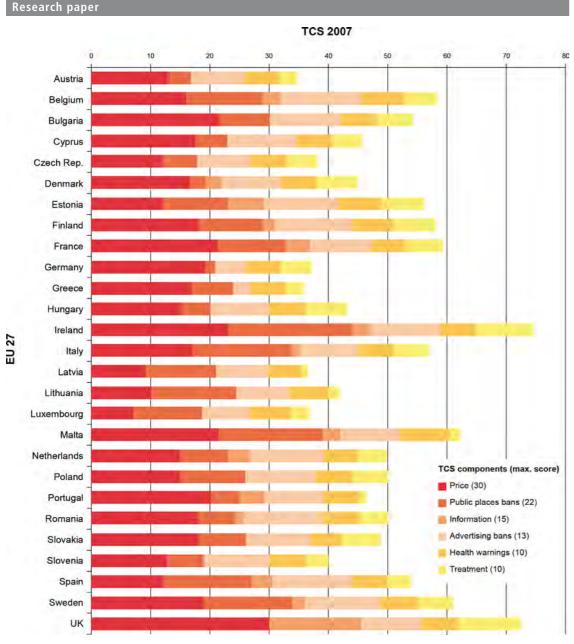


Figure 2 Tobacco Control Scale (TCS) total scores by its components in 2007 for the 27 European Union countries.

percentage of the smoking prevalence explained by the model was 28.9% (P=0.279). In men, the percentage of the smoking prevalence explained by the model was 31.1% (P=0.227) and was 23.0% (P=0.455) in women.

DISCUSSION Main findings

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A higher implementation of tobacco control policies as indicated by higher TCS scores in 2007 was associated with a lower prevalence of smokers among the EU population both in 2014 and with changes in prevalence across the whole period (2006–2014). Similarly, higher TCS scores in 2007 were moderately associated with higher quit ratios in 2014; however, no association was found when correlating TCS scores with changes in quit ratios across the whole period.

Interpretation of results

The individual TCS components that showed a higher association with both a lower smoking prevalence and higher quit ratios in 2014 were public places bans and health warnings. A

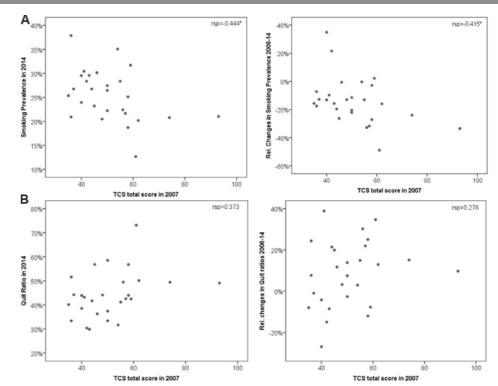


Figure 3 (A) Correlation between Tobacco Control Scale (TCS) total scores in 2007 and the smoking prevalence in 2014 (left) and the relative changes of smoking prevalence between 2006 and 2014 (right) in the EU27. (B) Correlation between TCS total score in 2007 and quit ratios in 2014 (left) and the relative change of quit ratio between 2006 and 2014 (right) in the EU27. *P<0.05. EU, Europen Union; rsp, Spearman's rank correlation coefficient.

study conducted in Europe also found a correlation between the level of smoke-free legislation among European countries and a decrease in the prevalence of smoking of cigarettes and an increase in the previous intent to quit smoking in the past months,²⁵ in agreement with previous conducted research.²⁶ The results of the present study are consistent with those of other studies, which demonstrated the positive impact of number of highest level implementations of MPOWER measures on reducing smoking prevalence over time.¹³ ¹⁴ Additionally, our study is a further advance over these previous studies since it does show the association between tobacco control policies implementation on smoking prevalence and on tobacco cessation through quit ratios.

It is possible that the countries that adopt tobacco control policies are those in which smoking has lost its social acceptance favouring a decline in the smoking prevalence. Our data indicate, however, that tobacco control policies matter. Therefore, we cannot exclude a two-way phenomenon as those countries with favourable secular trends in smoking should be more prepared to implement and enforce tobacco control policies. There are also indicators that the policies may precede the decline in smoking prevalence. For example, in the UK, the low prevalence at the beginning of 2000s derive from a steady decline observed since the early 1970s, directly linked to the increase in the price of tobacco through taxation.²⁷ Another example is the case of Spain, where the prevalence of smoking was high (about 70% in males aged 45–64 years) in the 1980s in the absence of strong

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tobacco legislation, and once legislation was enforced and new tobacco control policies were implemented in the late 1990s, we observed a steady decline of the prevalence of smoking among males and a level-off of the prevalence in females.²⁸

Tobacco tax and price increases are proven to be the fastest acting and most effective measures of all.¹³ ²⁹ ³⁰ However, our study shows only a low correlation between TCS price scores and tobacco smoking prevalence. Such results could be explained by the lack of variability among countries of the EU27 scores in this component, as 70% of their scores are between 11 and 19 points.⁵ Moreover, the smoking prevalence in these countries in 2014 did not differ much either, since also about 70% of them had a prevalence rate between 20% and 29%.

Other explanations include, first, the increase in the proportion of roll-your-own (RYO) over the past few years, particularly among young people, that have been attributed to a raise on the price of manufactured tobacco^{31–33} combined with the sustained cheaper prices for RYO. Therefore, our results could be underestimating the effect of price on smoking prevalence. While the TCS did not take into account RYO cigarettes to score the implementation of tobacco taxation policies,⁵ the smoking prevalence did include RYO smokers and not only manufactured ones.²³ Second, these results could be explained by an attenuation of the long-term effect of an increase on tobacco price. A study conducted in Australia showed that despite the increase in quitting activity in the months immediately after the tax increase, quitting activity fell back to previous levels after 3 months.³⁴

Research paper

Spearman's rank correlation coefficients (rsp) and 95% CI between TCS scores in 2007 (overall and individually for its six components) and smoking prevalence in 2014 in total and by sex and

Treatment -0.323 (-0.626 to 0.064)

ings Health warning: -0.414 (-0.686 t

(-0.631 to 0.057)

Advertising bans -0.330 (-0.631 to 0 0.093

to 0.121)

-0.272 (-0.591

to 0.070)

(-0.525 to 0.213)

Price

0.444 (-0.705 to

TCS

Table 1 S age groups

Public places bans -0.439 (-0.702 to 0.

170

0.394 (-0.673 to -0.117)

0.047)

0.419 (-0.631 to

-0.331 (-0.631 to 0.057)

to -0 039

0.413 (-0.685

0.416 (-0.687 to -0.043) 382 (-0.666 to -0.003)

-0.279 (-0.596 to 0.113)

0.512 (-0.746 to -0.163)

(-0.263 to 0.486)

(-0.544 to 0.188)

517

.032

.098 (-0.461 to 0.293)

.211 (-0.547 to 0.184)

0.245 (-0.572 to 0.149)

015 (-0.367 to 0.393)

0.218

029 291

628

0.394 (-0.673 to -0.017)

).354 (-0.647 to 0.030)

0.278 -0.230 (-0.561 to 0.165)

0.217 (-0.551 to 0.178)

0.300 (-0.610 to 0.091) 178 (-0.523 to -0.216)

0.325 (-0.628 to 0.062) 069 (-0.438 to 0.319) 0.157 (-0.506 to 0.238) 0.246 (-0.572 to 0.148) 0.263 (-0.584 to 0.130)

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0.291 (-0.604 to 0.100) 0.183 (-0.526 to 0.212) 0.361 0.003 (-0.377 to 0.383) 0.987

0.377 (-0.662 to 0.004) -0.351 (-0.645 to 0.033)

183 (-0.527 to 0.211) 0.271 (-0.591 to 0.121)

0.378 (-0.663 to 0.002) .287 (-0.601 to 0.105) 0.293 (-0.605 to 0.098)

).195 (-0.535 to 0.200) 192 (-0.533 to 0.203)

0.357 (-0.649 to 0.027)).338 (-0.636 to 0.048) 0.355 (-0.647 to 0.029)

0.148 (-0.500 to 0.246)

6

0.073 -0.169 (-0.516 to 0.225) 0.399

0.171 -0.393 (-0.672 to -0.015)

043

0.300 (-0.610 to 0.091)

0.191 (-0.532 to 0.204)

0.238 (-0.567 to 0.156)

0.501 (-0.740 to -0.149)

0.112 (-0.472 to 0.280) .358 (-0.650 to 0.026) .377 (-0.662 to 0.004)

.094 (-0.458 to 0.297)

0.287 (-0.602 to -0.104)

148 (-0.500 to 0.246)

.414 (-0.686 to -0.040)

011 (-0.371 to 0.389)

288 (-0.602 to 0.103)

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Table 2 Adjusted linear regression analysis examining the association between each component of the TCS in 2007 and the smoking prevalence of 2014 in 27 EU countries

TOBACCO CONTROL IN EUROPE AND LATIN AMERICA

	Price	Public places bans	Information	Advertising bans	Health warnings	Treatment	
Prevalence 2014	β (SE)	β (SE)	β (SE)	β (SE)	ß (SE)	ß (SE)	_
R ²							
Total	0.060 (0.249)	-0.263 (0.249)	0.006 (0.446)	-0.630 (0.537)	-1.095 (0.522)	-0.444 (0.556)	0.2893
P value	0.812	0.304	0.990	0.254	0.732	0.434	0.279
Sex							
Male	-0.090 (0.356)	-0.291 (0.358)	-0.121 (0.639)	-0.551 (0.769)	-2.641 (2.408)	-0.872 0.796)	0.3111
P value	0.804	0.426	0.852	0.482	0.286	0.286	0.227
Female	0.210 (0.220)	-0.236 (0.220)	0.133 (0.394)	-0.709 (0.474)	0.451 (1.484)	-0.015 (0.491)	0.2300
P value	0.352	0.297	0.740	0.151	0.764	0.976	0.455

EU, European Union; TCS, Tobacco Control Scale

Third, legal cross-border shopping and illicit trade could be also responsible at some extent of the attenuated effect of price on smoking prevalence since it might increase the affordability of tobacco products, mainly cigarettes, while it counteracts the governmental tax increases³

A study in 18 European MS found a positive association between the quit ratios and TCS score.¹⁵ Our study shows a direct but not statistically significant correlation between TCS score and quit ratios: however, no association was found with changes in quit ratios across the whole period. Lower associations between tobacco control policies and quit ratios could be explained because quit ratios may represent a less sensitive measure to monitor tobacco use among certain populations compared with tobacco smoking prevalence because of changes in the denominator per each measure or the different stages of the tobacco epidemic.³

Limitations and strengths

This is an ecological study, and consequently, any causal relationship between tobacco control policies and the outcomes assessed (smoking prevalence and quit ratios) is difficult to establish. However, the results of our study are in agreement with other studies showing a reduction in smoking prevalence and an increase in quit ratios after passing tobacco control policies.^{8 15 37} We are not trying to infer the relationship at the individual level but simply assessing an ecological effect. Other limitations of our study are the reduced number of EU MS introduced in the analysis as it reduces the statistical power and the lack of information about the stage of the tobacco epidemic across the different countries.³⁷ However, we have been able to study the correlations in separate strata of sex and age, since we computed the prevalence rates and quit ratios from the original Eurobarometer database. This information could help to better understand the relationships studied rather than using the crude prevalence and quit ratios estimates.

The use of self-reported data from questionnaires could be a source of bias, although self-reports on smoking status have acceptable validity.³⁸ The small sample size in each EU MS could be another limitation. However, the sample design of the Eurobarometer guarantees the representativeness by country.¹ Given the limited sample size (n=27 countries), the correlation coefficients could be also affected by some outlier observations. We statistically assessed that UK and Ireland, the two countries with higher TCS scores and lower smoking prevalence, are influential observations but not outliers. Hence, we opted to maintain both countries in the correlation analysis. Similarly, the sample size

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likely precluded significant associations of the TCS components with smoking prevalence in the multivariate analysis.

Finally, using the TCS as a measure of the tobacco control activities of each EU MS has some limitations since it scores the implementation of tobacco control policies but, at least in 2007, the TCS did not score their level of enforcement except for smoke-free policies.⁵ Admittedly, TCS scores in 2007 may not fully reflect tobacco control policies implemented in subsequent years that could in turn also affect the prevalence of smoking in 2014. However, the ranking of countries according to TCS scores has been relatively consistent across different editions of the scale and the magnitude of the correlation decreased as we used more recent TCS scores $(2010: r_{-} = -0.435; P = 0.02; 2013: r_{-} = -0.275; P = 0.17)$

Our study is the first to introduce a longitudinal perspective to the analysis of the impact of tobacco control policies in the EU. It evaluates the association between TCS scores and tobacco use indicators (smoking prevalence and quit ratios) across time using an adequate time window between the evaluation of policies and tobacco use indicators. Moreover, our study introduces the use of relative changes as an outcome variable taking into account the difference in the starting point of each country and hence trying to avoid an underestimation of the effect.

CONCLUSION

This study shows that, at the ecological level, higher implementation of tobacco control policies is associated to lower prevalence of smoking and higher quit rates over the last decade. Although variability in tobacco control policies exists among EU countries, it is relatively limited. Therefore, it would be interesting to develop scales, based in the original TCS, for other continents to be able to compare countries that are in different levels of the FCTC implementation process.^{13 39} Further steps should include an analysis of the

What this paper adds

- Higher Tobacco Control Scale scores in 2007 are associated with both lower smoking prevalence ($r_{-}=-0.444$; P=0.02) and higher quit ratios (r_{sp} =0.373; P=0.06) in 2014. European Union Member States with a higher level of
- implementation of tobacco control policies have both a higher decrease in their smoking prevalence and a higher increase in their guit ratios.

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Research paper

impact of relative changes in the TCS scores on changes in smoking prevalence and quit ratios over the last decade. EU27 should continue implementing comprehensive tobacco control policies as they have a positive effect in reducing the prevalence of smoking and increasing tobacco cessation rates in their population.

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PAPER II

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Paper III

The association between tobacco control policy implementation and country-level socioeconomic factors in 31 European countries

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The association between tobacco control policy implementation and country-level socioeconomic factors in 31 European countries

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ABSTRACT

Introduction. European countries have been pioneers in implementing tobacco control policies to reduce tobacco use; however, whether socioeconomic status (SES) of a country may influence the implementation of such policies is unknown. The aim of this study is to assess the association between country-level SES and the implementation level of tobacco control policies in 31 European countries.

Methods. An ecological study using data from Eurostat, Human Development Reports on several SES indicators and the Tobacco Control Scale (TCS) of 2016 to measure country-level tobacco control policies. We analysed the relationship between SES indicators and the TCS by means of scatter-plots and Spearman's rank correlation coefficients (r_{sp}) and multivariable linear regression analysis.

Results. In Europe, no statistically significant association was found between SES factors and the level of implementation of tobacco control policies. Only public spending on tobacco control was associated with all SES factors, except for GINI Index. The strongest associations of TCS scores for this policy domain was found with the Human Development Index (r_{sp} = 0.586; p<0.001) and the Gross Domestic Product *per capita* (in Euros) (r_{sp} = 0.562; p=0.001). The adjusted linear regression model showed an association of tobacco control policy implementation with countries' geographical location (Western Europe, β =-15.7; p=0.009, compared to Northern Europe).

Conclusions. No association was found between SES factors and the level of implementation of tobacco control policies; policymakers should be aware that tobacco control policies could be successfully implemented despite socioeconomic constraints, especially when these policies are of low cost and cost-effective (i.e., smoke-free bans and taxation).

INTRODUCTION

Effective tobacco control policies are proven to denormalise smoking, resulting in a decrease of smoking prevalence¹ and, consequently, in a reduction of tobacco-attributable morbidity and mortality². Most European countries have increasingly implemented stringent tobacco control policies to reduce tobacco use and its negative consequences on health. However, tobacco consumption remains the largest avoidable health hazard³.

Tobacco control progress in Europe has been accelerated mainly by the enforcement of the WHO Framework Convention on Tobacco Control⁴ and, in the European Union (EU), by the Tobacco Products Directive⁵. However, large differences still exist in the implementation and enforcement levels of tobacco control policies across Europe^{6,7}.

Evidence on which factors influence governments to enact tobacco control policies is needed to understand why differences between European countries still exist. Multiple factors are potentially slowing the process of implementing policies that could reduce tobacco consumption at a country-level, including poor political commitment, tobacco industry interference or smuggling⁸. Previous studies have explored political factors such as corruption, political ideology, or governmental structure as drivers of tobacco control progress. Their results suggest that despite the modest influence that political factors have on tobacco control policy development; a strong and transparent governance are key to ensure that effective tobacco control policies are implemented^{9,10}.

Income and education are associated with individual behaviours including smoking^{11,12}, but also with perceptions and knowledge about smoking and tobacco control¹³. Therefore, it may be reasonable to suspect that such socioeconomic factors might play a role in developing and implementing policies also at the country level. In this respect, we hypothesized that European countries with a higher socioeconomic status (SES) have a higher implementation level of tobacco control policies according to the six cost-effective measures assessed by means of the Tobacco Control Scale (TCS). Our aim was to assess the association between country-level SES and comprehensive tobacco control policy implementation in European countries.

METHODS

We conducted an ecological study with the country as the unit of analysis. We used data on tobacco control policies, measured by the TCS developed by Joossens and Raw¹⁴, for 31 out of the 35 European countries ranked in the TCS from 2016¹⁵, including 27 EU Member States (MS) as well as four non-EU MS (Iceland, Norway, Turkey, and the United Kingdom). Serbia, Switzerland, the Russian Federation and Ukraine were excluded due to systematic missing data in the databases consulted.

Data on SES indicators in 2016 were obtained from two sources: the Eurostat¹⁶ and the Human Development Reports ¹⁷. The Eurostat is the statistical office of the EU aimed to provide high quality statistics at European-level using data from statistical systems of the countries. The Human Development Reports, which are commissioned by the United Nations (UN) Development Programme, obtains data from international data agencies. Both sources, however, harmonise national data using a consistent methodology to allow comparability across countries16,18

Variables

Tobacco control policies

TCS scores were used to measure the implementation of tobacco control policies at a countrylevel in 2016. The scale is based on six cost-effective measures proposed by the World Bank that include dimensions such as: price (30 points), smoke-free laws (22 points), public spending on tobacco control (15 points), tobacco advertising, sponsorship and promotion (TAPS) bans (13 points), health warnings (10 points) and treatment (10 points). The score given to each policy dimension is weighted by its reported effectiveness according to scientific evidence on tobacco control¹⁹. The maximum possible score is 100 points, indicating a full implementation of all the policies considered¹⁴.

Socioeconomic indicators

Countries' SES can be defined by their income, wealth and poverty status, population educational level; and economic activity and working conditions²⁰. Hence, we selected indicators that assess these SES factors and inequalities in 2016, including: human development index, wealth, people at risk of poverty, unemployment, long-term unemployment, educational level, income inequality, severe material deprivation, and gender inequalities (see Table 1).

Tobacco consumption

Prevalence of current smokers of adult smokers (over 15 years-old) in 2014 (data for the most recent year before 2016) was obtained from Eurostat²¹.

The male-to-female smoking prevalence ratio was calculated and included as an independent variable to proxy the stage of the tobacco epidemic²². Gallus et al. suggested that countries with a higher ratio within sexes are supposed to be in previous stages of the epidemic than those with a ratio closer to 1^{23} .

European regions

European countries were grouped in regions (Eastern, Northern, Southern and Western Europe) according to the geographic regions for Europe of the UN²⁴.

Statistical analysis

First, we calculated age- and sex-standardised smoking prevalence of current smokers for each country, by means of direct method of standardisation using the European population of 2013 as the standard population; and, the male-to-female age- and sex-standardised smoking prevalence ratio. We conducted a descriptive analysis calculating the mean, the standard deviation (SD) and the interquartile range (percentile 25 and 75) for the variables of the study.

Second, we analysed the association between TCS scores (total and by its policy domains) (as dependent variable) and each of the SES indicators of European countries in 2016 (as independent variables) by means of scatter-plots and Spearman rank-correlation coefficients (r_{sp}) and the corresponding 95% confidence intervals (CI).

Finally, we conducted a multivariable linear regression analysis to examine the association between TCS total scores and the SES indicators in 2016 in Europe. For model selection, we used Akaike information criterion (AIC) to determine optimal specification of the linear regression and select the parameterized model with a higher efficiency. We performed statistical validation tests for all the models, which showed that the multivariable linear regression residuals that we fitted were appropriate with respect to the assumptions of linearity, normality of percentage point change and homoscedasticity; however, we observed that the variable Human Development Index (HDI) and Education Index showed collinearity with other variables, according to the Variance Inflation Factor (VIF). Thus, we excluded the HDI from the model as it is a composite measure that includes components of the Gini Index and Education Index. Analyses were performed with Stata 13.0 and SPSS 20.

RESULTS

Mean values (and SD) for dependent and independent variables are summarised in total and by European regions in Table 2. In Europe in 2016, the mean score of the level of tobacco control policy implementation according to TCS total score was 50.48 (10.58 SD), being higher in Northern Europe (mean: 57.40 (13.24 SD); Table 2) as the top three ranking countries are the United Kingdom (TCS score of 81 out of 100 points), Ireland (70 points) and Iceland (69 points)¹⁵. Moreover, mean age- and sex-standardized smoking prevalence in Europe was 24.7% and the mean male-to-female smoking prevalence ratio was 1.57 (0.56 SD), both being higher in Eastern Europe.

At the ecological level, no correlations with a p<0.05 were found between SES indicators and TCS total score. However, as shown in Table 3, the countries' scores on public spending on information campaigns showed a strong association with most of the SES indicators, except for the Gini Index and both variables related to unemployment. The strongest associations were found with HDI (r_{sp} = 0.586 (0.286 to 0.781); p<0.001) and GDP per capita (in Euros) (r_{sp} = 0.562 (0.252 to 0.767); p=0.001).

As shown in Table 4, crude linear regression models showed that the TCS total score in 2016 was 9.8 (p=0.039) and 11.4 (p=0.034) points lower in Southern and Western Europe, respectively; compared to Northern Europe. The multivariable linear regression model showed that only 31.4% (p=0.076; Table 4) of the TCS total score(s) in 2016 was explained by SES indicators after adjusting for male-to-female smoking prevalence ratio and countries' geographical region. Our adjusted results found that countries with higher education index (β =-0.40; p=0.382) and male-to-female smoking prevalence ratio (β =-10.31; p=0.069) had on average lower TCS total score(s), although neither relationships were statistically significant. Western Europe countries scored 15.69 points less on average in the total TCS than Northern countries (p=0.009)(Table 4).

DISCUSSION

Main findings

Overall, no associations were found between the selected direct indicators of countries' SES factors and their implementation level of tobacco control policies according to TCS scores, except for public spending on tobacco control. Differences in tobacco control efforts between European countries may partly be explained by their male-to-female ratio (used as a proxy of the stage of the epidemic at which countries are) and a geographical component²³.

Interpretation of the results

Our results do not show an association between the level of the wealth of a country and the implementation level of tobacco control policies as no statistically significant associations were found regarding SES indicators. Hence, although smoking has proven to be a burden for the poor, our results could not confirm that in Europe SES inequalities at national-level are associated with an implementation of tobacco control policies. However, although our findings do not show any relationship between SES and tobacco control policy implementation, the width of reported 95% CI for Spearman correlations, which include values of 0.5 or -0.5, was large enough to suggest that our results might underestimate a relationship between them. However, by using an ecological design we were not able to either evince it or explain it. Therefore, further policy research on tobacco control is needed to determine whether high SES

are a prerequisite for comprehensive tobacco control policies or not, which we know have the potential to reduce smoking inequalities, if they continue for a long term, covering and reaching all socioeconomic subgroups²⁵. Accordingly, previous studies have identified several low-income countries that have also succeeded to implement effective tobacco control policies¹³. Further research is needed to characterize the cultural, social, and ideological factors that drive progress on tobacco control that is key to advance in the field. It is probable that in order to unveil some of these drivers of policy implementation according to SES in Europe we will need to employ multimethod combining qualitative and quantitative research²⁶.

There was a strong association between countries' public spending on tobacco control and almost all SES indicators, except for Gini Index and those related to unemployment. Accordingly, European countries with higher SES seemed to invest more on mass media campaigns, tobacco control projects, educational programs, and support for non-governmental organizations. A plausible explanation could lay on the fact that high-quality anti-tobacco campaigns are expensive to produce and broadcast²⁶ since successful use of mass media requires sustained campaigns with broad population reach, which includes keeping campaigns "on the air" most months of the year²⁷.

Moreover, our results pointed out that tobacco control policy implementation could be associated to the male-to-female smoking prevalence ratio, a suggested proxy of the stage of the tobacco epidemic at which countries are²³, since, despite our results were not conclusive, the wide standard error of the estimates indicates that both Education Index and male-to-female smoking prevalence ratio could be of interest. European countries with a higher difference in the smoking prevalence between males and females; and hence at an earlier stage of the tobacco epidemic^{22,29}, have lower TCS scores. Previous studies have asserted that even though smoking prevalence in males and females have converged in high-income countries²², tobacco use rates for adult females remain relatively low in countries with lower SES indicators³⁰; hence, higher male-to-female ratio may also be interpreted as an indirect indicator of low SES. Thereupon, our results would indicate that tobacco control policy implementation levels are indirectly associated with SES factors as those countries with lower smoking rates in women and therefore, at an earlier stage, had implemented fewer tobacco control measures.

Our findings also indicated that tobacco control policy implementation is associated with a country's geographical location within Europe since countries in Western Europe showed a lower level of implementation of these policies compared to those in Northern Europe, meaning that tobacco control measures implemented in Western Europe are different in ways that other variables included in our model (i.e. SES) have not been able to capture. These results are consistent with a previous study that argues that smoke-free legislation and tobacco taxes are

rather poor in the countries in Western Europe as a result of a long tradition of influence of the tobacco industry in these countries³¹. For example, Austria and Germany have adopted few tobacco control policies, or have partially done it with poor enforcement (i.e., smoke-free laws)^{32–34}, despite the public support for additional tobacco control measures³¹. Politicians and researchers from both countries have historically had tight links with the tobacco control industry^{35,36}. The economic recession, in which European countries fell in 2008, could also have influenced our results since some countries such as Spain, Italy or Ireland in 2016 were still recovering from such economic crisis³⁷ and, thus, they still had lower SES indicators compared to the pre-crisis period when they may have implemented their tobacco control policies. One example of this phenomenon is Spain where the GDP per capita in Purchasing Power Standards –that is expressed in relation to EU28 average set to equal 100 –has decreased from 101 in 2008 when the first tobacco control law entered into force to 91 in 2016³⁸.

Limitations and strengths

This is an ecological study, and consequently, any causal relationship between national SES and the implementation of tobacco control policies in European countries is difficult to establish. However, we are not trying to infer the relationship at the individual-level but simply assessing an ecological effect.

The small sample size (n=31) of the study could be another potential limitation as it reduces the statistical power of the analysis; albeit our study includes all the countries ranked in the TCS report of 2016 (n=35), except those with systematic missing data for SES indicators. These exclusions could have entailed an underestimation of the association in the subset of countries included in our study, because all four countries excluded have a TCS score under 50 points[15]; and two are upper middle-income countries (Serbia and the Russian Federation) and one is a lower middle-income country (Ukraine). Moreover, our sample may not be representative of the WHO European Region, which consists of 53 countries, especially of Eastern Europe. Another limitation is the lack of a clear indicator to establish the tobacco epidemic stage²² across the different countries. In addition, as the attributable mortality rates were not available for all countries we could not make an approximation of these stages; however, and with the available data in our hands, we calculated the male-to-female smoking prevalence ratio as a proxy of the epidemic stage, and then we were in the position to control our analysis for this potential modifier of the effect.

Moreover, the use of the TCS as a proxy of the implementation tobacco control policies in European countries also has some limitations since it is based on policy enactment and not their enforcement¹⁵, except for smoke-free policies. Additionally, the dimension public spending has

some missing data. However, this scale has been useful in several evaluations of tobacco control and different health outcomes performance³⁹.

Another limitation to be noted is the possible bidirectional association between implementing tobacco control policies and SES. Countries with strong tobacco control policies are likely to have decreased social, economic and health inequalities at the population level. Nevertheless, due to the ecological nature of our study we are not able to establish this association that should be assessed through longitudinal studies.

Our study is the first to assess the association between tobacco control policies implementation and countries' SES to better understand the large differences that still exist in the implementation and enforcement levels of tobacco control policies across Europe.

Conclusions

Tobacco control policy implementation in Europe –according to our results –has not been found to be associated with SES indicators at a country-level. However, the SES effects on tobacco control policy implementation could not be absolutely discarded by using an ecological design. Further policy research is needed to understand how SES factors affect policymakers decisions on whether to implement or not population-based tobacco control measures since less costly policies including smoke-free places or tobacco products taxation have shown to be effective to reduce smoking prevalence.

Ethical approval Ethics approval for conducting this study based on secondary data from freely available databases was obtained from Hospital Universitari de Bellvitge (IDIBELL) [PR247/18].

Contributors Study design: AF, CM and EF. Collected data and prepared database for analysis: AF. Contributed to strategy of analysis: AF, FF, CM and EF. Analysed data: AF. Interpreted data results: AF, CM, LJ, FF, BA, OT, and EF. Drafted manuscript: AF. Critically revised manuscript: All authors. Approved final manuscript version: All authors. Guarantors: EF and CM, and both are considered senior authors.

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Competing interests None declared.

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PAPER

Table 1 Summary of SES indicators (description and data source)

Variable	Description	Data source
Human Development	Summary measure of key dimensions of human development: a	The United Nations
Index (HDI)	long and healthy life, being knowledgeable and a decent standard	Development Program Human
	of living that is calculated through the geometric mean of	Reports of 2016.
	normalised indices for each of the three dimensions.	
Gross Domestic	GDP reflects the total value of all goods and services produced	Eurostat for the year 2016.
Product (GDP) per	less the value of goods and services used for intermediate	A
capita (in Euros)	consumption in their production.	\sim
Gini Index	Gini index or coefficient is based on the comparison of	Eurostat for the year 2016.
	cumulative proportions of the population against cumulative	
	proportions of income they receive, and it ranges between 0 in the	
	case of perfect equality and 1 in the case of perfect inequality.	
People at risk of	The percentage of people living in a household with an	Eurostat for the year 2016.
poverty	equivalised disposable income below the risk-of-poverty	
	threshold, which is set at 60 % of the national median equivalised	
	disposable income (after social transfers).	
Material deprivation	MDI expresses the inability to afford some items considered by	Eurostat for the year 2016.
index (MDI)	most people to be desirable or even necessary to lead an adequate	
	life. Severe material deprivation rate in percentage is defined as	
	the enforced inability to pay for at least four of the deprivation	
	items.	
Unemployment rate	The number of people of 15 to 74 years of age (16 to 74 years in	Eurostat for the year 2016.
	Spain, Italy and the United Kingdom (UK)) that are not employed	
	as a percentage of the active population.	
Long-term	Computed as the share of unemployed persons for 12 months or	Eurostat for the year 2016.
unemployment rate	more in the total number of unemployed in the labour market.	
Gender Inequalities	GII measures gender inequality in three important aspects of	The United Nations
Index (GII)	human development: reproductive health, empowerment, and	Development Program Human
	economic status.	Reports of 2016.
Education Index	The Education Index is calculated using the mean years of	The United Nations
	schooling and expected years of schooling.	Development Program Human
		Reports of 2016.

Table 2 Summary of the Tobacco Control Scale score, the age- and sex-standardized smoking prevalence, the male-to-female smoking prevalence ratio, and the SES indicators of 31 European countries (total and by European regions).

	Total	Eastern Europe	Northern Europe	Southern Europe	Western Europe
Variables	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Tobacco Control Scale	50.48 (10.58)	47.83 (6.43)	57.40 (13.24)	47.55 (5.15)	46.00 (11.35)
Smoking prevalence (%)	24.66 (4.66)	28.28 (3.50)	21.61 (4.84)	26.05 (3.91)	24.02 (3.63)
Male-to-female smoking prev. ratio	1.57 (0,56)	1.79 (0.60)	1.50 (0.65)	1.71 (0.57)	1.25 (0.05)
Human Development Index	0.88 (0.04)	0.84~(0.03)	0.91 (0.04)	0.86 (0.03)	0.91 (0.01)
GDP per capita (thousand ϵ)	29.54 (19.73)	11.63 (3.74)	39.15 (19.00)	19.04 (5.91)	47.18 (21.80)
Gini Index	30.27 (4.49)	29.97 (5.31)	29.50 (4.33)	32.58 (5.01)	28.37 (1.84)
People at risk of poverty (%)	23.82 (8.04)	26.47 (11.05)	20.86 (5.93)	28.64 (8.01)	18.85 (1.47)
Material Deprivation Index (%)	18.16 (12.48)	27.13 (14.28)	12.09 (8.36)	25.00 (12.35)	9.03 (2.44)
Unemployment (%)	8.15 (3.96)	6.42 (2.00)	6.72 (2.06)	11.90 (5.13)	6.63 (2.08)
Long-term unemployment (%)	3.80 (3.21)	3.27 (1.57)	2.12 (1.26)	6.69 (4.53)	2.82 (1.20)
Education Index	0.85 (0.06)	0.83 (0.05)	0.90 (0.02)	0.80 (0.06)	0.87 (0.05)
Gender Inequality Index	0.12 (0.08)	0.21 (0.08)	0.09 (0.05)	0.13 (0.08)	0.07 (0.02)

GDP: Gross Domestic Product

Latvia, Lithuania, Norway, Sweden, United Kingdom; Southern Europe: Croatia, Cyprus, Greece, Italy, Malta, Portugal, Slovenia, Spain, Eastern Europe: Bulgaria, Czech Rep., Hungary, Poland, Romania, Slovakia; Northern Europe: Denmark, Estonia, Finland, Iceland, Ireland, Turkey; Western Europe: Austria, Belgium, France, Germany, Luxembourg, and the Netherlands.

þ Table 3 Spearman's rank-correlation coefficients (rsp) and 95% confidence intervals (CI) between SES indicators and TCS scores in 2016 (overall and components) in 31 European countries

TCS	IDH	GDP	Gini Index	At-risk of poverty	IDM	% Unemployment	% Long-term unempl.	Education Index	Gender Inequalities
Total	0.240 (-0.125; 0.548)	0.240 (-0.125; 0.548) 0.230 (-0.163; 0.520)	-0.044 (-0.393; 0.315)	-0.055 (-0.401; 0.306)	-0.055 (-0.401; 0.306) -0.108 (-0.445; 0.256)	-0.110 (-0.447; 0.254)	-0.159 (-0.486; 0.207)	0.168 (-0.198; 0.493)	-0.036 (-0.386; 0.322)
	0.194	0.274	0.813	0.771	0.563	0.555	0.392	0.366	0.846
Price	0.048 (-0.312; 0.396)	0.048 (-0.312; 0.396) 0.001 (-0.354; 0.355)	0.081 (-0.282; 0.423)	0.130 (-0.235; 0.463)	0.190 (-0.176; 0.510)	-0.003 (-0.357; 0.352)	-0.003 (-0.357; 0.352) -0.033 (-0.383; 0.325)	-0.007 (-0.361; 0.348)	0.205 (-0.161; 0.521)
	0.798	0.997	0.667	0.485	0.306	0.988	0.858	0.970	0.269
Smoke-free	0.251 (-0.114; 0.556)	0.251 (-0.114; 0.556) 0.251 (-0.114; 0.556)	0.019 (-0.338; 0.371)	0.013 (-0.343; 0.366)	-0.129 (-0.462; 0.236)	-0.114 (-0.450; 0.250)	-0.156 (-0.484; 0.210)	0.148 (-0.218; 0.477)	-0.065 (-0.410; 0.296)
laws	0.174	0.174	0.921	0.943	0.489	0.541	0.401	0.427	0.729
Public	0.586 (0.286; 0.781)	0.586 (0.286; 0.781) 0.562 (0.252; 0.767)	-0.292 (-0.590; 0.076)	-0.376 (-0.648; -0.018)	-0.292 (-0.590; 0.076) -0.376 (-0.648; -0.018) -0.455 (-0.700; -0.113)	-0.135 (-0.472; 0.237)	-0.227 (-0.543; 0.145)	0.467 (0.129; 0.708)	-0.476 (-0.714; -0.140)
spending	<0.001	0.001	0.117	0.041	0.011	0.478	0.227	0.009	0.008
TAPS bans	0.194 (-0.172; 0.513)	0.194 (-0.172; 0.513) 0.205 (-0.161; 0.521)	-0.240 (-0,547; 0,125)	-0.214 (-0.528; 0.152)	-0.192 (-0.512; 0.174)	-0.057 (-0.403; 0.304)	-0.125 (-0.459; 0.240)	0.154 (-0.212; 0.482)	-0.023 (-0.375; 0.334)
	0.295	0.269	0.194	0.248	0.300	0.763	0.502	0.409	0.901
Health	-0.021 (-0.373; 0.336)	-0.021 (-0.373; 0.336) -0.136 (-0.468; 0.230)	0.144 (-0.221; 0.474)	0.049 (-0.311; 0.396)	0.050 (-0.309; 0.398)	-0.129 (-0.462; 0.236)	-0.122 (-0.457; 0.242)	0.153 (-0.213; 0.481)	0.256 (-0.108; 0.560)
warnings	0.910	0.466	0.439	0.796	0.788	0.489	0.512	0.411	0.164
Treatment	0.230 (-0.136; 0.540)	0.230 (-0.136; 0.540) 0.286 (-0.076; 0.581)	0.057 (-0.303; 0.403)	-0.008 (-0.362; 0.347)	-0.133 (-0.465; 0.232)	0.105 (-0.259; 0.443)	0.032 (-0.326; 0.382)	0.059 (-0.302; 0.405)	-0.220 (-0.532; 0,146)
	0.214	0.119	0.760	0.964	0.476	0.573	0.863	0.752	0.235

Development Index; GDP: Gross-d

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Table 4 Crude and adjusted multivariate linear regression models examining the association between SES indicators and the TCS score of 2016 in 31 European countries.

	Crude		Adjusted	
	β (SE)	p-value	β (SE)	p-value
HDI (100 points)	0.732 (0.437)	0.104		
GDP per capita (1000 €)	0.127 (0.097)	0.199		
Long-term unemployment	-0.779 (0.595)	0.201		
Education Index (100 points)	0.396 (0.324)	0.232	-0.402 (0.452)	0.382
Male-to-female ratio				
≤1,33	REF		REF	
>1,33	-6.037 (3.702)	0.114	-10.311 (5.416)	0.069
Region				
Northern Europe ¹	REF		REF	
Eastern Europe ²	-9.567 (5.108)	0.072	-5.249 (6.349)	0.416
Southern Europe ³	-9.844 (4.545)	0.039	-8.921 (6.137)	0.158
Western Europe ⁴	-11.4 (5.108)	0.034	-15.690 (5.538)	0.009
R-squared			0.314	0.076

The crude linear regression model shows the results of a simple linear regression model of the dependent variable and the independent variable. HDI was excluded due to collinearity with the Education Index. The adjusted multivariable regression model assessed the effect of SES indicators (Education Index) adjusted for male-to-female ratio and geographical region. We performed the adjusted analysis with the model with the optimal AIC values and fulfilled all regression validation tests.

HDI: Human Development Index; GDP: Gross Domestic Product

1: Denmark, Estonia, Finland, Iceland, Ireland, Latvia, Lithuania, Norway, Sweden, United Kingdom; 2: Bulgaria, Czech Rep., Hungary, Poland, Romania, Slovakia; 3: Croatia, Cyprus, Greece, Italy, Malta, Portugal, Slovenia, Spain, Turkey; 4: Austria, Belgium, France, Germany, Luxembourg, and the Netherlands. SE: Standard error

Paper IV

Are smokers "hardening" or rather "softening"? An ecological and multilevel analysis across 28 European Union countries

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ORIGINAL ARTICLE COPD AND EPIDEMIOLOGY



Are smokers "hardening" or rather "softening"? An ecological and multilevel analysis across 28 European Union countries

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This study does not support the hardening hypothesis in the European Union, but suggests a softening of the smoking population. However, social inequalities in heavy smoking underline the need for interventions targeting smokers in vulnerable groups. http://bit.ly/2xfgM5v

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ABSTRACT

Background: Tobacco control policies can reduce smoking prevalence. These measures may be less effective where smoking prevalence has significantly declined, as the remaining smokers have "hardened". Our aim was to empirically evaluate the "hardening hypothesis" at the population level in the European Union (EU) and explore factors associated with hardcore smoking.

Methods: We conducted two separate analyses in the EU using data on smoking from the Eurobarometer surveys (2009–2017, n=112745). 1) A panel-data fixed-effects linear regression to investigate changes over time in the percentage of hardcore smokers in relation to standardised smoking prevalence at the country level. 2) A multilevel logistic regression analysis with hardcore (daily smokers, >15 cigarettes per day who have not attempted to quit in the last 12 months) or light (<5 cigarettes per day) smoking as the dependent variable and time as the main independent variable, controlling for individual and ecological variables.

Results: We studied 29010 current smokers (43.8% hardcore smokers and 14.7% light smokers). The prevalence of hardcore smoking among adult smokers increased by 0.55 (95% CI 0.14–0.96) percentage points per each additional percentage point in the overall smoking prevalence. The odds of being a hardcore smoker increased over time and were higher in middle-aged males and people with financial difficulties, while the odds of being a light smoker significantly declined among females.

Conclusion: This study does not support the "hardening hypothesis" in the EU between 2009 and 2017, but suggests a softening of the smoking population. Existing tobacco control policies are likely to be suitable to further decrease smoking prevalence in Europe.

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Introduction

Tobacco is the largest preventable health hazard in the European Union (EU) [1]. Despite the decline in tobacco smoking prevalence over recent decades, Europe remains the region with the highest smoking prevalence among adults (28%: males 38% and females 19%) and has some of the highest prevalence of tobacco use by adolescents [2].

To address the tobacco epidemic, the EU ratified the World Health Organization Framework Convention on Tobacco Control [3] and developed a Tobacco Product Directive, which was revised in 2014 [4]. Subsequently, all EU Member States have implemented key tobacco control policies [5]; however, large differences still exist in the implementation and enforcement levels of tobacco control policies across the EU [6, 7].

Established tobacco control policies have been shown to reduce smoking prevalence [6, 8]. However, it has been suggested that tobacco control measures are less effective in countries where a significant decline in smoking prevalence has been observed, as the population of smokers becomes more "hardened" [9]. This is known as the "hardening hypothesis", which proposes that when the prevalence of smoking decreases, smokers who quit first are those less dependent and hence the remaining smokers in the population are "hardcore smokers", including inveterate smokers with high consumption, high cigarette dependence and low motivation to quit [10, 11]. The confirmation of the hardening hypothesis in a population, for who tobacco control efforts may need to be specifically tailored [12]. Thus, the feasibility of tobacco endgame strategies, which suggest moving beyond tobacco control towards a tobacco-free future [13], would be compromised, given that they would be effective only assuming a transition from combustible tobacco to alternative forms of nicotine delivery systems [14].

The evidence is not yet conclusive to support or refute the hardening hypothesis [15]. A few previous studies have supported the hardening hypothesis; however, they were either cross-sectional analyses based on ecological data [16], individual-level data from a single country [17] with their known limitations [9] or meta-analyses of clinical trials that only include selected subpopulations of patients [10]. Other studies reject the hardening hypothesis [10, 18–23] and suggest that smokers could be softening instead [10, 11, 24]. Most of these studies have used data from one country at a time, except for two studies that have addressed this question jointly in several European countries together with the USA [10, 11]; however, none has systematically addressed this question across all 28 EU Member States. The EU provides a suitable context to explore this question, as there have been substantial declines in smoking prevalence over the past 10 years, in a background of common regulations [4], but also considerable variation among EU Member States.

The aims of this study were to empirically evaluate whether the hardening hypothesis can be confirmed at the population level in the 28 EU Member States, and to analyse the determinants of hardcore and light smoking considering both individual and contextual country-level characteristics.

Methods

We conducted a study in the 28 EU Member States by performing two separate analyses: one with individual and contextual data, and one with ecological data. We used data on smoking from waves 72.3 (2009), 77.1 (2012), 82.4 (2014) and 87.1 (2017) of the Eurobarometer survey [25–28]. Eurobarometer is a cross-sectional study of representative samples of the adult population (\geq 15 years old) conducted by the European Commission. The fieldwork was conducted in October 2009 (n=27788), February–March 2012 (n=26751), November–December 2014 (n=27801) and March 2017 (n=27901). Samples are independently selected in each wave. Each Eurobarometer survey uses a random, multistage sampling method and post-stratification sample weighting is applied independently in each wave. As a result, samples are representative of the population by age, sex and area of residence, both at a country level and at the EU level.

Data sources and variables

Tobacco consumption

Smoking prevalence was estimated from respondents answering "I currently smoke" to the question "Regarding smoking cigarettes, cigarillos, cigars or a pipe which of the following applies to you?" Smoking prevalence in 2009 was obtained from the proportion of respondents who gave the answer "I smoke at the present time" to the same question. We also calculated the prevalence of ex-smokers and never-smokers using the proportion of respondents that answered "I used to smoke but now I have stopped" and "I have never smoked", respectively. All smokers were also asked to report whether they smoke manufactured and roll-your-own cigarettes daily or occasionally, how many cigarettes they smoke per day, and whether they had ever tried to quit ("yes, in the last 12 months", "more than a year ago" or "no, never").

"Hardcore smokers" were defined as 1) current smokers, 2) who smoked manufactured cigarettes or roll-your-own daily, 3) who smoked on average at least 15 cigarettes per day and 4) who reported not having made any quit attempt in the last 12 months. There is no universally accepted definition of hardcore smokers [15]; therefore, we conducted a sensitivity analysis including an additional criterion to our definition: age \geq 26 years, which reflects the assumption that younger smokers may not have reached a stable level of average daily consumption or solidified their intentions regarding quitting [12, 24, 29]. We defined "light smokers" as occasional or daily current smokers who reported smoking less than 5 cigarettes per day [30].

Tobacco control policies

The Tobacco Control Scale (TCS; www.tobaccocontrolscale.org) is a scoring system developed by a panel of experts to quantify the national-level implementation of tobacco control policies. The six components of the TCS are: price (30 points), public place bans (22 points), public information campaigns spending (15 points), advertising bans (13 points), health warnings (10 points) and treatment (10 points). The score increases with the strength of tobacco control policies up to a possible maximum of 100 points, indicating a full implementation for all strategies considered. For each year, we used the most recent TCS report published before the year of the survey (TCS for 2007, 2010, 2013 and 2016).

Gross domestic product per capita

We obtained the gross domestic product (GDP) per capita in 2009, 2012, 2014 and 2017 from Eurostat (the official statistical office of the EU) [31].

Sociodemographic data

We also used information about sex (male and female), age (15–24, 25–34, 35–44, 45–54, 55–64 and \geq 65 years), difficulties in paying bills in the last 12 months (most of the time, from time to time and almost never or never), age when they stopped full-time education (\leq 15, 16–19 and \geq 20 years), marital status (married, single, divorced and other) and type of community (rural area or village, small or middle town and large town) as collected by Eurobarometer.

Statistical analysis

We calculated the age- and sex-standardised prevalence of never-, ex- and current smokers and hardcore and light smokers in each EU Member State (2009, 2012, 2014 and 2017) by means of the direct method of standardisation using the European population of 2013 as the standard population.

Time trends of standardised prevalence of smoking status (never-, ex-, current, hardcore and light smokers) separately by each EU Member State were graphically described (2009–2017).

We conducted an ecological analysis with the country as the unit of analysis to assess the association between the relative change in the prevalence of hardcore or light smokers among current smokers (dependent variables) and the relative change in smoking prevalence (independent variable) from 2009 to 2017. We conducted an analysis in the total population, and by sex, by means of scatter plots and Spearman rank correlation coefficients (r_{sp}) with the corresponding 95% confidence intervals. The relative change was calculated as a percentage of the prevalence in the earlier period. We used relative and not absolute change to account for the baseline differences between EU Member States.

We conducted a panel-data fixed-effects linear regression analysis both in the total population and stratified by sex, with the proportion of hardcore smokers among current smokers as the dependent variable and smoking prevalence as the main independent variable to investigate the percentage of hardcore smokers in relation to smoking prevalence. We adjusted the panel-data regression for time to account for underlying trends and the total TCS score of each EU Member State. GDP per capita was not included in the model as it did not improve the fit of the model. The fixed-effects specification accounts for time-invariant unobserved factors within each country [32].

We conducted a multilevel logistic regression analysis with two levels of analysis (individual and country) to account for clustering of observations within countries to assess the association of being a hardcore or a light smoker (dependent variable) with time (continuous variable, by calendar year), age, sex, difficulties in paying bills, marital status, education and type of community (independent variables) adjusting for TCS score (per 10 points change) and GDP per capita (per EUR 1000 change). We used Akaike and Bayesian information criteria to determine the optimal specification of the logistic regression model. We observed a

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statistically significant effect modification between time and education for hardcore smokers and between time and sex for light smokers; therefore, we stratified the analysis by education and sex, respectively.

A sensitivity analysis was conducted with the alternative definition of hardcore smokers using age $\geqslant\!26$ years for the main analyses.

Results

Our sample had 29010 current smokers (26.6%) from which 43.8% were hardcore smokers and 14.7% were light smokers across the four waves of the Eurobarometer surveys. By age group, young smokers (15–24 years old) had the lowest rate of hardcore smokers (27.2%), while middle-aged smokers (45–54 years old) had the highest rate of hardcore smokers (50.6%) (supplementary table S1).

In the EU, as a whole, age- and sex-standardised smoking prevalence decreased from 28.7% in 2009 to 26.5% in 2017, while hardcore smoking increased from 36.7% to 41.6% and light smoking decreased from 19.2% to 16.9% among current smokers (figure 1). In most countries where the prevalence of hardcore smokers has decreased, light smokers have increased and *vice versa*, although there was variation among EU Member States (figures 1 and 2).

At the ecological level, we explored the association between the relative change in hardcore and light smoking prevalence among current smokers and the relative change in smoking prevalence from 2009 to 2017. A decreasing smoking prevalence was associated with a decreasing proportion of hardcore smokers among all current smokers (r_{sp} =0.432, p=0.019; males: r_{sp} =0.270, p=0.158; females: r_{sp} =0.366, p=0.051) (figure 3a) and an increasing prevalence of light smokers (r_{sp} =-0.334, p=0.076; males: r_{sp} =-0.289, p=0.128; females: r_{sp} =-0.044, p=0.819) (figure 3b). The sensitivity analysis with the alternative definition of hardcore smokers a showed a correlation in the same direction (r_{sp} =0.253, p=0.185), although it did not reach statistical significance.

The panel-data regression analysis showed that per each additional percentage point in smoking prevalence, the prevalence of hardcore smoking increased by 0.55 percentage points (0.32 percentage points in males and 0.72 percentage points in females). The prevalence of light smokers decreased by 0.30 percentage points for each percentage point increase in overall smoking prevalence, adjusting for time and TCS scores (table 1). The sensitivity analysis showed similar results with an increase of 0.29 percentage points in the prevalence of hardcore smokers per each additional percentage point in the prevalence of smoking in the general population, although the association was not statistically significant.

The multilevel logistic regression analysis showed a significant interaction between time (by calendar year) and education when assessing hardcore smoking as the dependent variable and between time and sex when analysing light smoking as the dependent variable. Therefore, all analyses are presented stratified by education level and sex.

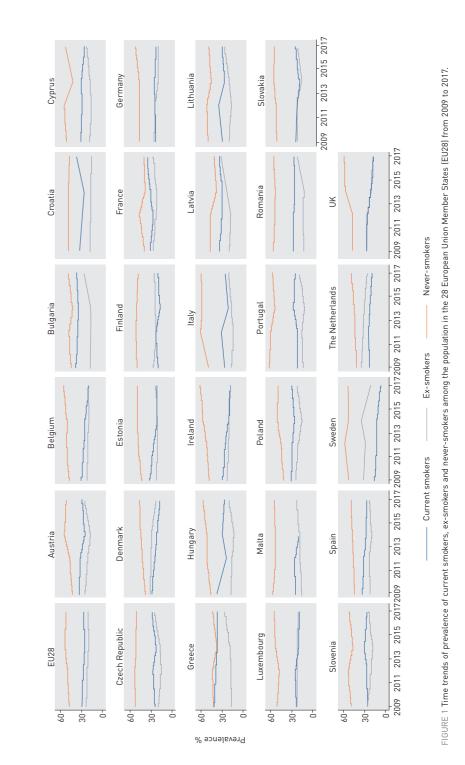
As shown in table 2, the odds of being a hardcore smoker increased over time among all education groups. Middle-aged individuals (35–64 years old) were the most likely to be hardcore smokers. Among the higher educated groups, we observed that individuals having some or many difficulties in paying bills had also higher odds of being hardcore smokers. Finally, among individuals who stopped full-time education when they were ≥ 20 years old, being divorced, separated or widowed also increased the odds of hardcore smoking. Conversely, odds of hardcore smoking were lower for females compared with males in all groups and, in the lowest educated group, it also decreased among residents of countries with a higher TCS score (OR 0.88, 95% CI 0.81–0.95). The sensitivity analysis showed that the odds of hardcore smoking did not increase over time in any group, but it showed similar results for age, sex and difficulties in paying bills.

The odds of being a light smoker did not significantly change over time among males and declined over time among females (OR 0.98, 95% CI 0.96–0.99). Consistent with the findings about hardcore smoking, middle-aged individuals and those having difficulties in paying bills had lower odds of being light smokers. Males and females with higher education were more likely to be light smokers compared with those with low or no formal education. In males, the odds of being a light smoker were also higher in countries with a higher GDP and higher TCS scores (table 2).

Discussion

Main results

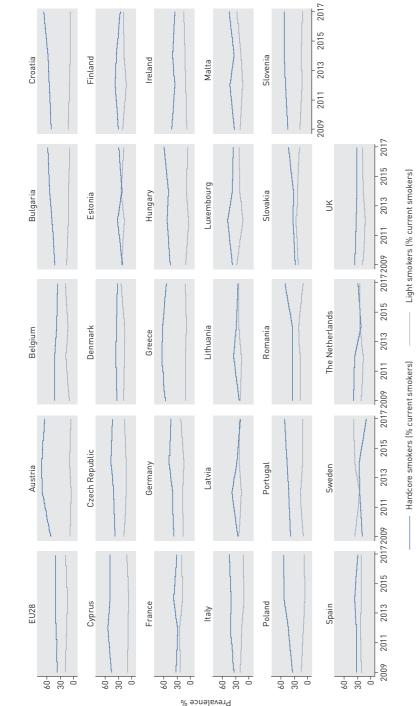
Our study shows that hardcore smoking prevalence is not increasing in those EU Member States where smoking prevalence is declining. Otherwise, contrary to the "hardening hypothesis", it is the prevalence of light smoking that is increasing. Moreover, our findings show that the odds of being a hardcore smoker are higher among middle-aged males who had difficulties in paying bills in the last 12 months and lower



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to 2017. States (EU28) from 2009 Member the 28 European Union current smokers in among (and light smoking dcore a har ę pre/ of trends Time 1 FIGURE 2

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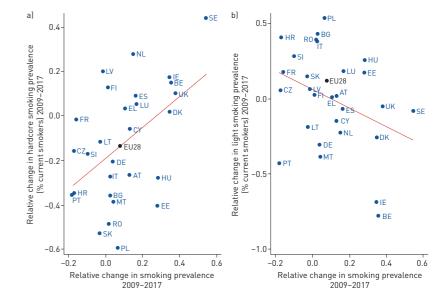


FIGURE 3 Correlation between relative changes in a) hardcore smoking and b) light smoking prevalence among current smokers and in smoking prevalence from 2009 to 2017. AT: Austria; BE: Belgium; BG: Bulgaria; HR: Croatia; CY: Cyprus; C2: Czech Republic; DK: Denmark; EE: Estonia; FI: Finland; FR: France; DE: Germany; EL: Greece; HU: Hungary; IE: Ireland; IT: Italy; LV: Latvia; LT: Lithuania; LU: Luxembourg; MT: Malta; PL: Poland; PT: Portugal; RO: Romania; SK: Slovakia; SI: Slovenia; ES: Spain; SE: Sweden; NL: The Netherlands; UK: United Kingdom; EU28: overall average in the 28 European Union Member States. Relative changes in prevalence were calculated as a percentage of the prevalence in the earlier period. The red line shows the fitted values.

in countries with stronger tobacco control policies. Hardcore smoking was also associated with marital status and education.

Interpretation of the results

Smoking prevalence has decreased overall over time in the EU; however, in some countries it has increased (e.g. in France and Croatia) [6]. In these countries, the prevalence of hardcore smokers has also increased,

TABLE 1 Panel-data linear regression analysis for hardcore and light smoking prevalence as a function of smoking prevalence, time (year) and Tobacco Control Scale (TCS): overall and stratified by sex

	Hardcore smoking 1 year change	Light smoking 1 year change
Total		
Smoking prevalence	0.550* (0.137-0.963)	-0.297* (-0.5470.044)
Year	0.664* (0.277-1.052)	-0.084 (-0.322-0.153)
TCS	-0.222 (-0.495-0.051)	0.149 (-0.018-0.317)
Males		
Smoking prevalence	0.320 (-0.092-0.732)	-0.176 (-0.434-0.082)
Year	0.616* (0.123-1.109)	-0.039 (-0.348-0.270)
TCS	-0.158 (-0.499-0.184)	0.184 (-0.031-0.398)
Females		
Smoking prevalence	0.717* (0.162-1.273)	-0.164 (-0.607-0.279)
Year	0.627* (0.105-1.149)	-0.035* (-0.451-0.381)
TCS	-0.251 (-0.633-0.131)	0.070 (-0.235-0.374)

Data are presented as β (95% CI). β coefficients represent the percentage point change per each additional percentage point in smoking prevalence. *: p<0.05.

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TABLE 2 Multilevel logistic regression analysis stratified by age when stopped full-time education for hardcore smoking and by sex for light smoking

	Hardcore smoking		Light smoking		
	≤15 years	16-19 years	≥20 years	Males	Females
Time	1.04* (1.02–1.07)	1.03* (1.02–1.05)	1.02* (1.01–1.03)	1.00 (0.98–1.02)	0.98* (0.96-0.99)
Age					
15-24	1	1	1	1	1
25-34	1.29 (0.94-1.77)	1.80* (1.57-2.07)	1.70* (1.54–1.88)	0.62* (0.51-0.75)	0.68* (0.57-0.81
35–44	1.49* (1.10-2.03)	2.26* (1.97-2.59)	2.30* (2.08-2.55)	0.47* (0.39-0.58)	0.56* (0.47-0.67
45-54	1.62* (1.20-2.19)	2.50* (2.17-2.87)	2.72* (2.45-3.01)	0.44* (0.36-0.55)	0.57* (0.47-0.68
55-64	1.38* (1.02-1.86)	2.43* (2.10-2.82)	2.60* (2.34-2.90)	0.47* (0.38-0.58)	0.55* (0.45-0.66
≥65	1.01 (0.74–1.38)	1.64* (1.38–1.95)	1.93* (1.71–2.17)	0.71* (0.56-0.89)	0.65* (0.52-0.81
Sex					
Male	1	1	1		
Female	0.56* (0.49-0.63)	0.48* (0.45-0.52)	0.50* (0.48-0.53)		
Difficulties paying bills					
Almost never or never	1	1	1	1	1
From time to time	1.13 (0.97–1.31)	1.32* (1.17–1.37)	1.23* (1.16–1.31)	0.68* (0.59-0.77)	0.74* (0.67-0.83
Most of the time	1.11 (0.94–1.32)	1.25* (1.06-1.30)	1.23* (1.14–1.32)	0.70* (0.59-0.84)	0.59* (0.51-0.68
Marital status					
Married	1	1	1	1	1
Single	1.03 (0.85-1.24)	0.92 (0.84-1.02)	0.96 (0.89-1.03)	1.06 (0.92-1.21)	1.03 (0.90-1.17)
Divorced	1.10 (0.94–1.30)	1.10 (0.99–1.21)	1.12* (1.04-1.21)	0.84 (0.70-1.01)	0.94 (0.83-1.07)
Other	1.38 (0.68-2.80)	0.85 (0.58-1.24)	0.79 (0.60-1.03)	0.85 (0.52-1.40)	1.03 (0.60-1.78)
Age when stopped full-time education years					
≼15				1	1
16-19				1.17 (0.98–1.39)	1.13 (0.97-1.31
≥20				1.83* (1.52-2.21)	1.74* (1.48-2.04
Type of community					
Rural area or village	1	1	1	1	1
Small or middle town	1.07 (0.93-1.24)	0.98 (0.90-1.06)	0.99 (0.93-1.05)	1.00 (0.88–1.14)	1.01 (0.90-1.13
Large town	1.11 (0.95-1.31)	1.05 (0.96-1.15)	0.99 (0.93-1.06)	1.05 (0.91-1.21)	1.04 (0.92-1.17
GDP (per EUR 1000)	1.00 (0.99-1.01)	1.00 (0.99-1.01)	1.00 (0.99-1.00)	1.01* (1.00-1.02)	1.00 (0.99-1.01
TCS (per 10 points)	0.88* (0.81-0.95)	0.97 (0.92-1.03)	0.92* (0.84-1.00)	1.08* (1.00-1.17)	1.04 (0.97-1.12

Data are presented as OR (95% CI). GDP: gross domestic product; TCS: Tobacco Control Scale. *: p<0.05.

except for Latvia, where the prevalence increases in young cohorts (and mainly in females) who are less likely to become hardcore smokers in the short term. Our results suggest that, despite an overall increase in hardcore smoking prevalence, smokers in the EU are not hardcoring since hardcore smoking is decreasing and not increasing for each percentage point decrease in smoking prevalence. These results are in line with previous cross-sectional studies conducted in Europe that concluded that smoking prevalence was correlated to a higher Heavy Smoking Index and number of cigarettes smoked per day [10, 11].

European countries are at different stages of the tobacco epidemic based on the comparative levels of smoking prevalence and smoking-attributed mortality in males and females [33]. Most Eastern European countries are at stage 3, which involves a flattening or downturn of male smoking prevalence with some convergence of smoking prevalence in both sexes and a steep increase of deaths attributable to smoking, with the rest of the countries at late stages 3 and 4 where, although prevalence is decreasing, smoking-attributable mortality continues to rise. Hereto, our analysis was stratified by sex to account for such differences, as GALLUS *et al.* [34] suggested that countries at an earlier stage of the epidemic had a relatively high male-to-female smoking prevalence ratio. Our findings showed that in females the relation between increased smoking prevalence and higher hardcore smoking prevalence was stronger than in males despite the fact that females are already at advanced stages of the epidemic in high-income countries and even though the uptake of smoking among females is generally delayed compared with males [33]. Consistent with this, FERNANDEZ *et al.* [10] observed that the relation between dependence and smoking prevalence was higher in females.

Despite an overall increase in the prevalence of hardcore smokers, our findings do not support the hardening hypothesis in the EU at a population level. Instead, the increase of light smoking among smokers implies a softening of the smoking population. This softening of the smoking population suggests

that current tobacco control policies (*e.g.* smoke-free policies, tobacco taxation and advertising bans) have been effective not only in motivating light smokers to quit smoking, but also in influencing hardcore smokers to quit smoking or to reduce their daily cigarette consumption [6, 11, 24]. Other explanations could be that social denormalisation of smoking over time has fuelled quitting across the smoking population [24] or that light smokers, who are less addicted to nicotine, continue to smoke because of psycho-social factors rather than a physical addiction [10].

In addition, at an individual level, our findings suggest that the odds of hardcore smoking in the EU have increased over time after adjusting for sociodemographic and environmental factors. However, these results have not accounted for the changes in smoking prevalence and therefore should not be interpreted as evidence suggesting hardening [35].

Both hardcore and light smoking are associated with tobacco control policies, as the stronger the implementation, the lower the odds of hardcore smoking. Our results are consistent with a previous study also conducted in the EU that concluded that higher tobacco control efforts were correlated with higher quit ratios (percentage ex-smokers over ever-smokers) [6]. Disaggregating the effects of individual tobacco control policies was beyond the scope of this analysis, but future analyses could provide more insight into the issue.

Moreover, hardcore and light smoking can be associated to individual socioeconomic and demographic characteristics. Hardcore smoking was more prevalent among males, 35–64 years old, lower educated groups and individuals with more difficulties in paying bills. Conversely, light smoking was more frequent in females and higher educated individuals. These results are consistent with previous studies that also observed that smokers today belong to more deprived population groups than in the past [29, 36]. Therefore, regardless of whether the population of smokers is hardening or not, the social gradient in heavy smoking highlights the socioeconomic inequalities and the increased burden of smoking-related diseases among people in low socioeconomic groups [37]. To increase health equity, tobacco control policies should be tailored to subgroups of heavy smokers (including socially deprived and psychiatric distressed smokers [38]) to successfully continue softening the population of smokers.

Limitations and strengths

Although we analysed data from 28 EU Member States that allowed us to detect time trends across the EU, our ecological analyses were essentially based on a relatively small sample. EU Member States differ in several social, cultural and other factors, such as the stage of the tobacco epidemic [33]. Our efforts to account for differences across countries included stratifying analyses by sex since countries at an earlier stage of the epidemic present a higher male-to-female smoking prevalence ratio [34], as well as using a fixed-effects specification for our panel regression to control for unobserved country-level factors that may influence the results.

Our study might have overestimated the prevalence of hardcore smokers compared with previous studies, as we could not include a measure of nicotine dependence [39, 40] nor long-term smoking history (being a smoker for at least 5 years) of current smokers that are frequently used criteria as the Eurobarometer survey did not record this information in all four waves. However, to account for this possible limitation we conducted a sensitivity analysis including only smokers at least 26 years old [24, 29]. Moreover, we used secondary data from the smoking supplement of Eurobarometer, which is a periodic survey to monitor smoking indicators in the EU but lacks detailed information on other participant's characteristics, including could be a source of bias, although self-reports on smoking study have acceptable validity [41].

Our study is the first to systematically approach the hardening hypothesis in all of the EU Member States, which are subject to common regulations, and to introduce a longitudinal perspective to this approach, including data from four cross-sectional surveys with consistent methods across countries and over time.

Conclusions

In conclusion, our study does not support the "hardening hypothesis" in the EU between 2009 and 2017, but rather suggests a softening of the smoking population over this period. These findings indicate that existing tobacco control policies may be suitable to further decrease smoking prevalence in Europe as we gradually move towards endgame strategies. However, social inequalities in heavy smoking underline the need for tailored interventions targeting smokers in vulnerable socioeconomic groups who may find it more difficult to quit or reduce smoking [35, 36].

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Paper V

A tool to monitor tobacco control policies' implementation: The Tobacco Control Scale in Latin America. Adaptation process and pilot study

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Tobacco Control

A tool to monitor tobacco control policies' implementation: The Tobacco Control Scale in Latin America. Adaptation process and pilot study

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ABSTRACT

Background Monitoring tobacco control policy implementation is key to reduce tobacco consumption in Latin America (LA). This study aims to report the adaptation of the Tobacco Control Scale (TCS) to LA countries and the level of tobacco control policy implementation in this region according to the scale.

Methods Ecological cross-sectional survey. The questionnaire to measure tobacco control policies was a translated (into Spanish and Portuguese) and adapted version of the last TCS as used in Europe. The resulting TCS-LA maintains the same structure that the original TCS, with 8 policy domains and 100 points (pts) as maximum score; however, three policy domains were adapted because the exact same rationale could not be applied. At least two non-governmental tobacco control experts were contacted per country to answer the TCS-LA.

Results 17 out of 18 countries completed the questionnaire. Panama (70 pts), Uruguay (68 pts) and Ecuador (61 pts) are the countries that exhibit stronger tobacco control policies according to the TCS-LA; while Guatemala (32 pts), Paraguay (30 pts) and Bolivia (29 pts) have implemented a lower number of tobacco control policies. Eight countries had implemented half of the tobacco control policies measured by the TCS-LA.

Conclusions Panama, Uruguay and Ecuador are the top-three leading countries in tobacco control in LA; however, tobacco control in the region has room for improvement since nine countries have a total score under 50 points. The TCS is a feasible and adaptable tool to monitor tobacco control in other WHO Regions beyond Europe.

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WHAT THIS PAPER ADDS

- WHO-FCTC has contributed to change the policy environment in Latin America (LA); however, tobacco control policies are still scarce in some of these countries.
- Advancing with effective tobacco control measures requires monitoring.
- There is a need of developing useful monitoring instruments according to contextual characteristics of each region that assure comparability across countries and regions.
- This is especially true in developing countries where such progress is less well-known or reported.
- The Tobacco Control Scale (TCS)-LA offers a full-picture of countries ahead in tobacco control in LA and countries' major loopholes, even in countries with a good overall score.
- The TCS, developed for European countries, can feasibly be adapted to LA and likely to other regions to systematically monitor tobacco control policies.

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INTRODUCTION

Tobacco use is one of the major public health problems of our time since it is the largest cause of preventable death worldwide killing over eight million people annually. In Latin America (LA) and the Caribbean, tobacco consumption varies widely across countries. The countries with the highest smoking prevalence in adults in 2015 were Chile (38.7%) and Cuba (35.9%), while the lowest were Ecuador (7.4%) and Panama (6.5%)[1]. The increase of tobacco consumption in some LA countries has contributed to a shift from communicable to non-communicable diseases as the leading cause of death in the recent decades[2]. These facts highlight the importance of public health efforts to reduce tobacco consumption in this region.

The World Health Organization's (WHO) Framework Convention on Tobacco Control (FCTC) prompted an increase in the percentage of the world's population protected by at least one effective tobacco control measure at the highest-level of achievement. This percentage increased from 15% in 2007 to over 60% in 2018, as most countries have made great strides in implementing tobacco control measures since it came into force in 2005[3]. This improvement has also been seen in LA, where countries are making progress in adopting new tobacco control policies[1].

The WHO FCTC has contributed to change the policy environment in the region[4]. As March 2020, 16 out of 18 LA countries had ratified the WHO FCTC[4]. However, national comprehensive regulations ruling on tobacco control are still scarce in some of these countries[1], with only a few countries having executed the WHO FCTC through the passage of effective tobacco prevention and control policies at the highest-level[1].

Moving forward with effective tobacco control policies requires comprehensive evaluation using data on several indicators, including tobacco use patterns and trends, exposure to tobacco smoke, health consequences and financial cost of the smoking epidemic. This information is useful for raising awareness, motivating decision makers to adopt new measures or strengthen existing ones, and mobilizing greater resources to control the epidemic[5,6].

In Europe, Joossens and Raw developed the Tobacco Control Scale (TCS) in 2006 to systematically monitor tobacco control policies implementation. It consists of a questionnaire based on six cost-effective policy interventions that should be prioritized[7]. The TCS has contributed to provide useful indicators of the level of implementation of tobacco control policies and guide researchers, advocates and policymakers about what components should be boosted in each country. Additionally, the TCS has been useful for depicting which countries or

groups of countries are pioneers and which are laggards on the implementation of such measures[8]. Furthermore, it has been used to assess variations in several outcomes (i.e. smoking prevalence, and attitudes towards smoke-free policies) according to the policies undertaken[9]. Thus, its adaptation and application to other regions would be valuable for national and regional, but also, global tobacco control.

There is a need of developing useful instruments according to contextual characteristic of each region assuring comparability across countries and regions. This is especially true in developing countries where such progress is less well-known or reported. To our knowledge, the description of tobacco control policy implementation in LA is still limited[10] as, although the WHO reports biannually on this topic, its results are subject to governmental approval. Therefore, this paper reports a) the adaptation and further development of the TCS to assess the implementation of tobacco control policies in LA; and b) the level of implementation of tobacco control policies in this region according to the TCS adapted to LA (TCS-LA).

METHODS

Development of the LA version of the TCS

To develop the TCS-LA, we first translated the 32-item original questionnaire following the WHO recommendations[11]. Thus, two bilingual experts (AF, SN) translated the domains, items, and responses from English to standard Spanish and Brazilian Portuguese, respectively; to obtain the first version. The translations were crosschecked by a panel of Spanish and LA tobacco control researchers that suggested some language-related changes to improve the understanding by LA audiences.

For the purpose of adaptation, we also developed a set of questions about the adequacy and clarity of the vocabulary used, potential missing subjects on tobacco control that should be tackled in the TCS to correctly represent the situation in their country, the difficulties encountered to obtain the required information and why; and an open question about further suggestions and comments.

Study design

This is an ecological cross-sectional survey with the country as the unit of analysis. Selected informants from 18 countries in LA (Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, and Uruguay) were requested to provide data about tobacco control policies implementation in each country, based on the rationale of the TCS 2019 Report[12].

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Informants

Non-governmental experts on tobacco control professionally active in each country were selected as informants. Informants participated voluntarily and had the option to refuse to answer the questionnaire, in which case they were asked to recommend another in-country informant(s). We identified them from our personal contacts, and previous tobacco control reports and articles from the literature and tobacco control organization in LA. We assembled a contact list of 33 informants from 18 LA countries.

Data collection

Data collection lasted from 22nd January to 29th February 2020. Two informants per country were invited by e-mail to complete an online questionnaire in Spanish or Brazilian Portuguese within two weeks (available on request). Reminders to participate were sent 7 and 13 days after the invitation e-mail was sent. Moreover, we asked the informants to provide national legislations on tobacco control in PDF, if available. We obtained response from at least two informants in each country, except from Dominican Rep., Panama, and Peru (with only one informant). No informant from Cuba answered the survey.

Adaptation of the scale

The TCS-LA has the same structure, with eight policy domains, and the same scoring, with a maximum total score of 100 points, as the last TCS report for European countries by Joossens *et al.* from 2019[12]. Therefore, the adaptation process consisted in contextualizing the scoring computation of those domains for which the same rationale could not be applied i.e. because, unlike in most of the European Union (EU), there is not a common currency in LA countries. To adapt the scale to the LA context, the rationale to assess the score(s) of three policy domains has suffered some modifications compared to the last European report. Table 1 summarizes the differences between the TCS 2019 rationale (Europe) and our adaptation for this region.

Three researchers (AF, CM and EF) independently assigned a score to each domain according to responses given by the informants and, if disagreements between informants emerged, the national legislation and/or the WHO report on the tobacco epidemic were consulted[3]. Countries that have not ratified the WHO FCTC as 31st December 2019 were subtracted one point from their total score as it is also done in the 2019 TCS for European countries[12]. The adapted TCS-LA is presented in Table S1, which shows the points allocated to each policy, with

a maximum total score of 100. The rationale for the scoring allocated to each policy domain is described in Table S2.

Evaluation of the adaptation by informants

Based on informant's open responses we have conducted a thematic analysis and classified the thematic topics in three groups (language, missing domains, and difficulties) that provide information about the adequacy and feasibility of using the TCS-LA as a tool to monitor tobacco control policies in the region[13].

Table 1 Summary of the adaptations performed from the 2019 European TCS scoring rationale
 [12] to the TCS for Latin America development by policy domains.

	Europe (Joossens <i>et al.</i>)	premium and cheapest brands based on the	
Price	The price of the Weighted Average Price (WAP) for cigarettes in 2018, considering Purchasing Power Standards (PPS). Countries with a WAP of €10 a pack and an EU average PPS receive 30 points.		
Smoke-free legislation	Smoke-free legislation enforcement is assessed using the Eurobarometer 458 of 2017 about attitudes of Europeans towards tobacco and electronic cigarettes[14].	Smoke-free legislation enforcement is assessed according to informants' median level of reporte compliance level with a Likert scale from 1 to 10	
Public spending	Tobacco control spending per capita by the government in 2018, expressed in PPS. A country which spends 62 per capita, based on the EU average GDP per capita expressed in PPS receives 10 points.	Tobacco control spending per capita by the government in 2019, expressed in PPP. A countr spending 2.20 1\$ per capita, based on the averag GDP per capita in PPP of Latin American region received 10 points.	
Advertising and promotion bans	Advertising and promotion bans enforcement is not considered to assign scores in this policy domain.	Advertising and promotion bans enforcement is assessed according to informants' report on compliance (yes/no).	

Note: Policy domains not included in this table have not suffered any changes compared to the TCS in Europe in 2019. PPP: Purchasing Power Parity; I\$: International dollars.

RESULTS

Our final sample included 17 out of 18 countries in LA. We did not obtain response from any of the two informants contacted in Cuba; therefore, no score was derived for the country.

The scale score(s)

Panama with 70 points (pts) and Uruguay with 68 points are the countries with the highest scores in the LA region; while Guatemala (32 pts), Bolivia (30 pts) and Dominican Rep. (29 pts) have the lowest scores (Table 1). Eight countries (Panama, Uruguay, Ecuador, Costa Rica,

Brazil, Peru, Chile, and El Salvador) have a score of 50 points or more (Figure 1). Differences in total scores across LA countries are small as the median gap-points equals three. The highest gap-point between countries are of seven points between Uruguay (68 pts) and Ecuador (61 pts) and the latter and Costa Rica (54 pts) (Table 2).

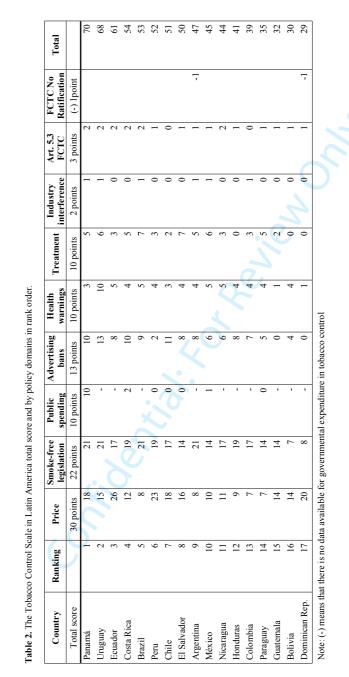
[Figure 1 about here]

As shown in Table 2, by policy domains, *price* scores are headed by Ecuador (I\$10.4; 26 pts), Peru (I\$9.2; 23 pts) and Dominican Rep. (I\$8.0; 20 pts); while Paraguay (I\$2.8; 7 pts) and Colombia (I\$3.0; 7 pts) are at the bottom. The mean score for this policy domain is 13.8 pts (SD 5.7) with six countries scoring at least half of the total score.

The median score for *smoke-free legislation* was 17 points. Most countries had a score between 21 and 14 points out of the 22 possible, except Bolivia (7 pts) and Dominican Rep. (8 pts). *Tobacco advertising, promotion, and sponsorship* (TAPS) bans are leaded by Uruguay (13 pts) followed by Chile (11 pts) and Colombia, Costa Rica and Panama with 10 points each; while the Dominican Rep. and Guatemala (0 pts) and Peru (2 pts) have the lowest scores. Similarly, *health warning labels* ranking is also leaded by Uruguay (10 pts) who achieved the highest score possible in this domain since it is the sole country in the Region that has implemented plain packaging. Guatemala and the Dominican Rep., with one point each, are at the bottom position in the health warning labels rank. *Treatment* is led by Brazil and El Salvador with 7 points each. Moreover, treatment is, together with the domain assessing *tobacco industry interference*, the policy domain that presents the highest number of countries not scoring any point (Bolivia, Honduras, and Dominican Rep.) (Table 2).

Regarding *public spending on tobacco control*, Panama, Costa Rica, and Mexico scored for spending at least 0.1 I\$ per capita on tobacco control. Panama is the only country that received the maximum score (10 pts.) This policy domain, however, presents a higher variability among countries as most informants did not report on this question because of the unavailability of the data. As a result, 10 out of 17 countries have missing data for this policy domain, which accounts for a direct loss of 10 points for those countries. However, countries' total scores with and without this policy domain show a 0.895 Spearman-rank correlation coefficient (p<0.001; 95% CI 0.726 to 0.962).

In LA, countries lacked enough initiatives to achieve the maximum score for *illicit tobacco trade* (median=0) and *tobacco industry interference* domains (median=1) (Table 2). Finally, Dominican Rep. and Argentina lost one point each since, as March 2020, they had not ratified the WHO FCTC.



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Opinions about the adequacy of the TCS-LA and barriers to report on the domains

Twenty out of 33 informants answered the optional questions regarding adequacy to LA context, representing 13 out of 17 countries included in the sample. Seventeen informants declared that the language and structure of the questionnaire was sufficiently precise; however, an informant from Brazil reported that not all the items were sufficiently clear and one from El Salvador pointed out some Spanish language variations to be fully-comprehensible in the LA Region. Accordingly, this informant reported that "the only term that is not used in LA is "pubs" in El Salvador that would be "cerveserías" (breweries), "cantinas" (saloon) or restaurants "(Table 3). Only three out of 20 informants considered that the required information was difficult to obtain and eight neither easy nor difficult. Most repeated difficulties encountered were "the process of requesting and delivering information is very bureaucratic and/or for confidential use, [...] takes more than 15 days to give a response" and that "it takes time to sustain the response with updated official sources". Another informant highlighted that "the hardest is obtaining information about the budget" and "assessing the compliance level of each smoke-free and TAPS ban because of its relativity or subjectivity depending on the location and/or informants' perspectives" (Table 3).

Moreover, regarding missing policy domains to correctly reflect LA tobacco control context, informants suggested that TCS in LA should probably include further contextual policy domains relevant for their region such as the *use and regulation of the other tobacco products* (5/20), *tobacco farming* (2/20), *cross-border* and *Internet* advertising (1/20), *taxation* (4/20), *international cooperation* (2/20), *illicit trade* (2/20) and *tobacco consumption monitoring* (3/20). Other comments cover several technical aspects about the online questionnaire, including that: a) some categories did not offer an intermediate or no applicable response options (6/20); b) informants should be able to detail whether each measure is ruled by a national or regional legislation (3/20); c) the questionnaire after each policy domain or item, should include an open-ended response to comment particular aspects related to the policy assessed (1/20).

Table 3. Literal responses of informants regarding the themes of the thematic analysis identified by country.

	Literals		
Language	"In general, it is well translated. I consider that the only term that is not for use in LA is 'PUBS', in El Salvador would be breweries, cantinas or restaurants"		
Missing domains	"The next study should probably add	"national tobacco control policies, to	

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	the use and regulation of the other tobacco products"	tobacco farming substitution"
	"cross-border" and "Internet advertising"	
Difficulties	"the process of requesting and delivering information is very bureaucratic and/or for confidential use, [] takes more than 15 days to give a response"	"Each response must have an official and verifiable information endorsement, and for Mexico it is not difficult but takes time to sustain the response with updated official sources"
0	"the hardest is obtaining information about the budget"	"The classification of the level of compliance of the tobacco control policies is difficult to assess because it is relative/subjective"
Other	"for some response categories there were no intermediate options or no applicable options"	"there should be a field to detail whether each measure has independent legislation or whether there is a comprehensive law that brings together several elements"
	"After each section there could be a space for clarification."	

DISCUSION

Main results

Panama, Uruguay, and Ecuador are the top-three leading countries in implementing tobacco control policies in LA according to the TCS-LA. Despite efforts made in the LA Region, nine countries have scores of 50 points or less (Argentina, Mexico, Nicaragua, Honduras, Colombia, Paraguay, Guatemala, Bolivia, and Dominican Rep.) meaning that they still have substantial of room for improvement in tobacco control. The policy domains that have lower median score(s) are *public spending on tobacco control, treatment, tobacco industry interference* and *illicit tobacco trade*.

Interpretation of the results

General considerations

The TCS-LA offers a full-picture of countries ahead in tobacco control in LA as well as countries' major loopholes, even in countries with a good overall score, according to non-governmental experts in tobacco control. Hence, our results are based on the perspectives of the Civil Society and are likely not affected by governmental political agenda. The WHO Reports on the global tobacco epidemic derive from governmental data and are subject to official approval. Moreover, civil society in LA has been the engine that has permitted many of the accomplishments seen in tobacco control[15] and, thus, understanding these agents' perceptions is also necessary to continue advancing in this field.

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Our results are broadly in line with those from 2018 Reports published by the WHO and the Pan American Health Organization (PAHO)[1,3]. However, after comparing both data with ours, some differences have been observed mainly in the policy domains treatment and TAPS bans, but also among others. These differences could be due to possible improvements in the legislation in some countries (i.e. Colombia passing a resolution on tobacco packaging and labelling in December 2018[16]). Alternatively, these differences could be explained by how ad hoc questionnaires are designed and what is the rationale of each Report since different questions could lead to different answers from informants, which in turn would lead to different results. Moreover, our results are at national-level and, thus, in some federal countries they may not reflect the full-picture of the legislation. This is the case of Mexico, for example, where although the national legislation may not completely ban smoking indoors in public places, there are 13 subnational laws that completely ban smoking in all public settings that are included in the TCS-LA scale, covering approximately 55% of the population[17]. The original rationale of the TCS was designed and has always been used to monitor tobacco control policies at the country level, without considering subnational bans or other specificities, and hence we decided to use the same approach in the TCS-LA adaptation.

Nevertheless, despite its potential pitfalls, the TCS-LA is a useful tool not only to monitor tobacco control policy implementation in the LA Region, but also to act as momentum for further policy advancement in the Region, according to our informants.

Considerations by policy domains

Price score(s) were assigned according to I\$ average price of 20 cigarette packs of the premium and the cheapest brands despite in Europe this policy domain is scored based on the Weighted Average Price (WAP) for cigarettes[12]. Under the Tobacco Excise Duty Directive 2011/64/EU, EU Member states excise duties must account for $\geq 60\%$ of the WAP[18]. However, in LA, unlike in Europe, excise taxes from cigarette retail prices vary from 8.3% to 71.2% (median 40.0%)[19]. And, therefore, he gap in prices between the premium and the cheapest cigarette brand is wider in those countries with lower tobacco taxes[19]. Meaning that scores assigned to *price* according to the price of a 20-cigarette pack of one brand would depend on whether this brand is a premium brand or not. A weighted average price between the premium and the cheapest brands according to their market share would be ideal but, unfortunately, market share (or highest percentage of total sales) is not available for each country in the region.

Moreover, in some LA countries such as Mexico, Brazil, Uruguay or Guatemala single-cigarette sales are common[20] despite existing bans prohibiting this practice[20,21]. Single-cigarette sales are mostly sold in the informal economy sectors[21,22]. Unfortunately, the TCS-LA was

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unable to address this phenomenon as single-cigarette vendors are often unrecognized, unrecorded, and unregulated by the legal system[21]. Regulating single-cigarette sales at the informal economic sector remains a challenge to fully-enforce WHO FCTC Article 16[23].

The public spending on tobacco control is a controversial domain as 10 out of 18 countries did not report government funding on mass media campaigns, tobacco control projects, educational programs, and support for non-governmental organizations. However, such underreporting does not necessarily mean that countries did not invest in tobacco control activities, but that the information was not publicly available in an official source or, if available, that the amount allocated to each activity was not sufficiently specified. A good example is Uruguay. Although tobacco control programs are funded through a National Program for Tobacco Control since 2005[24], data on governmental expenditure is not available to civil society as reported by our informants directly losing 10 points in the TCS-LA. However, such underreporting is not exclusive of LA since in European countries this policy domain is also the one with more missing data (data only for 31 out of 36 countries)[12]. On the other hand, for some countries reporting public budget for tobacco control, informants were unable to disaggregate the exact amount directed to mass media campaigns, tobacco control projects, educational programs, and support for non-governmental organizations. This could lead to an overestimation of the score(s) for these policy domains by including funding for tobacco dependence treatment, research projects, management of funds and enforcement, which should not be included. All this should encourage LA countries to improve data transparency, availability, and quality regarding public spending in tobacco control activities.

Adaptation process

This study shows that the original TCS developed for European countries can feasibly be adapted to LA and likely to other regions to systematically monitor tobacco control policies. Yet, over the adaptation process, some difficulties emerged mainly across those policy domains involving different currencies, like *price* and *public spending*, since in the TCS 2019 in Europe 19 out of 36 countries ranked have the Euro as common currency, unlike countries in LA where each country has a local currency. Moreover, Joossens *et al.* calculated the *price* scores using open data from EU databases published annually. Such databases are not publicly available for LA countries and, therefore, our score(s) had to be based on data from informants. However, as an alternative method to score the price domain was used, we conducted a sensitivity analysis using WHO Report to validate the methodology used to address this domain.

Another difficulty encountered was how to address enforcement of the legislation through compliance. Joossens *et al.* used data from the Special Eurobarometer on tobacco, which is a

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cross-sectional study of a representative sample of the adult population conducted by the European Commission in all the EU Member States[14]. However, there are no representative cross-country population-based surveys on tobacco control legislation compliance for the LA region, and, therefore, we had to turn to informants.

Limitations and strengths

The TCS-LA is built on data obtained from informants and not from legislative documents themselves; and consequently, our study might be limited by the used source of data. However, informants provided updated information regarding the enactment and enforcement of the legislation, which goes beyond the information provided by the sole legislation documents. Yet, potential subjective answers were minimized by recording data from at least two informants per country (except for Dominican Rep., Panama and Peru) and by cross-checking the information with national legislation provided in PDF by the informants and countries' profiles from the last WHO Report from 2018[3], when disagreements emerged. Moreover, we prioritized contacting non-governmental tobacco control experts to mitigate potential self-complacency bias.

Another limitation could be that the legislation compliance level is not assessed using population representative surveys (as the Eurobarometer in EU Member States), but through subjective assessments from the informants because there is no population representative survey available with a comparable methodology across countries in this Region. However, taking into account the level of enforcement of smoke-free laws and TAPS bans and not only implementation is key to fully monitor tobacco control policies that tries to counteract one of the main limitations of the TCS in Europe as it only measures enforcement for smoke-free laws in hospitality venues and workplaces. Another potential limitation could be that, although the questionnaire was sent in Spanish (except for Brazil) that is the common language in most LA countries, there are local linguistic differences that could hamper informants understanding some of the items. However, almost all informants reported that the language and structure of the questionnaire was adequate and clear.

The TCS-LA is the first to offer a full picture of tobacco control policies in LA that is key to effectively monitor the implementation of tobacco control policies as recommended by the MPOWER[3]. Moreover, our paper provides a complete explanation of the adaptation process of the TCS to the LA context ensuring the reproducibility of results, showing that the TCS is adaptable to other Regions and contexts. Finally, our study also includes a qualitative evaluation of the adaptation process by the informants on its adequacy to monitor tobacco control in LA and to understand potential missing domains.

CONCLUSION

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Panama and Uruguay are the leading countries in tobacco control in LA; however, tobacco control in the LA Region has room for improvement since eight countries have a total score of 50 points or less. Future monitoring activities are needed to address progress in policy development in tobacco control across countries. The TCS has proven to be adaptable to broader regions apart from Europe, thus setting a precedent for future adaptation to other regions. Policymakers and stakeholder, however, should promote monitorization of tobacco control policies to ensure its sustainability over time since monitoring activities should also cover the impact of tobacco control policy interventions and tobacco industry activities that is ., polic, ...nood of success of th key to increase the likelihood of success of the measures included under the WHO FCTC.

PAPER V

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Ethical approval

The study protocol received ethical approval from IDIBELL's Ethics Committee (PR247/18). All informants gave their informed consent to participate in the study.

Contributorship Statement

Conceptualization and design of the study: AF, AP, CM and EF. Adaptation of the TCS to LA (rationale): AF, AP, CM, EB, EF and LJ. Translation of the questionnaire: AF and SN, with the contextual language validation of AP, EB and MC. Allocation of the scores: AF, CM and EF. Visualization: AF. Data curation: AP, EB, EF and LJ. Drafted manuscript: AF. Critically revised manuscript: All authors. Approved final manuscript version: All authors. Guarantors: EF and CM, and both are considered senior authors.

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Competing Interests None declared

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FIGURES



Figure 1. Total scores of the TCS in Latin America.

Note: Intervals have been determined by quartiles (P₂₅ 34.6; P₅₀ (median) 45.8; P₇₅ 53.4). PA (Panama), UY (Uruguay), EC (Ecuador), CR (Costa Rica), BR (Brazil), PE (Peru), CL (Chile), SV (El Salvador), AR (Argentina), MX (Mexico), NI (Nicaragua), HN (Honduras), CO (Colombia), PY (Paraguay), GT (Guatemala), BO (Bolivia), DO (Dominican Rep.), and CU (Cuba).

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Discussion

The Tobacco Control Scale (TCS) has served as the cornerstone for fulfilling the main objective of this thesis consisting of evaluating tobacco control policies in European and Latin American countries. Therefore, first we conducted a literature search to understand its strengths and limitations as a measure to monitor tobacco control policy implementation at country-level to determine its potential use as a research tool. Our results showed that, despite its limitations, the TCS has been commonly used to assess differences in tobacco-related outcomes according to tobacco control policy implementation. Thus, we used it as a tool to measure tobacco control policies in our subsequent research assessing its association with several outcomes (i.e., smoking prevalence and quit ratios, countries' socioeconomic status (SES) and hardcore and light smoking) and, even, to monitor the implementation of tobacco control policies in other regions and socio-political context such as Latin America by adapting the scale for the first time.

1. Interpretation of the results

1.1. The Tobacco Control Scale and other tools to measure implementation of tobacco control policies at country-level

To evaluate the implementation of national and regional tobacco control policies at the individual and population-level is key to better understand which policies work and why. Cross-country evaluation, however, requires the use of common measuring tools to allow valid cross-national comparisons and minimise errors. In other words, measurement is critical to policy evaluation as most measures are subject to a range of potential biases and limitations as indicators of their target policy dimensions since policy dimensions are complex constructs and can be operationalised in many ways[68].

In Europe, according to our findings, the TCS has covered this need for a crosscountry comparable tool of the level of implementation of tobacco control policies. The TCS has been commonly used to assess in and within country variations in tobacco-related and health outcomes according to the policies instituted[77]. However, although being designed for European countries only, the TCS has had

an international outreach as a research tool since some non-European countries have used its rationale to monitor the status of tobacco control policies in their context[78,79].

Our findings, therefore, suggest that the TCS, despite its original design as a means to advocate for comprehensive tobacco control policies, has been applied by the tobacco research community as an objective indicator of such policies to conduct evaluation studies. However, although being the most commonly used tool in Europe, the TCS is not the only tool of such characteristics available for these purposes since other studies have measured country-level tobacco control policies using a total score obtained from summing the scores (from 1 to 5) assigned to each MPOWER policy dimension in the WHO's Reports on the Global Tobacco Epidemic[80,81]. However, the availability of more than one evaluation instrument opens the question of what tool is the most appropriate for our research and determining which tool to use requires addressing each tool's main strengths and limitations.

As summarized in Table 2, MPOWER's composite score has some clear advantages over the TCS total score because it is available for all countries, not only for European countries, and up to date is comparable across countries and over time as the rationale of this instrument has not changed since its development. The MPOWER score has however some disadvantages for research purposes. First, it assigns the same weight to each of the six individual MPOWER scores without taking into consideration that some MPOWER measures have been proven to be more effective than other measures (i.e., taxation)[80]. Second, MPOWER's composite score has a narrower score range (from 6 to 29) than the TCS score (from 0 to 100), which limits variation across countries and may prevent to address variability within countries[82]. Third, while the TCS assesses policy implementation and even enforcement for smoke-free policies, the MPOWER reports score tobacco control policies on the presence of legislation, not evaluating the implementation of such policy, which may result in erroneous assumptions about the status of a country's tobacco control policy at the time the MPOWER report is published[81]. Finally, unlike the MPOWER's composite score, the TCS is not affected by the government's political agenda, as it is built on information from objective databases (i.e., Eurostat) and the reports of tobacco control independent experts who act as key informants[77].

Given the above and despite its limitations and lack of a formal validity assessment, the TCS is a reliable tool for assessing the implementation of tobacco control policies in Europe, or at least the best approximation developed thus far. The TCS, however, has been used at face-value because no attempts have been made to formally validate the scale[77]. Evaluating the reliability of the scale scores' is often a major challenge as in the case of the TCS which construct validity is a complex issue given the composite structure of the TCS itself, though some dimensions are based on objective data (i.e., price, exposure to SHS) from population-based surveys like the Special Eurobarometer on Tobacco and reports of the European Commission; others are based on the answers of one or two informants to an ad hoc questionnaire (i.e., public spending on mass media campaigns at national level)[33,77].

Table 2. Comparison of the TCS and the MPOWER composite score as researchtools to measure country-level tobacco control policy implementation

Tools	Range	Limitations	Strengths
TCS	0-100	 Not comparable across year 	 Cross-country comparability
		 Only available for Europe Assess implementation but not enforcement, except for smoke- free policies 	 Weighted score by effectiveness of each policy domain Wider score range (0-100 pts)
MPOWER	6–29	 Self-calculated score Assess legislation not implementation Affected by government's political agenda 	 Cross-country and temporal comparability Almost all world's countries

To gain a broader perspective of tobacco control as a public health need and build a stronger tool for tobacco research, the TCS should be adapted and extended to other countries of the WHO European Region, and to the reality of other regions of the globe, such as Latin-America or Asia, incorporating local and cultural characteristics of these regions while preserving the comparability among countries worldwide.

1.2. Challenges of cross-cultural adapting a measure of country-level tobacco control policy implementation

One of the biggest challenges of this research has been adapting the TCS to Latin American (LA) countries because the socio-political and cultural context of this region is different from that for European countries.

The cross-cultural adaptation process is key when an instrument is used in a different language, setting and time to reduce the risk of introducing bias. There is no universal agreement on how to adapt an instrument of this purposes in another cultural setting. However, there is an agreement that conducting a comprehensive linguistic translation process, although it is important, does not ensure construct validity and reliability[83].

Translating the scale from English to Spanish was a challenging process since, although our researchers are native Spanish speakers, some vocabulary is different in each Latin American country and, therefore, our translation involved transferring the meaning of concepts contained in the English scale to common (or standard)

Spanish words[84] to rise a similar effect among respondents in all LA-countries in order to ensure semantic equivalence between scales[85]. Hence, translating processes should involve experts in the field to ensure content validity that refers to the extent to which the items on a test are fairly representative of the entire domain the test seeks to measure[86], especially in studies that include countries with different dialectal variant of a language.

Over the adaptation process, however, other challenges emerged mainly related to some contextual differences between Latin America and Europe, countries' transparency, and lack of public databases and cross-country population-based surveys. First, the main difference between both regions was found for those policy domains involving different currencies, like *price* and *public spending on tobacco control.* Countries in LA have an own local currency each unlike in Europe, where half (19 out of 36) of the countries ranked in the TCS 2019 have the Euro as common currency. This difference implied an impossibility to use the same rationale of the European scale to score each of the above policy domain, which implied some modifications that could have introduced some differences on the adapted scale [34,84].

Another challenge of this adaptation process was data transparency of countries since, while Joossens *et al.* calculated the scores for *price* domain using open data from EU databases published annually. Similar databases are not publicly available for LA countries and, therefore, our score(s) had to be based on data from informants with the limitations that a subjective source adds[84]. However, it is worth mentioning that the EU has very particular structural characteristics as a supranational organization that allows cross-country comparisons since all official databases (i.e. Eurostat) harmonize national data using a consistent methodology[87,88]. This is however a strength of using the TCS in Europe in comparison to other WHO Regions.

Another of the challenges encountered was the lack of cross-country populationbased representative samples available for LA region. In the last TCS report[34], enforcement of the tobacco legislation through was addressed compliance using data from the Special Eurobarometer on tobacco, which is a cross-sectional study of a representative sample of the adult population conducted by the European Commission in all the EU MS[17]. Unfortunately, there are no representative crosscountry population-based surveys on tobacco control legislation compliance for the LA region, and, therefore, we had to turn to informants for the TCS-LA[84]. These differences could be introducing potential biases to the adaptation process; however, would be ensuring the operational equivalence of both scales by being able to compare between the characteristics of the target and source population[85].

Accordingly, although major challenges were encountered in the adaptation process, our study demonstrates that the TCS originally developed for European countries can feasibly be adapted to LA region and likely to other regions to systematically monitor tobacco control policies.

1.3. Effectiveness of comprehensive tobacco control policies to significantly reduce the prevalence of tobacco use

The WHO FCTC has accelerated the implementation of tobacco control measures. Evidence shows that a strong implementation of FCTC key demand-reduction policy measures has led to dose-response effects for comprehensive tobacco control policies[45] since best results are achieved when a comprehensive set of measures is implemented together[33].

Accordingly, our findings suggest that the implementation of more stringent tobacco control policies is associated with a lower smoking prevalence and a higher decrease in the prevalence of smokers among the EU population[89]. Moreover, the results show that both hardcore and light smoking are associated with tobacco control policies as the stronger its implementation, the lower the odds of heavy smoking[90]. However, could be argued that those adopting higher-level tobacco control policies are those countries in which smoking has lost its social acceptance favoring a decline in the smoking prevalence. Our findings, though, indicate that the implementation tobacco control policies matters and, therefore, the possibility that this is a two-way phenomenon cannot be excluded, as there are indicators that policies may precede the declines in smoking prevalence. For example, in the United Kingdom, the low prevalence at the beginning of 2000s derive from a steady decline observed since the early 70s, directly linked to the increase in the price of tobacco through taxation[91]. Or the case of Spain, where the smoking prevalence was high (about 70% in males aged 45-64) in the 80s in absence of strong tobacco legislation; and once enforced in the late 90s, there was a steady decline of smoking prevalence among males and a level-off the prevalence in females[92].

Moreover, our findings suggest that there has been an increase of light smoking among smokers in EU, which implies a softening of the smoking population[90]. This softening of the smoking population suggests that current tobacco control policies (such as smoke-free policies, tobacco taxation and advertising bans) have been effective not only in motivating smokers to quit smoking, but also influencing heavy smokers to quit smoking or to reduce their daily cigarette consumption[89,93,94]. Other explanations could be that social denormalization of smoking over time has fueled quitting across the smoking population[94], or that light smokers, which are less addicted to nicotine, continue to smoke because of psycho-social factors rather than a physical addiction[95].

Among tobacco control measures, not all are proved to have the same effect on smoking. Research shows that tobacco tax and price increases are the fastest acting and most effective of all these measures[88]; however, we found a low correlation between tobacco price and smoking prevalence[89]. This could be explained by a lack of variability among EU countries scores in this policy domain and the smoking prevalence, as 70% were in between 11-19 points and 20-29% prevalence rates[89].

Other explanations include, firstly, the increasing proportion of roll-your-own use over the past years, particularly among youth, attributed to a price raise of manufactured tobacco[96,97] as compared to roll-your-own. Secondly, an attenuation of the long-term effect of an increase on tobacco price as previous studies have shown that in spite of an increase in quitting rates in the months immediately after the tax increase, quitting attempts fell back to previous levels after three months[98]. Thirdly, legal cross border shopping and illicit trade could also be at some extend responsible for such attenuated effect of price on smoking prevalence because it might increase the affordability of tobacco products whilst it counteracts the governmental tax increases[99].

Moreover, this research found a strong association of both lower smoking prevalence and higher quit ratios with smoke-free laws and health warnings[89]. These results are in line with a previous study conducted in Europe that also found a correlation between the level of smoke-free legislation and a decrease in smoking prevalence and an increase in the previous intents to quit smoking[100]. Our results were also consistent with those of other studies that show a positive impact of the number of MPOWER measures implemented at highest-level of on reducing smoking prevalence over time[45,80]. However, our results go one step further as they show not only the association of tobacco control policies implementation with smoking prevalence, but also with tobacco cessation through quit ratios[89].

Projections for global smoking prevalence for the years 2020 and 2030 with and without the implementation, starting in 2010, of the MPOWER policy package show that, even if no additional tobacco control efforts are put in place between now and 2030, the world's overall adult smoking prevalence will decline slightly within that period (from 23.7% to 22.0%)[101]. These results suggest, on the one hand, that smoking prevalence is not likely to rise over the next 20 years, but on the other hand, that, due to expected population growth, the global number of smokers will increase by 10% in 2030. Moreover, the stability of global prevalence can be deceiving, as different regions of the world are likely to exhibit substantial movement in smoking prevalence, albeit in different directions as, while the Americas, Europe, the Western Pacific and South-East Asian regions are trending down, the African and Eastern Mediterranean regions are trending up[101].

The application of MPOWER measures globally would produce a substantial reduction in smoking, preventing many millions of premature tobacco-related deaths[101]. Gravely *et al.* found that each additional measure implemented at the highest-level is associated with an average decrease in smoking prevalence of 1.57 percentage points, this is, a relative decrease of 7.09% in the prevalence[45]. If we assume that MPOWER strategies have similar effects on other tobacco product use (i.e., e-cigarettes), the reduction in global tobacco consumption could be much greater[101]. However, some studies advert that without substantial innovation in tobacco control policies, further reductions in smoking in developed nations will come frustratingly slowly[102].

1.4. Differential impact of country-level tobacco control policies

1.4.1. The stages of the tobacco epidemic

European countries are -still today -at different stages of the tobacco epidemic based on the comparative levels of smoking prevalence and smoking-attributed mortality in men and women[12]. Eastern European countries are at stage 3 that involves a flattening or downturn of men smoking prevalence with some convergence of smoking prevalence in both sexes and a steep increase of deaths attributable to tobacco-related diseases; while the rest of European countries are at late stages (3 and 4) of the epidemic where, although smoking prevalence is decreasing, smoking attributable mortality continues to increase. Hereto, separate analysis for men and women are recommended to account for the lag between the timing of the adoption of cigarettes by large numbers of men and adoption by large numbers of women[12], which we did by stratifying all our analysis by sex[89,90].

For ecological studies, where separate analyses for men and women are not possible (i.e. no available data), to account for such differential effects, Gallus *et al.*[103] suggests using a male-to-female smoking prevalence ratio as a proxy of the stage of the tobacco epidemic since countries at an earlier stage had a relatively high male-to-female smoking ratio. Therefore, to address whether tobacco control policy implementation was driven by countries' SES in Europe, the male-to-female smoking prevalence ratio as a proxy potential effect modifier[88].

Moreover, although Lopez *et al.*[11] original model of the stages of the epidemic and Thun *et al.*[12] posterior update distinguished only between men and women, the extension to socioeconomic position follows the underlying logic of the model since high income groups are the first to adopt cigarettes early in the epidemic, and also to reject cigarettes at the later stages[104]. Therefore, in the last phases of the tobacco epidemic, inequalities are expected to initially get stronger, but to taper progressively later on, as the lower SES groups follow the higher SES groups in their rejection of cigarette smoking[102]. These distinct patterns of evolution over time contribute crucially to inequality in mortality and to a critical public health problem by increasing the equity-gap.

1.4.2. Socioeconomic inequalities and vulnerable groups

In Europe, smoking prevalence has fallen in most countries over the last decades[90]. Yet, despite national population-based tobacco control policies are important[105], they have been accompanied by an accelerated increase in inequalities in smoking[106,107] since most of these national policies were designed to target the general population and not to decrease SES inequalities in smoking[24]. This has led to a growing concern over the potential for population-level policies to worsen such inequalities[108].

Bosdriesz *et al.* have observed that the distribution of smoking across different SES groups follows different patterns in different regions and, thus, it is likely to be influenced by region-specific factors[107]. These growing relative disparities could result, according to Khlat *et al.*[104], from different scenarios, including a slower pace of smoking decline in the lower SES groups compared to the higher SES, or a stalling in the lower SES groups as opposed to a regular decline in the higher SES, or a parallel decline or even a rise in the lower SES.

NOISCUSSION

In this sense, our results suggest that hardcore and light smoking (five or less cigarettes per day) are associated to individual socioeconomic and demographic characteristics since hardcore smoking was more prevalent among men, 35 to 64 years-old, lower educated groups and individuals with more difficulties to pay bills. Conversely, light smoking was more frequent among women and high educated individuals. These results are consistent with previous studies which also observed that smokers today belong to more deprived population groups than in the past[109,110]. Therefore, regardless of whether the population of smokers is becoming more addicted or not, the social gradient in hardcore smoking highlights the socioeconomic inequalities and the increased burden of smoking related diseases among people in low socioeconomic groups[111]. However, inequities in tobacco use in Europe exist not only on economic status or education, but also on gender and ethnicity[105].

Women are especially vulnerable to the adverse health effects of tobacco use. Women who smoke are at a greater risk of developing stroke, coronary health diseases, and reproductive health harms compared to men[112]. Tobacco use among women is a major concern in tobacco control as increasing rates of use threaten progress made in gender equity. Indeed, the contribution of smoking to inequities in mortality for European women is likely to rise further, because of the delayed consequences of increased smoking in women[105].

We already showed that, amongst women, implementation of tobacco control policies at a higher country-level had a softer effect on lowering smoking prevalence compared to men in the EU. A same pattern was observed in regard with higher smoking cessation rates[89], indicating that policy implementation could be having a differential impact on the population depending on gender. Previous studies have observed that, although stronger policies have been linked to a lower likelihood of smoking initiation in women, multiple studies have found gender based differences in the effects of tobacco control policies[113].

Moreover, our paper[90] also suggests a stronger relation between an increased smoking prevalence and a higher hardcore smoking prevalence among women compared to men, despite the fact that women are already at advanced stages of the epidemic in high-income countries, and even though the uptake of cigarette smoking among women is generally delayed compared to men[11]. Consistently, Fernandez *et al.* observed that the relation between dependence and smoking prevalence was higher in women[95].

The findings of this thesis –together with other available evidence –demonstrate that within a generation the tobacco epidemic in Europe has transitioned from high and medium SES to lower SES groups[105]. Hill *et al.* [106], however, suggest that, although there is strong evidence that increases in tobacco price have a proequity effect on smoking behavior, other tobacco control measures are unlikely to help reduce inequalities in smoking without specific efforts to make these more accessible and effective for disadvantaged smokers.

Therefore, to increase health equity, jurisdictions –including national, regional, and local governments –should tailor tobacco control policies addressed to subgroups of smokers (especially, targeting those more underprivileged such as social deprived, persons with comorbidities and psychiatric distressed smokers[114]) to succeed to continue softening the population of smokers[90]. However, specific strategies and policies to achieve this are not yet outlined in the WHO FCTC and its guidelines, progress in implementing gender-responsive tobacco control strategies has been slow[115].

2. Limitations and strengths

Ecological studies –with countries as the unit of analysis –have as major limitation that any causal relationship between tobacco control policy implementation and outcomes assessed (current tobacco smoking, quit ratios, heavy and light smoking, or SES) is difficult to establish. However, results presented in this dissertation add to the body of knowledge on the effects of the implementation of tobacco control policies on reducing smoking[116], increasing smoking cessation ratios[117] or softening the population of smokers[93]. We were not trying to infer these relationships at an individual level but learning about how the impact of several policies at the country-level could influence individual and population behavioural indicators, such as smoking prevalence or cessation rates[88–90].

Another limitation in our ecological studies is the small sample sizes (from 27 to 31 countries) which may affect the statistical power increasing the likelihood of a Type II error, this is, the probability of incorrectly retaining the null hypothesis. Given our limited sample sizes, the Spearman correlation coefficients could be also affected by some outlier or influential values observations. Or precluded some significant associations between different TCS policy domains and outcomes assessed in the multivariate analysis. Despite their potential limitations, our analysis included all the European countries for which data was able depending on the objective of each sub-study[88–90].

Moreover, European countries differ in several socio-political, cultural, and other factors such as the stage of the tobacco epidemic[12]. The lack of information about these factors across the different countries could be another limitation. However, our efforts to account for differences across countries included stratifying analyses by sex since countries at an earlier stage of the epidemic present a higher male-to-female smoking prevalence ratio[103], and by age, as well as, using a fixed-effects specification for panel regression to control for unobserved country-level factors that may influence the results[88–90]. This information could help to better understand the relationships studied rather than using the crude prevalence and quit ratios estimates.

Furthermore, on the one hand, we used secondary data from the tobacco supplement of the Eurobarometer that is a periodic survey that monitors smoking indicators in the EU[17]. However, the use of self-reported data from questionnaires could be a source of bias, although self-reports on smoking status have acceptable validity[118]. And, on the other, from the TCS to measure country-level tobacco control policy implementation that, as explained in the Discussion section, has some limitations[88–90]. First, it scores implementation of tobacco control policies but not enforcement except for smoke-free policies[33]. Second, the ranking of countries, according to their TCS score, has slightly changed across years in the different editions (i.e., the UK has remain in the top position from 2007 to 2016)[89]. This low variance across countries may reduce the robustness of the results of the studies conducted. Third, the information described by the TCS score(s) does not incorporate the most recent national legislation on tobacco control due to its cross-sectional design and, thus, the impact of such policies might be underestimated when using the TCS score(s)[77].

It is also worth mentioning that the TCS-LA is built on data obtained from informants and not from legislative documents themselves; and consequently, our study might be limited by the used source of data. However, potential subjective answers were minimized by recording data from at least two informants per country and by crosschecking the information with national legislation and countries' profiles from the last WHO Report from 2018[1], when disagreements emerged[84].

Finally, regarding the literature review, publication bias is a potential source of error when the units of the investigation are published papers[119]. We searched the available literature in PubMed, the main biomedical database, as well as in Web of Science and Google Scholar and checked all the references to identify other articles not published in academic journals. However, the possibility that unpublished manuscripts or other documents addressing the topic of interest may have been missed cannot be ruled out; but it was a priori decision taken by the experience of research team, that was composed of tobacco control and policy experts and it also included the author of the TCS. Under these circumstances, selection (publication) bias seems unlikely to have affected the study[77].

Despite its limitations, this PhD thesis is the first to assess all publications using the TCS as an indicator of tobacco control policy implementation and to characterize its use on tobacco control research[77]. We also introduce a longitudinal perspective to the analysis of the impact of tobacco control policy implementation in the EU on smoking prevalence and quit ratios using an adequate time-window between tobacco control policy implementation and smoking indicators. And, we use relative changes as an outcome variable considering the difference in the starting point of each country and hence trying to avoid an underestimation of the effect[89].

Our study is also the first to assess the association between tobacco control policies implementation and countries' SES to better understand the large differences that still exist in the implementation and enforcement levels of tobacco control policies across Europe[88]. To systematically approach the hardening hypothesis in the EU

and, to introduce a longitudinal perspective to this approach, including data from four cross-sectional surveys with consistent methods across countries and over time[90]. And, finally, to offer a full picture of tobacco control policies in LA that is key to effectively monitor the implementation of tobacco control policies following the recommendations of the MPOWER[84].

3. Implications

This PhD thesis provides comprehensive results of country-level tobacco control policy implementation. In addition, it assesses the impact these policies have over smoking indicators and the tobacco epidemic. Further, it provides unique epidemiological evidence that tobacco control policies are effective to reduce smoking prevalence and soften the population of current smokers by increasing smoking cessation rates and reducing prevalence of high-dependent smokers. Below, the main implications of this research have been summarized according to several areas to further advance in tobacco control.

3.1. For public health and policymakers

Our findings suggest that existing tobacco control policies are effective to reduce tobacco use in Europe[89] and, therefore, such policies could be suitable to further decrease tobacco smoking in EU MS (and, even worldwide) as countries gradually move toward endgame strategies since the odds of becoming a hardcore smoker are lower among citizens living in countries that have implemented high country-level tobacco control policies[90]. Hence, our results should encourage policymakers to continue to implement stringent tobacco control policies and ensure its enforcement to continue to shift the tobacco epidemic towards a tobacco-free future.

Moreover, smoke-free laws and large pictorial health warnings have proven to be the most-effective measures to reduce smoking prevalence in the EU[89]. Previous studies have found these policy domains to be two of the most cost-effective measures after taxation for tobacco control[44,120]. These findings should convince governments that tobacco control measures from the MPOWER package work and, indeed, that they have positive effects on lower costs since are costeffective relative to other health similar population-based interventions[120].

However, despite its positive effects on reducing tobacco smoking, our findings suggest that tobacco control policies with a population-based design could

be increasing health inequalities amongst smokers as the odds of becoming a hardcore smoker are higher among those smokers with a lower educational level and with more difficulties to pay bills[90]. Social inequalities in hardcore smoking underline the need for governments to develop tailored interventions targeting smokers in vulnerable socioeconomic groups who may find it more difficult to quit or reduce smoking[109,121].

Policymakers and stakeholders should engage in promoting a periodic and systematic monitorization of tobacco control policies to ensure its sustainability over time since monitoring activities should also cover the impact of tobacco control policy interventions and tobacco industry activities that is key to increase the likelihood of success of the measures included under the WHO FCTC[84].

3.2. For research

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Our findings from the publications review should encourage researchers to follow some recommendations when using the TCS for future research, that are: first, to ascertain to fully understand the TCS scoring methodology since even though comparability is ensured among countries in a given year, this is not the case across years; second, researchers should consider a certain time gap between the TCS measure and the outcomes, bearing in mind that the TCS may not include the most recently adopted policies and that policies need time to have an effect; third, knowing the limitations of the TCS in measuring implementation (vs enforcement) of tobacco control policies is of most importance; and fourth, researchers need to account that low variance of some tobacco control policies across countries may also reduce the robustness of the parameter estimates[77]. Considering these lessons learnt will better the application of the scale into research and diminish the likelihood of introducing new potential limitations to their research.

A logical next step for future applications of the TCS to research would be to study the impact of tobacco control policies enforcement in terms of several tobacco-related indicators (i.e., smoking prevalence, quit ratios, exposure to SHS, tobacco sales, etc.), and to assess the impact of these policies at the population-level. Yet, to achieve this goal more extensive cross-country population-based surveys are needed to include new enforcement measures in future editions of the scale (i.e. about compliance of smoke-free laws in public places different than workplaces and hospitality venues or of advertising, promotion and sponsorship bans)[77]. Besides, further research is needed to better understand how SES factors affect policymakers' decisions on whether to implement or not population-based tobacco control policies[88] to have tools to advocate for more stringent tobacco control policies.

Monitoring tobacco control policy implementation requires building strong research tools to ensure comparability across countries that are in different levels of the WHO FCTC implementation process[45,122]. Accordingly, we suggest adapting and extending the TCS to other countries of the WHO European Region and to the reality of other regions of the globe, such as Asia or Africa, trying to incorporate local and cultural

characteristics of these regions whilst preserving the comparability among countries worldwide[77]. In this sense, our adaptation of the TCS to the LA region sets a clear precedent for future adaptation to other regions[84].

Conclusions

Conclusions

The conclusions are presented as response to each of the five-hypothesis enumerated at the beginning of this thesis.

H1: The Tobacco Control Scale has been commonly used in research as a proxy to assess tobacco control policy implementation at a country-level in Europe

- The TCS has been commonly used in observational mostly ecological studies directed to assess variations of a concrete outcome according to the policies undertaken in Europe as a proxy for tobacco control implementation.
- And, to detect changes in individual and population outcomes and to establish conclusions about how policies have an effect in specific population groups.

H2: A higher level of implementation of tobacco control policies correlates with both lower smoking prevalence and higher smoking cessation rates

- Higher implementations of tobacco control policies are associated with a lower smoking prevalence among the EU population both in 2014 and relative changes in prevalence of smokers across the period 2006–2014.
- Higher implementations of tobacco control policies are moderately associated with higher quit ratios in 2014, but no association is found for relative changes across the whole period.
- Policies showing a stronger association with a lower smoking prevalence and higher quit ratios are smoke-free laws and large pictorial health warnings.

- Tobacco control policy implementation in Europe has not been found to be associated with SES indicators at a country-level, except for public spending in tobacco control.
- Differences in tobacco control policy implementation between countries may partly be explained by their male-to-female ratio (used as a proxy of the stage of the epidemic at which countries are) and a geographical component.

H4: Smokers in those EU countries where smoking prevalence has declined are softening rather than hardening.

- The prevalence of hardcore smokers has increased in the EU.
- The hardcore smoking prevalence is not increasing in those EU Member States where the smoking prevalence is declining and that it is the prevalence of light smoking the one increasing.
- The smoking population in the EU MS is not hardening but rather softening.
- The odds of being a hardcore smoker increased over time among all education groups. These odds were higher among middle-aged men who had difficulties to pay the bills in the last 12 months that lived in countries with a lower country-level of tobacco control policy implementation.

H5: The TCS can be adapted to the Latin American context and used in these countries to systematically monitor tobacco control policy implementation

- The TCS has been adapted and appears as a feasible evaluation tool for Latin American countries.
- According to the TCS-LA, currently Panama, Uruguay, and Ecuador are the topthree leading countries in implementing tobacco control policies in the region.
- The tobacco control policy domains in LA countries that are less-implemented are treatment, tobacco industry interference and illicit tobacco trade.

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Annexes

Annex 1 Ethical approval

Bellvitge Hospital Universitari

Generalitat de Catalunya Departament de Salut

INFORME DEL COMITÉ DE ÉTICA DE INVESTIGACIÓN CLÍNICA SOBRE PROYECTOS DE INVESTIGACIÓN

El Comité de Ética de Investigación Clínica del Hospital Universitari de Bellvitge, en su reunión de fecha 7 de Junio de 2018 (Acta 11/18) tras examinar toda la documentación presentada sobre el proyecto de Tesis Doctoral con nuestra ref. **PR247/18**, titulado:

"EVALUATION OF TOBACCO CONTROL POLICIES IMPLEMENTATION IN EUROPEAN AND LATIN-AMERICAN COUNTRIES"

De la Dra. Ariadna Feliu Josa (Dirigida por el Dr. Esteve Fernández Muñoz) Programa de Prevención y Control del Cáncer de la Unidad de Control del tabaco del Institut Català d'Oncologia ICO- L'Hospitalet, como DOCTORANDA, se ha acordado dar INFORME FAVORABLE al mencionado proyecto.

Presidente Vicepresidente Secretario Vocales:

Dr. Francesc Esteve Urbano Dra. Pilar Hereu Boher Dr. Enric Sospedra Martínez Dr. Jordi Adamuz Tomás Dra. María Berdasco Menéndez Dra. Concepción Cañete Ramos Dr. Enric Condom Mundo Dr. Xavier Corbella Virós Sra. Consol Felip Farrás Dr. José Luis Ferreiro Gutiérrez Dra. Ana María Ferrer Artola Dr. Josep Ricard Frago Montanuy Dr. Xavier Fulladosa Oliveras Dra. Margarita García Martín Dr. Carles Lladó i Carbonell Dr. Josep Manel Llop Talaveron Sra. Sonia López Ortega Dr. Sergio Morchón Ramos Dr. Joan Josep Queralt Jiménez Dr. Ricard Ramos Izquierdo Dra. Gemma Rodríguez Palomar Dra. Nuria Sala Serra Dr. Petru Cristian Simon

Médico - Medicina Intensiva Médico - Farmacología Clínica Farmacéutico - Farmacia Hospitalaria Enfermero - Enfermería Bióloga - miembro no sanitario Médico - Neumología Médico - Anatomía Patológica Médico - Medicina Interna Miembro Laico - Docencia Médico - Cardiología Farmacéutica - miembro sanitario Médico - Cirugía General y Digestiva Médico - Nefrología Médico - Oncología Médica Médico- Urología Farmacéutico - Farmacia Hospitalaria Graduado Social - Atención a la Ciudadanía Médico - Medicina Preventiva Jurista Médico - Cirugía Torácica Farmacéutica - Atención Primaria Bióloga - miembro no sanitario Médico - Farmacología Clínica

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Bellvitge Hospital Universitari

Institut Català de la Sálut

Generalitat de Catalunya **Departament de Salut**

Que este Comité cumple la legislación española vigente para este tipo de proyectos, así como las normas ICH y las Normas de Buena Práctica Clínica.

Que en dicha reunión del Comité de Ética de Investigación Clínica se cumplió el quórum preceptivo legalmente.

Lo que firmo en L'Hospitalet de Llobregat, a 7 de Junio de 2018

Bellvitge Hospital Comitè Ètic d'Investigació Clínica

Fdo. Dr. Enric Sospedra Martínez Secretario del CEIC

Annex 2 Paper II: Supplementary tables



Relative change in prevalence 2006-2014	TCS	Price	Public places bans	Information	Advertising bans	Health warnings	Treatment
Total p-value	Iotal -0.415 (-0.687, -0.041) 0.006 (-0.375, 0.385) alue 0.032 0.978		-0.502 (-0.740,-0.150) -0.331 (-0.648, 0.084) 0.008	-0.331 (-0.648, 0.084) 0.114	-0.229 (-0.561, 0.165) 0.250	-0.061 (-0.431, 0.326) 0.761	-0.564 (-0.777,-0.234) 0.002
Sex Male p-value	Sex		-0.484 (-0.730,-0.128) -0.358 (-0.665, 0.053) 0.011	-0.358 (-0.665, 0.053) 0.086	-0.252 (-0.577, 0.141) 0.204	-0.025 (-0.401, 0.359) 0.903	-0.446 (-0.707,-0.080) 0.020
Female -0.352 p-value 0.072	Female -0.352 (-0.646, 0.032) -0.087 (-0.452, 0.303) p-value 0.072		-0.411 (-0.684,-0.037) -0.191 (-0.552, 0.230) 0.033	-0.191 (-0.552, 0.230) 0.371	-0.173 (-0.519, 0.221) 0.387	0.016 (-0.366, 0.393) 0.938	-0.608 (-0.803,-0.297) 0.001
Age 15 -24	Age 15 -24 -0.182 (-0.525, 0.213)	0.082 (-0.308, 0.448)	0 (-0.590, 0.123)	-0.353 (-0.662, 0.041)	0.058 (-0.329, 0.428)	-0.168 (-0.515, 0.226)	-0.095 (-0.459, 0.295)
202.0 Praile				160.0 160.0	6//.U		
p-value 0.377	25-34 -0.177 (-0.522, 0.217))-value 0.377	-0.202 (-0.540,0.193) 0.313	-0.143 (-0.534,0.202) 0.335	-0.048 (-0.443, 0.363) 0.825	(cof.0, cf.c) sto.0- 0.930	0.205 (-0.189, 0.543) 0.303	-0.322 (-0.626, 0.066) 0.101
35-44 p-value	35-44 -0.275 (-0.593, 0.117) p-value 0.165	0.137 (-0.257, 0.491) 0.497	-0.418 (-0.045,-0.689) 0.030	-0.098 (-0.482, 0.318) 0.650	-0.107 (-0.468, 0.285) 0.596	0.151 (-0.243, 0.502) 0.451	-0.517 (-0.750,-0.171) 0.006
45-54 -0.28 ² p-value 0.151	45-54 -0.284(-0.599, 0.108) -0.084 (-0.450, 0.306)		-0.352 (-0.646, 0.032) 0.072	-0.146 (-0.519, 0.274) 0.497	-0.116 (-0.475, 0.276) 0.563	0.013 (-0.369, 0.391) 0.949	-0.536 (-0.761,-0.196) 0.004
55-64 -0.24 p-value 0.219	55-64 -0.244 (-0.571, 0.149) -value 0.219	-0.089 (-0.453, 0.301) 0.660	-0.265 (-0.586, 0.128) 0.182	-0.163 (-0.531, 0.258) 0.448	-0.132 (-0.488, 0.261) 0.512	-0.204 (-0.542, 0.191) 0.308	-0.233 (-0.563, 0.162) 0.249
> 65 -0.55 p-value 0.003	> 65 -0.551 (-0.770,-0.216) value 0.003	-0.087 (-0.452,0.303) 0.667	-0.522 (-0.753,-0.177) 0.005	-0.400 (-0.692, 0.033) 0.053	-0.351 (-0.645, 0.033) 0.073	-0.011 (-0.389, 0.371) 0.957	-0.432 (-0.697,-0.062) 0.025

Table 3. Table S1. Correlation (r_{sp}) and 95% confidence intervals (CI) between Tobacco Control Scale (TCS) score in 2007 (overall and individually for its six components), and relative change in smoking prevalence in 2006-2014 in total and by sex and age groups.

ANNEXES

Table 4. Table S2. Correlation (r_{sp}) and 95% confidence intervals (CI) between TCS score in 2007 (overall and individually for its six components) and quit ratio in 2014 in total and by sex and age groups

Quit ratio 2014	TCS	Price	Public places bans	Information	Advertising bans	Health warnings	Treatment
Total 0.373 p-value 0.055	Total 0.373 (-0.008, 0.660)	0.043 (-0.343, 0.416)	0.364 (-0.019, 0.654)	0.312 (-0.105, 0.635)	0.250 (-0.144, 0.575)	0.377 (-0.004, 0.662)	0.290 (-0.102, 0.603)
	value 0.055	0.833	0.062	0.138	0.209	0.053	0.143
Sex Male 0.524 p-value 0.005	Sex Male 0.524 (0.179, 0.754) value 0.005	0.570 0.570	0.477 (0.118, 0.725) 0.012	0.474 (0.087, 0.736) 0.019	0.346 (-0.039, 0.642) 0.077	0.462 (0.099, 0.716) 0.015	0.299 (-0.091, 0.610) 0.129
Female 0.129	Female 0.129 (-0.264, 0.485)	-0.149 (-0.500, 0.245)	0.220 (-0.174, 0.554)	0.099 (-0.316, 0.441)	0.073 (-0.316, 0.441)	0.117 (-0.276, 0.476)	0.263 (-0.130, 0.585)
p-value 0.521	p-value 0.521	0.459	0.269	0.647	0.718	0.562	0.185
Age 15 -24 0.261 p-value 0.189	Age 15 -24 0.261 (-0.132, 0.583) -value 0.189	-0.103 (-0.464, 0.289) 0.611	0.243 (-0.136, 0.581) 0.222	0.268 (-0.151, 0.606) 0.205	0.348 (-0.037, 0.643) 0.075	0.262 (-0.131, 0.584) 0.187	0.139 (-0.254, 0.493) 0.488
25-34 0.380	25-34 0.380 (-0.001, 0.664)	-0.004 (-0.383, 0.377)	0.455 (0.091, 0.712)	0.374 (-0.034, 0.676)	0.181 (-0.214, 0.525)	0.144 (-0.249, 0.497)	0.293 (-0.098, 0.605)
p-value 0.051	-value 0.051	0.986	0.017	0.072	0.367	0.472	0.138
35-44 0.214	35-44 0.214 (-0.180, 0.549)	-0.113 (-0.473, 0.279)	0.284 (-0.107, 0.599)	0.064 (-0.348, 0.456)	0.119 (-0.273, 0.477)	0.133 (-0.261, 0.488)	0.373 (-0.009, 0.659)
p-value 0.283	-value 0.283	0.574	0.151	0.766	0.554	0.510	0.056
45-54 0.266	45-54 0.266 (-0.127, 0.587)	0.080 (-0.310, 0.446)	0.282 (-0.109, 0.598)	0.134 (-0.285, 0.510)	0.127 (-0.266, 0.484)	0.258 (-0.135, 0.581)	0.222 (-0.172, 0.555)
p-value 0.180	-value 0.180	0.693	0.154	0.533	0.527	0.194	0.266
55-64 0.276	55-64 0.276 (-0.116, 0.594)	0.074 (-0.315, 0.442)	0.199 (-0.196, 0.538)	0.307 (-0.110, 0.632)	0.247 (-0.147, 0.573)	0.423 (0.052, 0.692)	0.169 (-0.226, 0.516)
p-value 0.164	-value 0.164	0.713	0.320	0.145	0.215	0.028	0.401
> 65 0.501	> 65 0.501 (0.150, 0.740)	0.139 (-0.255, 0.493)	0.422 (0.049, 0.691)	0.377 (-0.031, 0.677)	0.498 (0.146, 0.739)	0.261 (-0.132, 0.583)	0.112 (-0.280, 0.472)
p-value 0.008	/alue 0.008	0.490	0.029	0.070	0.008	0.188	0.579

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Table 5. Table S3. Correlation (r_{sp}) and 95% confidence intervals (CI) between TCS score in 2007 (overall and individually for its six components), and relative change in quit ratios in 2006-2014 in total and by sex and age groups

Relative change in quit ratio 2006-2014	TCS	Price	Public places bans	Information	Advertising bans	Health warnings	Treatment
Total0.278p-value0.160	Total 0.278 (-0.114, 0.595) value 0.160	-0.142 (-0.495, 0.252) 0.481	0.505 (0.155, 0.742) 0.007	0.169 (-0.252, 0.536) 0.430	0.176 (-0.219, 0.521) 0.380	0.107 (-0.285, 0.468) 0.596	0.204 (-0.191, 0.542) 0.308
Sex Male 0.336 p-value 0.087	Sex Male 0.336 (-0.051, 0.635) value 0.087	-0.106 (-0.467, 0.286) 0.600	0.500 (0.149, 0.740) 0.008	0.325 (-0.091, 0.644) 0.122	0.210 (-0.185, 0.547) 0.293	0.132 (-0.262, 0.487) 0.513	0.120 (-0.273, 0.478) 0.553
Female 0.220 (Female 0.220 (-0.175, 0.554)	0.009 (-0.372, 0.388)	0.365 (-0.017, 0.654)	0.009 (-0.396, 0.411)	0.147 (-0.246, 0.499)	0.015 (-0.367, 0.393)	0.207 (-0.188, 0.544)
p-value 0.2271	<i>p</i> -value 0.2271	0.963	0.061	0.968	0.463	0.941	0.300
Age 15 -24 0.086 p-value 0.671	Age 15 - 24 0.086 (-0.304, 0.451) -value 0.671	0.082 (-0.308, 0.448) 0.684	0.128 (-0.265, 0.484) 0.525	0.205 (-0.216, 0.562) 0.336	0.011 (-0.370, 0.390) 0.955	0.028 (-0.356, 0.403) 0.891	-0.041 (-0.415, 0.344) 0.838
25-34 0.207	25-34 0.207 (-0.188, 0.544)	0.159 (-0.236, 0.508)	0.292 (-0.098, 0.605)	0.097 (-0.319, 0.481)	-0.008 (-0.387, 0.373)	-0.064 (-0.434, 0.324)	0.208 (-0.187, 0.545)
p-value 0.301	-value 0.301	0.430	0.139	0.653	0.969	0.750	0.297
35-44 0.199	35-44 0.199 (-0.196, 0.538)	-0.172 (-0.518, 0.222)	0.376 (-0.005, 0.662)	0.144 (-0.275, 0.518)	0.144 (-0.250, 0.497)	-0.249 (-0.575, 0.144)	0.312 (-0.078, 0.618)
p-value 0.320	-value 0.320	0.390	0.053	0.501	0.474	0.210	0.114
45-54	45-54 0.146 (-0.248, 0.498)	-0.008 (-0.387, 0.373)	0.283 (-0.109, 0.598)	0.060 (-0.352, 0.452)	-0.003 (-0.383, 0.377)	0.131 (-0.262, 0.486)	0.166 (-0.228, 0.514)
p-value	p-value 0.467	0.969	0.153	0.781	0.988	0.516	0.408
55-64 0.137	55-64 0.137 (-0.257, 0.491)	-0.024 (-0.401, 0.359)	0.251 (-0.143, 0.576)	0.175 (-0.245, 0.540)	0.050 (-0.336, 0,422)	0.385 (0.006, 0.667)	-0.078 (-0.445, 0.311)
p-value 0.497	-value 0.497	0.904	0.207	0.413	0.804	0.048	0.700
> 65 0.398	> 65 0.398 (0.021, 0.676)	-0.036 (-0.411, 0.349)	0.387 (0.008, 0.668)	0.116 (-0.301, 0.496)	0.414 (0.040, 0.686)	0.219 (-0.176, 0.553)	0.229 (-0.166, 0.560)
p-value 0.040	value 0.040	0.858	0.046	0.589	0.032	0.273	0.229

Annex 3 Paper IV: Supplementary tables

Table 6. Table S1. Descriptive analysis of the percentage of hardcore and light smokers among the sample in total and by age, sex, difficulties to pay the bills, marital status, age when stopped full-time education and type of community.

		Curi	rent smoker:	5	
	Total	Hardcore	e smokers	Light s	mokers
	(N=112,745)	N	Freq. (%)	N	Freq. (%)
Total	29,010	12,711	43.82%	4,265	14.70%
Age					
15-24	3,513	954	27.16%	815	23.20%
25-34	5,558	2,224	40.01%	873	15.71%
35-44	5,984	2,803	46.84%	758	12.67%
45-54	6,067	3,069	50.59%	742	12.23%
55-64	4,854	2,396	49.36%	598	12.32%
65+	3,034	1,265	41.69%	479	15.79%
Sex					
Men	15,577	7,871	50.53%	1,731	11.11%
Women	13,433	4,840	36.03%	2,534	18.86%
Difficulties to pay bills					
Low	4,935	2,373	48.09%	521	10.56%
Middle-Low	9,408	4,399	46.76%	1,167	12.40%
Middle-High	14,185	5,732	40.41%	2,506	17.67%
Marital status					
Married ¹	17,647	8,060	45.67%	2,426	13.75%
Single	6,283	2,377	37.83%	1,127	17.94%
Divorced ²	4,662	2,151	46.14%	634	13.60%
Other	368	103	27.99%	73	19.84%
Age when stopped					
full-time education					
Up to 15 years	4,589	2,319	50.53%	483	10.53%
16 to 19 years	15,490	7,218	46.60%	1,960	12.65%
20+ years	7,573	2,792	36.87%	1,502	19.83%
Type of community					
Rural area or village	9,283	4,147	44.67%	1,291	13.91%
Small-middle town	10,756	4,540	42.21%	1,639	15.24%
Large town	8,927	3,995	44.75%	1,331	14.91%

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¹Or living with a partner

² Or separated or widow

Annex 4 Paper V: Supplementary tables

Table 7. Table S1. The Tobacco Control Scale in Latin America rationale and score(s) distribution by policy domain, based on the TCS 2019 Report[34].

Policy domains Maximum score:	100
Price of cigarettes	30
Average price of a 20-cigarette pack of the premium and the cheapest brand based on the affordability in 2018, standardized according to PPP.	
Smoke-free work and other public places	22
Workplaces excluding cafes and restaurants – one only of	10
Complete ban without exceptions (no smoking rooms); enforced (over 7.5 in compliance)	10
Complete ban without exceptions (no smoking rooms); enforced (7.5 to 5.0 in compliance) OR	8
Complete ban, but with closed, ventilated, designated smoking rooms under strict rules; enforced (over 7.5 in compliance)	
Complete ban, but with closed, ventilated, designated smoking rooms; enforced (7.5 to 5.0 in compliance)	6
Meaningful restrictions; enforced (over 5.0 in compliance)	4
Legislative restrictions, but not enforced (less than 5.0 in compliance)	2
Cafes and restaurants – one only of	8
Complete ban (no smoking rooms); enforced (over 7.5 in compliance)	8
Complete ban, but with closed, ventilated, designated smoking rooms (over 7.5 in compliance)	6
Meaningful restrictions; enforced (over 5.0 in compliance)	4
Legislative restrictions; but not enforced (less than 5.0 in compliance)	2
Public transport and other public places and private cars	4
Complete ban in trains without exceptions	1
Complete ban in other public transport without exceptions	1
Ban in private cars when minors or children are present	1
Complete ban in educational, health, government and cultural places	1
Spending on public information campaigns	10
Tobacco control spending per capita in I\$ by the government in 2019, expressed in PPP.	

Comprehensive bans on advertising and promotion	13
Points for each type of ban included – additive	
Complete ban on tobacco advertising on television and radio	2
Complete ban on outdoor advertising (i.e., posters)	2
Complete ban on advertising in print media (i.e., newspapers and magazines)	1,5
Complete ban on indirect advertising (i.e., cigarette branded clothes, watches, etc.)	1
Ban on display of tobacco products at the point of sale	2
Ban on point-of-sale advertising	2
Ban on cinema advertising	1
Ban on sponsorship	1
Ban on internet advertising	0,!
Large direct health warning labels	10
Plain packaging	4
Size of warning – one only of	3
50% or less of packet	1
51–79% of packet	2
80% or more of packet	3
Pictorial health warnings – additive	3
Pictorial health warnings on cigarette packs	2
Pictorial health warning on hand rolling tobacco	1
Treatment to help smokers quit	1
Recording of smoking status in medical notes	1
Legal or financial incentive to record smoking status in all medical notes or patient files	1
Brief advice in primary care	1
Family doctors reimbursed for providing brief advice	1
Quitline	2
National quitline or quitlines in all major regions of country	1
ADDITIONAL POINT FOR	
Quitline counsellors answering at least 30 hours a week (not recorded messages)	1
Network of smoking cessation support and its reimbursement – one only of	4
Cessation support network covering whole country, free	4
Cessation support network but only in selected areas, e.g., major cities; free	3
Cessation support network covering whole country, partially or not free	3
Cessation support network but only in selected areas, e.g., major cities, partially or not free	2

Reimbursement of medications – one only of	2
Medications totally reimbursed or free to users	2
Medications partially reimbursed	1
Illicit tobacco trade	3
Ratification of the Illicit Trade Protocol	1
Track and trace system for tobacco products, fully FCTC Protocol compliant	2
Track and trace system for tobacco products, but not fully FCTC Protocol compliant	1
Tobacco Industry Interference	2
A whole range of measures, well enforced, to restrict tobacco industry interference	2
or some measures, well enforced, to restrict tobacco industry interference	1
Note: "Maaningful restrictions" refers to countries where the smoke free legislation only applies	to some

Note: "Meaningful restrictions" refers to countries where the smoke free legislation only applies to some regions of the country, contains exceptions (i.e. bars, small size establishments or during specific hours) or allows smoking in indoor premises which are not defined as closed.

Table 8. Table S2. Rationale of the scoring allocated to each policy domain in the TCS-LA.

Price (30 points)

The score corresponding to the average price of a 20-cigarette pack of the premium brand and the cheapest bran in each country based on the affordability was calculated in International Dollars (I\$) in 2018 for each country. I\$ is a hypothetical currency with the same purchasing power of goods and services in all countries that is calculated by converting national currencies into I\$ using a PPP exchange rate[123]. The PPP exchange rate or conversion factor from local currency to I\$ was obtained from the World Bank database[124].

Countries with a \geq 1\$12 price average price per pack of 20-cigarrette received 30 points. The cut-off point price was calculated adding a 10% to the highest price in 1\$ among all the countries included in the study. The price of a 20-cigarette pack of the premium brand and the cheapest brand in each country in the local currency was obtained from the last WHO report on the tobacco epidemic, that is the latest data available from the WHO (Table 9.2 in the WHO report [1]).

Smoke-free public and workplaces and public places (22 points)

The score corresponding to smoke-free public and workplaces was estimated according to the implementation and enforcement of smoking bans in each country. The distribution of the scores for this component is the same as the one applied by Joossens et al. in the TCS 2019 in Europe (Table S1)[34]. To assess the enforcement of these policies, informants were also asked to rate in a Likert scale from 1 (no compliance) to 10 (full compliance) the compliance level of the smoking bans in each of the places. For workplaces and bars and restaurants, after calculating the median compliance level between both informants, those countries with a good-enough compliance (<5.0) were subtracted two points; and four points to those with a low compliance (<5.0) (i.e. Chile has a complete ban for bars and restaurants (8 points.); however, its mean compliance level is seven (good-enough) and, thus, it scores 6 points.

Public spending on tobacco control (10 points)

The score corresponding to public information campaigns was assessed according to tobacco control spending per capita by the government in 2019, expressed in PPP. Government funding on mass media campaigns, tobacco control projects, educational programs; and support for non-governmental organizations in the local currency was reported by informants in each country. Public expenditure per capita was calculated in I\$ after converting national currencies using a PPP exchange rate[124]. A country spending I\$2.20 per capita based on the average GDP per capita in PPP of LA region (GDP=16,590.2) received 10 points. The cutting point was set to be comparable to the score(s) from the TCS 2019 Report in Europe[34].

Comprehensive advertising and promotion bans (13 points)

The score corresponding to comprehensive advertising, promotion and sponsorship policies was estimated according to the implementation and enforcement of these bans in each country. The distribution of the scores for this component is the same as the one applied by Joossens et al. in the TCS 2019 in Europe (Table S1)[34]. To assess the enforcement of these policies, informants were asked to apprise the compliance (yes/no) for each of the channels (i.e. television, cinema, etc.) and to rate in a Likert scale from 1 (no compliance) to 10 (full compliance) the compliance level. Only those countries reporting full-compliance (over 7.5) received the total score assigned to each of the channels and those scoring 7.5 or less were subtracted 50% of total score assigned to each channel (i.e. Colombia bans point of sale advertising; however, it compliance level is 6 and, therefore, its score for this channel is one out of two possible points).

Large direct health warning labels (10 points)

The score corresponding to large direct health warning labels was estimated according to the type of regulations existing in each country reported by the informants. The distribution of the scores for this component is the same as the one applied by Joossens et al. in the TCS 2019 in Europe (Table S1)[34].

Treatment to help smokers quit (10 points)

The score corresponding to treatment to help smokers quit was estimated according to the type of regulations existing in each country reported by the informants. The distribution of the scores for this component is the same as the one applied by Joossens et al. in the TCS 2019 in Europe (Table S1)[34].

Illicit tobacco trade (3 points)

The score corresponding to illicit tobacco trade reflects whether countries had ratified the Protocol to Eliminate Illicit Trade in Tobacco Products aimed to eliminate all forms of illicit trade in tobacco products, in accordance with the terms of Article 15 of the WHO-FCTC[125]. Parties to the Protocol were obtained from the United Nations Treaty Collection depositary[126]. Moreover, informants were asked to report whether their countries had a track and trace system for tobacco products and its level of compliance with the WHO-FCTC Protocol, as January 2020. The distribution of the scores for this component is the same as the one applied by Joossens et al. in the TCS 2019 in Europe (Table S1)[34].

Tobacco Industry Interference (2 points)

The score corresponding to tobacco industry interference was estimated according to the range of measures, well enforced, to restrict tobacco industry interference that informants reported from each country. The distribution of the scores for this component is the same as the one applied by Joossens et al. in the TCS 2019 in Europe (Table S1)[34].

Table 9. Table S3. Price score according to the average price of 20-cigarette pack of the premium and cheapest brand price in 2018 from WHO Report[1] in 17 Latin American countries.

Countries	Price premium brand	Price cheapest brand (I\$)	Average price (premium and cheapest brand) (1\$)	Tools (REF.=12,00 I\$) (max=30 points)
Argentina	4.25	1.93	3.09	8
Bolivia	7.78	3.11	5.45	14
Brazil	3.92	2.45	3.19	8
Chile	9.15	5.34	7.25	18
Colombia	3.94	2.01	2.98	7
Costa Rica	5.38	3.84	4.61	12
Dominican Rep.	10.33	5.63	7.98	20
Ecuador	10.71	10.06	10.39	26
El Salvador	7.53	5.10	6.32	16
Guatemala	6.62	4.41	5.52	14
Honduras	4.68	2.55	3.62	9
México	5.49	2.74	4.12	10
Nicaragua	5.08	3.81	4.45	11
Panamá	7.59	6.75	7.17	18
Paraguay	4.79	0.80	2.80	7
Peru	11.04	7.36	9.20	23
Uruguay	6.17	5,73	5,95	15

	-	-	-	-	-	
Countries	Bars and restaurants (max=8 points)	Public transport (max= 2 points)	Public places (max=1 point)	Private cars (max=1 point)	Workplace (max= 10 points)	Total (max= 22 points)
Argentina	8	2		0	10	21
Bolivia	2	Ч	0	0	4	7
Brazil	8	2		0	10	21
Chile	9	2		0	8	17
Colombia	9	2		0	8	17
Costa Rica	8	2		0	8	19
Dominican Rep.	2	2	0.25	0	4	8
Ecuador	9	2		0	8	17
El Salvador	4	Η		0	8	14
Guatemala	4			0	8	14
Honduras	9	2		0	10	19
México	4	2	0.25	0	8	14
Nicaragua	4	Ч	Ξ	Η	10	17
Panamá	8	2	Ч	0	10	21
Paraguay	4	Ξ	Ч	0	8	14
Peru	9	2	Ξ	0	10	19
Uruguay	8	2	Ξ	0	10	21

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Table 11. Table S5. Tobacco Control Budget (TCB) score(s) in 2019 in 17 Latin American countries.

Countries	Population 2018 /1000	TCB (local currency)	Local currency (ISO)	Purchasing power parity (PPP) (local currency to 1\$)	TCB (1\$)	TBC per capita (I\$)	GDP per capita (current 1\$)	TBC per capita in PPS LA=16,590.20	Total (max. 10 points)
Argentina	44,494.50	I	ARS	15.90	I	I	20610.60	I	I
Bolivia	11,353.14	I	BOB	3.10	I	I	7873.20	I	I
Brazil	209,469.33	I	BRL	2.00	I	I	16096.40	I	I
Chile	18,729.16	82,000,000.00	CLP	404.80	202,569.17	0.01	25222.50	0.01	0
Colombia	49,648.68	I	СОР	1312.70	I	I	15012.90	1	I
Costa Rica	4,999.44	368,029,411.00	CRC	392.70	937,177.01	0.19	17671.10	0.18	Ч
Dominican Rep.	10,627.17	I	DOP	I	I	I	11734.40	I	I
Ecuador	17,084.36	I	USD	0.50	I	I	8331.80	I	I
El Salvador	6,420.74	100,000.00	USD	0.50	200,000.00	0.03	8462.40	0.06	0
Guatemala	17,247.81	I	GTQ	4.00	I	I	5138.80	I	I
Honduras	9,587.52	I	HNL	11.60	I	I	19844.60	I	I
Mexico	126,190.79	140,131,205.00	NXM	9.40	14,907,575.00	0.12	5533.60	0.35	2
Nicaragua	6,465.51	I	OIN	11.60	I	I	25553.70	1	I
Panamá	4,176.87	4,935,717.99	USD	0.6	8,226,196.65	1.97	13599.90	2.40	10
Paraguay	6,956.07	662,536,676.32	ΡYG	2453.8	270,004.35	0.04	14418.10	0.04	0
Peru	31,989.26	209,300.00	PEN	1.6	130,812.50	0.00	17748.20	0.00	0
Uruguay	3,449.30	I	NγU	22.5	I	I	23572.20	I	I

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Note: A country spending 1\$2.20 per capita based on the average GDP per capita in PPP of LA region (GDP= 16,590.2) received 10 points. (-) means that there is no data available for governmental expenditure in tobacco control.

Table 12. Table S6. Tobacco advertising, promotion and sponsorship bans score(s) on 1st January 2020 in 17 Latin American countries.

	Σ	Cinema	Outdoors	Drint	Point of	Diculary	Snoncorchin	Internet	Indiract	Total
Countries	and radio (max= 2 pts)		(max= 2 pts)	(max= 1.5 pts)	sales (max= 2 pts)	(max= 2 pts)	(max= (max= 1 pts)	(max= 0.5 pts)	(max= 1 pts)	(max= 13 pts)
Argentina	2	-	2	1.50	0	0		0.25	0.5	8
Bolivia	2	0.5	Ч	0.75	0	0	0	0	0	4
Brazil	2	1	2	1.50	1	Ч	0.5	0.25	0	თ
Chile	2	1	2	1.50	1	Ч	1	0.25	1	11
Colombia	Ч	0.5	2	0.75	1	0	Ч	0.25	0.5	7
Costa Rica	2	0.5	2	1.50	2	0	1	0.25	1	10
Dominican Rep.	0	0	0	0	0	0	0	0	0	0
Ecuador	2	Ч	2	1.50	0	0	-	0.25	0	00
El Salvador	2	Ч	2	1.50	0	0	Ч	0.25	0.5	8
Guatemala	0	0	0	0	0	0	0	0	0	0
Honduras	2	Ч	Ч	1.50	1	0	-	0.25	0	00
Mexico	2	Ч	2	0	0	0	0.5	0	0.5	9
Nicaragua	2	Ч	2	0	0	0	0	0.50	0	9
Panamá	2	0.5	2	1.50	2			0.25	1	10
Paraguay	1	0.5	Ч	0.75	0	0	0.5	0.25	0.5	IJ
Peru	2	0	0	0	0	0	0	0.25	0	2
Uruguay	2	Ч	2	1.50	2	2		0.50	1	13

*pts: Points

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Table 13. Table S7. Large health warning labels score(s) on 1st January 2020 in 17
Latin American countries.

200	Countries	Plain packaging (max= 4 points)	Size (max= 3 points)	Pictorial health warnings (max= 3 points)	Total (max= 10 points)
	Argentina	0	1	3	4
	Bolivia	0	1	3	4
	Brazil	0	2	3	5
	Chile	0	1	2	3
	Colombia	0	1	3	4
	Costa Rica	0	1	3	4
	Dominican Rep.	0	1	0	1
	Ecuador	0	2	3	5
	El Salvador	0	1	3	4
	Guatemala	0	1	0	1
	Honduras	0	1	3	4
	México	0	2	3	5
	Nicaragua	0	2	3	5
	Panamá	0	1	2	3
	Paraguay	0	1	3	4
	Peru	0	1	3	4
	Uruguay	4	3	3	10

Table 14. Table S8. Treatment score(s) in 2019 in 17 Latin American countries.

Reimbursement (max= 2 points) 10 points)	0	0	2	0			0		2	0				2		0	ſ
Network Cessation Support (max= (max= 2 points)	m	0	4	2	2	m	0	m	m	2	0	m	m	m	m	2	ſ
Quitline (max= 2 points)	2	0		0	0	0	0	0	2	0	0	2	0	0	2		C
Brief advice (max= 1 point)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	C
Recording smoking status (max= 1 point)	0	0	0	0			0				0	0	0	0	0	0	-
Countries	Argentina	Bolivia	Brazil	Chile	Colombia	Costa Rica	Dominican Rep.	Ecuador	El Salvador	Guatemala	Honduras	Mexico	Nicaragua	Panamá	Paraguay	Peru	

Table 15. Table S9. Illicit tobacco trade score(s) in 2019 in 17 Latin American countries.

Countries	Ratification FCTC Illicit trade Protocol (max=1 point)	Track and Trace system (max=2 points)	Total (max=3 points)
Argentina	0	1	1
Bolivia	0	1	1
Brazil	1	1	2
Chile	0	0	0
Colombia	0	0	0
Costa Rica	1	1	2
Dominican Rep.	0	1	1
Ecuador	1	1	2
El Salvador	0	1	1
Guatemala	0	1	1
Honduras	0	1	1
México	0	1	1
Nicaragua	1	1	2
Panamá	1	1	2
Paraguay	0	1	1
Peru	0	1	1
Uruguay	1	1	2

TOBACCO CONTROL IN EUROPE AND LATIN AMERICA

Table 16. Table S10. Tobacco Industry Interference score(s) in 2019 in 17 LatinAmerican countries.

Countries	Total (max=2 points)
Argentina	1
Bolivia	0
Brazil	1
Chile	0
Colombia	1
Costa Rica	0 0 0 0 0 1
Dominican Rep.	0
Ecuador	0
El Salvador	0
Guatemala	0
Honduras	0
México	
Nicaragua	0
Panamá	1
Paraguay	0
Peru	0
Uruguay	1

Annex 5 Tobacco Control Scale website

The Tobacco Control Scale website was launched at the 7th European Conference on Tobacco or Health (ECToH) in Porto (Portugal) in March 2017. The TCS website was built by the Institut Català d'Oncologia WHO Collaborating Centre in Tobacco Control in collaboration with the Association of European Cancer Leagues.

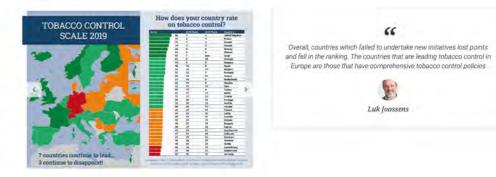
The main objective behind the development of this website is gathering all available TCS Reports (2005-2007, 2010, 2013, 2016 and 2019) and other TCS-related information, including a chart builder that provides users to build different charts and graphs with the TCS Reports score(s) and a repository of publications using the TCS Reports.

Tobacco Control Scale

HOME HISTORY RATIONALE METHODS THE REPORTS GRAPHICS REPOSITORY NEWS ABOUT US

TOBACCO CONTROL SCALE

Monitoring the implementation of tobacco control policies systematically at country-level across Europe



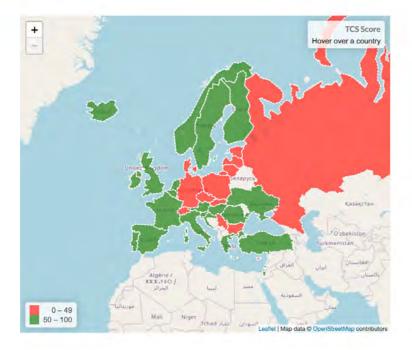
THE REPORTS

The Tobacco Control Scale website was launched at the 7th ECTOH 2017 as a joint initiative of the Association of European Cancer Leagues and the Tobacco Control Unit of the Catalan Institute of Oncology, a WHO Collaborating Center for Tobacco Control



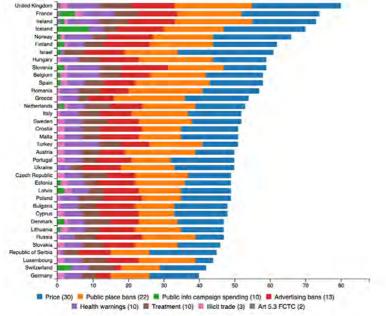
Мар Ranking Evolution

~
19

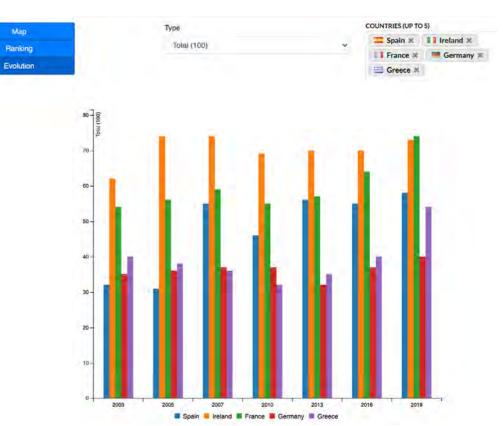


Map	8
Ranki	ng
Evolut	inn

Year Component 2019 1 Total (100) 🗹 Break down score



TOBACCO CONTROL IN EUROPE AND LATIN AMERICA



ABOUT US

Authors



Luk Joossens









Martin Raw Ð Advocacy Officer of ECL

Ð Honorary Associate Professor

Ariadna Feliu Researche

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Esteve Fernandez UCT Director

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Annex 6 The Tobacco Control Scale 2019 in Europe

The Tobacco Control Scale is a three-yearly Report. The Last edition was launched at the 8th European Conference on Tobacco or Health (ECToH) in Berlin (Germany) in February 2020. As a result of our collaboration in Paper II[89], Luk Joossens invited Prof. Esteve Fernández (director of this thesis) and myself to participate in the development of the 2019 Report in Europe[34]. Working closely with the first author of the TCS has helped us to better understand its rationale and methodology behind the TCS score(s) what has been key to adapt this scale to another region, Latin America.



A report of the Association of European Cancer Leagues



ANNEXES

The Tobacco Control Scale 2019 in Europe

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This report was launched at the Eighth European Conference on Tobacco or Health, Berlin, Germany, 19-22 February 2020.

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www.europeancancerleagues.org | www.tobaccocontrolscale.org

EXECUTIVE SUMMARY

This report describes the results of a survey of tobacco control activity in 36 European countries in 2019, using the Tobacco Control Scale (TCS), first described in the 2006 Luk Joossens and Martin Raw paper, *The Tobacco Control Scale: a new scale to measure country activity.* The data used for the 2019 survey refer to legislation in force on the 1 January 2020, 2018 price data, and the tobacco control budget in 2018. Any legislation, price increases or funding introduced or enforced after those dates are not included.

The scale quantifies the implementation of tobacco control policies at country level, and is based on six policies described by the World Bank, which they say should be prioritised in a comprehensive tobacco control programme, namely:

- · Price increases through higher taxes on cigarettes and other tobacco products;
- · Bans/restrictions on smoking in public and workplaces;
- Better consumer information, including public information campaigns, media coverage, and publicising research findings;
- Comprehensive bans on the advertising and promotion of all tobacco products, logos and brand names;
- · Large, direct health warning labels on cigarette boxes and other tobacco products;
- Treatment to help dependent smokers stop, including increased access to medications.

The scale allocates points to each policy, with a maximum score of 100: price (30 points), smoke free public places (22 points), spending on public information campaigns (10 points: reduced from 15 points in previous editions), comprehensive advertising bans (13 points), large health warnings (10 points), cessation support (treatment) (10 points), combatting illicit trade (3 points: NEW for TCS 2019) and tobacco industry interference (2 points: NEW for TCS 2019). Countries which have not ratified the WHO Framework Convention on Tobacco Control will lose one point (NEW: new for TCS 2019).

HEADLINE RESULTS AND ISSUES:

- Three countries (Slovenia, Greece and Austria) improved their score with 14 or more points.
- Seven leading countries have 60 points or more. The top score is 80 out of 100 (UK).
- Fifteen countries are doing reasonably well with 50 to 59 points.
- The remaining 14 countries fail to score at least 50 points so need to do much more.
- Three countries had very low scores, with fewer than 45 points. The lowest ranking is 40
 out of 100 (Germany)

A major concern is the lack of funding for tobacco control. No country spends €2 per capita on tobacco control, with only Iceland coming close. The TCS scores for spending are extremely low and we are seeing reduced funding in several countries. The second major issue of concern is tobacco industry influence, which remains the largest obstacle to the introduction of effective tobacco control policies.

RECOMMENDATIONS:

- 1. Implement at least the six World Bank priority measures; a comprehensive tobacco control policy is an obligation under Article 4 of the WHO Framework Convention on Tobacco Control (FCTC).
- 2. Spend a minimum of €2 per capita per year on tobacco control.
- 3. Address tobacco industry interference in public health policy making, in accordance with the guidelines on Article 5.3 of the WHO FCTC.
- 4. Implement the FCTC Article 6 guidelines on tobacco taxation and revise the EU Tobacco Tax Directive in 2020, which should result in significant tax increases and smaller tax differences between cigarettes and hand rolled tobacco.
- 5. Introduce comprehensive smoke free legislation in line with the FCTC Article 8 guidelines, including a ban on smoking in private cars when minors are present.
- 6. Introduce standardised/plain packaging for all tobacco products.
- 7. Ban the display of tobacco products at the point of sale.
- 8. Accelerate the implementation of tobacco cessation support in line with Article 14 of the WHO FCTC and its guidelines.
- 9. Ratify the WHO FCTC Protocol to eliminate the illicit trade in tobacco products and adopt tracking and tracing standards in line with the Protocol.
- 10. Invest in research to monitor and measure the effect of tobacco control policies in line with Article 20 of the WHO FCTC.

INTRODUCTION

In this report, we describe the results of a survey of tobacco control activity in 36 European countries in 2019 using the Tobacco Control Scale (TCS), first described in the Luk Joossens and Martin Raw 2006 paper, The Tobacco Control Scale: a new scale to measure country activity (1). Here we report the results of the 2019 survey, indicate the changes in the ranking compared to the previous survey (2016) and discuss the results.

The TCS, which quantifies the implementation of tobacco control policies at country level, is based on six policies described by the World Bank (2), which they say should be prioritised in a comprehensive tobacco control programme. The six policies are:

- · Price increases through higher taxes on cigarettes and other tobacco products;
- · Bans/restrictions on smoking in public and workplaces;
- Better consumer information, including public information campaigns, media coverage, and publicising research findings;
- · Comprehensive bans on the advertising and promotion of all tobacco products, logos and brand names;
- · Large, direct health warning labels on cigarette boxes and other tobacco products;
- Treatment to help dependent smokers stop, including increased access to medications.

METHODS

The survey was conducted in 2004, 2005 (1), 2007 (3), 2010 (4), 2013 (5), 2016 (6) and now in 2019. In 2004, the survey involved 28 countries: 25 European Union (EU) countries plus Switzerland, Iceland and Norway. In 2005 and 2007 the survey was repeated in 30 European countries (27 EU countries plus Switzerland, Iceland and Norway) (3), and in 2010 with 31 European countries (the 2007 sample plus Turkey) (4). The 2016 survey was conducted with 35 European countries: the 2010 sample plus Croatia, Serbia, Ukraine and the Russian Federation. In 2019, Israel was added to the list of countries. The correspondents who provided information in 2019 are shown in Table 1.

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Table 1: Contributors who provided information in 2019

Country	Name	Organisation
Austria	Manfred Neuberger	Medical University of Vienna
Belgium	Suzanne Gabriels	Belgian Foundation against Cancer
Bulgaria	Gergana Geshanova	Smoke Free Coalition, Bulgaria
Croatia	-	WHO tobacco control profile 2019
Cyprus	-	WHO tobacco control profile 2019
Czechia	Eva Kralikova, Kamila Zvolska	Charles University and the General University Hospital
Denmark	Niels Them Kjær	Danish Cancer Society
Estonia	Marge Reinap	WHO Office, Estonia
Finland	Mervi Hara	Suomen ASH
France	Emmanuelle Béguinot	Comité National Contre le Tabagisme
Germany	Ute Mons	The German Cancer Research Center
Greece	Constantine Vardavas	University of Crete
Hungary	Tibor Demjen	Hungarian Focal Point for Tobacco Control
Iceland	Vidar Jensson	Department of Health
Ireland	Mark Murphy, Nuala O'Reilly	ASH Ireland, Council of the Irish Heart Foundation, Department of Health
Israel	Shira Kislev	Smoke Free Israel
Italy	Lorenzo Spizzichino, Daniela Galeone	Ministry of Health
Latvia	Dana Muravska	Ministry of Health, Public Health Department
Lithuania	Vaida Liutkutė	Health Research Institute
Luxembourg	Lucienne Thommes	Fondation Cancer, Luxembourg
Malta		WHO tobacco control profile 2019
Netherlands	Fleur Van Bladeren	Dutch Cancer Society (KWF Kankerbestrijding)
Norway	Maxime Compaoré	Norwegian Cancer Society
Poland	Krzysztof Przewozniak	Maria Sklodowska-Curie National Research Institute of Oncology, Collegium Civitas, Warsaw.
Portugal	Sofia Ravara	University of Beira Interior; CHCB Universitary Hospital, Covilhã,
Romania	Magdalena Ciobanu	Ministry of Health
Russian Fed.	Daria Khaltourina	Risk Prevention Department of the Federal Research Institute for Health Organization and Informatics of Ministry of Health of the Russian Federation
Serbia	Srmena Krstev	National Focal Point for Tobacco Control
Slovakia	Robert Ochaba	Dept. of Health Promotion, Public Health Institute of the Slovak Republic
Slovenia	Jan Peloza	No Excuse Slovenia, The Institute for Youth Participation, Health and Sustainable Development
Spain	Cristina Martínez, Esteve Saltó	Catalan Institute of Oncology (ICO), Universitat de Barcelona (UB)
Sweden	Margaretha Haglund	Tobaksfakta
Switzerland	Verena El Fehri	Association Suisse pour la Prévention du Tabagisme (until December 2019)
Ukraine	Lilia Olefir	Advocacy Center « Life »
United Kingdom	Martin Dockrell, Ailsa Rutter, Deborah Arnott, Debbie Storm	Public Health England, Fresh, ASH (UK) and ASH Scotland (UK)
Turkey	Elif Dağlı	Health Institute Association

The Tobacco Control Scale, showing the points allocated to each policy, with a maximum total score of 100, is shown in Table 2. Further explanatory notes on scoring are in Table 3

Table 2. The Tobacco Control Scale 2019

POLICY DOMAIN	Max. score
PRICE OF CIGARETTES.	30
The Weighted Average Price for cigarettes in 2018	
The price of the Weighted Average Price (WAP) for cigarettes in 2018, taking into account Purchasing Power Standards (PPS). The country with a WAP of €10 a pack and an EU average Purchasing Power Standard receives 30 points. One point = €0,33 (€0,17-49) taken into account the PPS.	
In countries without WAP information, the reference price used is the price of a pack of 20 Marlboro or another premium brand in 2018 minus 10%, taking into account the PPS.	30
Smoke free work and other public places	22
Workplaces excluding cafes and restaurants – one only of	10
Complete ban without exceptions (no smoking rooms); enforced	10
Complete ban, but with closed, ventilated, designated smoking rooms under very strict rules; enforced	8
Complete ban, but with closed, ventilated, designated smoking rooms (not areas or places); enforced (at least 75% of the workplaces are smoke free)	6
Meaningful restrictions; enforced (more than 50% of the workplaces are smoke free)	4
Legislative restrictions, but not enforced (less than 50% of the workplaces are smoke free)	2
Cafes and restaurants – one only of	8
Complete ban; enforced	8
Complete ban, but with closed, ventilated, designated smoking rooms (not areas or places); enforced	6
Meaningful restrictions; enforced (50% of bars and restaurants are smoke free) (see Table 3)	4
Legislative restrictions, but not enforced (less than 50% of the bars and restaurants are smoke free)	2
Public transport and other public places and private cars	4
Complete ban in trains without exceptions	1
Complete ban in other public transport without exceptions	1
Ban in private cars when minors or children are present	1
Complete ban in educational, health, government and cultural places	1
Spending on public information campaigns	10
Tobacco control spending per capita by the government in 2018, expressed in Power Purchasing Standards. A country which spends €2 per capita, based on the EU average GDP per capita expressed in PPS receives 15 points. One point = €0,20 (€0,10-29) taken into account the PPS.	
Comprehensive bans on advertising and promotion	13
Points for each type of ban included – additive	
Complete ban on tobacco advertising on television and radio	2
Complete ban on outdoor advertising (e.g. posters)	2
Complete ban on advertising in print media (e.g. newspapers and magazines)	1.5
Complete ban on indirect advertising (e.g. cigarette branded clothes, watches, etc)	1
Ban on display of tobacco products at the point of sale	2
Ban on point of sale advertising	2
Ban on cinema advertising	1

Table 2. The Tobacco Control Scale 2019 (cont.)

Ban on sponsorship	1
Ban on internet advertising	0
Large direct health warning labels	1
Plain packaging (the removal of trademarks, logos, colours and graphics, except for the government health warning, and brand name presented in a standardized typeface) in combination with pictorial health warnings on the front and the back of the tobacco product package	4
Size of warning – one only of	3
50% or less of packet	1
51–79% of packet	2
80% or more of packet	3
Pictorial health warnings – additive	З
Pictorial health warnings on cigarette packs	2
Pictorial health warning on hand rolling tobacco	1
Treatment to help smokers stop	1
Recording of smoking status in medical notes	1
Legal or financial incentive to record smoking status in all medical notes or patient files	1
Brief advice in primary care	1
Family doctors reimbursed for providing brief advice	1
Quitline	2
National quitline or quitlines in all major regions of country ADDITIONAL POINT FOR	1
Quitline counsellors answering at least 30 hours a week (not recorded messages)	
Network of smoking cessation support and its reimbursement – one only of	4
Cessation support network covering whole country, free	4
Cessation support network but only in selected areas, e.g. major cities; free	3
Cessation support network covering whole country, partially or not free	3
Cessation support network but only in selected areas, e.g. major cities, partially or not free	2
Reimbursement of medications – one only of	2
Medications totally reimbursed or free to users or Medications partially reimbursed	2 1
Illicit tobacco trade (new)	3
Ratification of the Illicit Trade Protocol	1
Track and trace system for tobacco products, fully FCTC Protocol compliant or Track and trace system for tobacco products, but not fully FCTC Protocol compliant	2 1
Tobacco Industry Interference (new)	2
A whole range of measures, well enforced, to restrict tobacco industry interference or some measures, well enforced, to restrict tobacco industry interference	2 1
Not ratifying the WHO Framework Convention on Tobacco Control (new)	2

Table 3. Notes and explanations on the scoring of the TCS 2019

PRICE

Gross Domestic Product (GDP) per capita can be expressed in PPS (Purchasing Power Standard). PPS per capita has been used to take account of the real purchasing power in different countries. In the EU, the GDP per capita expressed in PPS varies from 50 in Bulgaria to 68 in Greece, 115 in Belgium and 254 in Luxembourg. The EU average = 100. A country with a weighted average price of €10 a pack, based on the EU average PPS (100), receives the maximum 30 points. For example, Belgium has a PPS of 115. Therefore, to achieve the maximum points, Belgium would require an actual WAP of €11.50: 10 (reference WAP) x 1.15 (PPS/100) = €11.50. Likewise, for Bulgaria, the WAP required to achieve the maximum score would be €5:

Bans on smoking in public and workplaces with no exemptions and no smoking rooms

Only total bans work well and comply with Article 8 of the WHO Framework Convention on Tobacco Control (FCTC) and Council Recommendation on Smoke Free environments of 30 November 2009 (2009/C 296/02)

SMOKING ROOMS

A smoking room is a closed indoor premise with ceilings, floor and walls. Norms for smoking rooms may vary. In some countries, very strict conditions apply to smoking rooms (size, ventilation norms, closure of the doors, cleaning), which makes it almost impossible to build them (e.g. France, Italy and Finland).

MEANINGFUL RESTRICTIONS: WORKPLACES

We have given points for "meaningful restrictions" but emphasise that this means that the legislation is imperfect, and thus is not encouraged. 'Meaningful restrictions: workplaces' means smoke free legislation that only applies to some regions of the country (e.g. in federal countries like Germany and Switzerland), the legislation contains exceptions, or allows smoking in indoor premises which are not defined as closed (such as places and areas). 'Enforced meaningful restrictions' means that at least 50% of those who work indoors are never or almost never exposed to tobacco smoke at work.

MEANINGFUL RESTRICTIONS: BARS AND RESTAURANTS

'Meaningful restrictions: bars and restaurants' means, for example, that the smoke free legislation only applies to some regions of the country (e.g. in federal countries like Germany and Switzerland), the legislation contains exceptions (such as bars, small size establishments or during specific hours) or allows smoking in indoor premises which are not defined as closed (such as places and areas). 'Enforced meaningful restrictions' means that at least 50% of the bars and restaurants are smoke free.

Spending on public information campaigns

Government funding at national level (for federal countries the sum of all funding by governments of the different regions, but not of the local communities) in 2018 for mass communication campaigns, tobacco control projects, educational programs, support for non-governmental organizations. The financing of a quitline is not included, but the promotion budget for a quitline is included. Tobacco control spending from sources other than the government, such as the private sector, is not included in our figure. Funding for tobacco dependence reatment (including reimbursement of medications and quitlines), research projects, magement of funds and enforcement of legislation are not included in our figure. A country which spends $\epsilon 2$ per capita on tobacco control, based on the EU average GDP per capita expressed in PPS, receives 10 points. In the EU, the GDP per capita expressed in PPS varies from 50 in Bulgaria to 68 in Greece, 115 in Belgium and 254 in Luxembourg. The EU average = 100. Belgium, for instance, would receive 10 points if the spending was $\epsilon 2.30$ per capita ($\epsilon 2 \times 1.5$). Likewise, Bulgaria would receive 10 points, if the spending was $\epsilon 1$ per capita ($\epsilon 2 \times 0.50$).

In 2019, we made some changes in scoring system: we reduced the number of points for tobacco control budget from 15 points to 10 points and added 3 points for combating illicit tobacco trade and 2 points for controlling tobacco industry interference. Countries who ratified the International Protocol to Eliminate the Illicit Trade of Tobacco Products (the WHO FCTC Protocol) received 1 point. A track and trace system for tobacco products, but not fully FCTC Protocol compliant, is 2 points and a track and trace system for tobacco products, but not fully FCTC Protocol compliant, would be 1 point. A whole range of measures, well enforced, to restrict tobacco industry interference is 2 points and some measures, well enforced, to restrict tobacco industry interference is 1 point. A single measure to limit industry tobacco interaction at the Ministry of Health (and not the whole government) is not enough to obtain 1 point. Examples of policies could include the recording and disclosure of meetings with the tobacco industry, the limitation of interactions with the tobacco industry to those only strictly necessary or a code of conduct for public officials which they should comply in their dealings with the tobacco industry.

The data used for the 2019 survey refer to legislation in force on the 1 January 2020, 2018 price data, and the tobacco control budget in 2018. Any legislation, price increases or funding introduced or enforced after those dates are not included.

A questionnaire was used to collect information about countries' tobacco control budgets and tobacco dependence treatment provision. The following other data sources were used:

PRICE

- The weighted average price of a pack of 20 cigarettes in 2018 was based on the March 2019 European Commission report "Excise duty tables. Part III Manufactured Tobacco." https://ec.europa.eu/taxation_customs/sites/taxation/files/resources/documents/taxa tion/excise_duties/tobacco_products/rates/excise_duties-part_iii_tobacco_en.pdf (7).
- GDP expressed in Purchasing Power Standards (PPS) per capita and GDP in 2018, and country 2018 population data were collected from the statistical office of the European Union or IMF.
- The retail price of a pack of cigarettes (premium brand) for the non-EU countries: WHO Report on the Global Tobacco Epidemic, 2019. Geneva, World Health Organization, 2019 Table 9.2.4 Retail price for a pack of cigarettes in Europe.

ADVERTISING

- World Health Organization. Appendix VII Tobacco control profiles countries. In: WHO Report on the Global Tobacco Epidemic 2019. Geneva: World Health Organization; 2019. https://www.who.int/tobacco/surveillance/policy/country_profile/en/ (8).
- An update of the legislation on advertising from the contributors or from health officials.

SMOKEFREE LEGISLATION

- European Commission. Overview of smoke free legislation and its implementation in the EU. Brussels: European Commission, 2013 (9).
- European Commission. Eurobarometer 458, Attitudes of Europeans towards Tobacco and Electronic Cigarettes. Brussels: European Commission; 2017. http://data.europa. eu/88u/dataset/S2146_87_1_458_ENG (10).

LABELLING

Canadian Cancer Society. Cigarette package health warnings. International status report. Ottawa: Canadian Cancer Society, 2018 (11).

DATABASES

- World Health Organization. Appendix VII Tobacco control profiles countries. In: WHO Report on the Global Tobacco Epidemic 2019. Geneva: World Health Organization; 2019 https://www.who.int/tobacco/surveillance/policy/country_profile/en/ (8)
- WHO FCTC data base which includes often country reports submitted in 2018 (12).
- WHO European Region Tobacco control database (13).
- Smoke Free Partnership smoke free map (14).
- Campaign for Tobacco Free Kids, Tobacco Control Laws (15).

TOBACCO CONTROL AND CESSATION BUDGET

Information was collected in November and December 2019 from the contributors or from health officials.

TOBACCO INDUSTRY INTERFERENCE

- STOP, Global Tobacco Industry Interference Index 2019.
- Information was collected in November and December 2019 from the contributors or from health officials.

ILLICIT TOBACCO TRADE

- Ratification of the Protocol to Eliminate the Illicit Trade in Tobacco Products: United Nations Treaty Collection. https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY &mtdsg_no=IX-4-a&chapter=9&lang=en
- Framework Convention Alliance, Why the EU Tracking and Tracing system works only for the EU, Policy Briefing, 2018. https://www.fctc.org/wp-content/uploads/2019 /07/FCA-Policy-Briefing_Why-the-EU-tracking-and-tracing-systems-works-only-forthe-EU.pdf

RESULTS

Table 4 shows the 2019 TCS scores of each country, in rank order, with their 2016 ranking shown for comparison.

THE HEADLINE RESULTS ARE:

- · Three countries improved their score with 14 or more points.
- Seven leading countries have 60 points or more, top score 80 out of 100 (UK).
- Fifteen countries are doing reasonably well with 50 to 59 points.
- The remaining 14 countries fail to score at least 50 points so need to do much more.
- Three countries had very low scores, with fewer than 45 points.

Table 4. 36 European countries ranked by total TCS score in 2019

Ranking 2019 (ranking 2016)		Country	Price (30)	Public place bans (22)	Budget (10)	Ad bans (13)	Health warning (10)	Treat- ment (10)	Illicit trade (3)	Art 5.3 (2)	Total (100)
1 (1)	-	United Kingdom	25	22	0	12	9	9	2	1	80
2 (4)		France	22	18	4	11	9	7	2	1	74
3 (2)	▼	Ireland	18	22	1	13	9	8	1	1	73
4 (3)	▼	Iceland	23	17	9	13	4	4	0	0	70
5 (5)	-	Norway	22	17	1	13	8	4	1	0	66
6 (6)	-	Finland	18	18	2	13	5	5	1	0	62
7 (new)		Israel	27	15	1	11	1	6	0	0	61
8 (28)		Slovenia	12	16	2	13	9	6	1	0	59
8 (9)		Hungary	15	21	0	11	5	6	1	-	59
10 (8)	▼	Spain	15	21	1	9	5	5	2	0	58
10 (17)		Belgium	16	16	1	8	9	6	2	0	58
12 (7)	▼	Romania	16	21	0	8	5	6	1	0	57
13 (31)		Greece	18	20	-	7	5	3	1	0	54
14 (9)	▼	Netherlands	14	15	1	9	5	7	1	1	53
15 (9)	▼	Sweden	14	15	0	9	5	7	2	0	52
15 (13)	▼	Italy	15	16	0	9	5	6	1	0	52
17 (9)	▼	Turkey	10	15	0	8	10	6	2	0	51
17 (13)	▼	Malta	16	12	0	11	5	5	2	-	51
17 (23)		Croatia	16	11	0	12	5	5	2	-	51
20 (15)	▼	Portugal	18	11	-	10	5	4	2	0	50
20 (35)		Austria	11	20	0	7	5	5	2	0	50
20 (17)	▼	Ukraine	17	15	-	11	4	3	0	0	50
23 (15)	▼	Poland	14	11	0	11	5	7	1	0	49
23 (26)		Latvia	14	12	2	10	5	4	2	0	49
23 (31)		Czechia	12	15	0	8	5	7	2	0	49
23 (21)	▼	Estonia	13	14	1	11	5	3	2	0	49
27 (19)	▼	Bulgaria	15	11	-	11	5	5	1	0	48
27 (26)	▼	Cyprus	15	10	0	11	5	5	2	-	48
29 (17)	▼	Russian Fed.	8	15	0	13	4	6	1	-	47
29 (28)	▼	Lithuania	12	13	1	10	5	4	2	0	47
29 (23)	▼	Denmark	13	11	2	8	5	7	1	0	47
32 (30)	▼	Slovakia	12	12	-	9	5	6	2	0	46
33 (23)	▼	Serbia	19	11	0	9	1	4	1	0	45
34 (33)	▼	Luxembourg	5	16	0	9	5	7	2	0	44
35 (21)	▼	Switzerland (-1)	13	11	4	2	5	7	0	0	41
36 (33)	▼	Germany	14	11	0	4	5	4	2	0	40

"-" means no information is available, " 0 " means insufficient to obtain one point.

-1: Switzerland is the only country in this survey which has not ratified the WHO Framework Convention on Tobacco Control (FCTC): minus one point.

DISCUSSION

Three countries (Slovenia, Greece and Austria) improved their score with 14 or more points. Israel was included in our survey for the first time and was doing very well in prices, with the highest price score for the 36 countries. Overall, countries which failed to undertake new initiatives lost points and fell in the ranking. The countries that are leading tobacco control in Europe are those that have comprehensive tobacco control policies.

Seven countries (UK, France, Ireland, Iceland, Norway, Finland and Israel) have 60 points or more, 15 countries have scores in the 50s (Slovenia, Hungary, Spain, Belgium, Romania, Greece, Netherlands, Sweden, Italy, Turkey, Malta, Croatia, Portugal, Austria, Ukraine), and the remaining 14 countries failed to reach 50% of the total score possible. Three countries (Germany, Switzerland and Luxembourg) had very low scores, with fewer than 45 points, lowest ranking 40 out of 100 (Germany).

The EU Tobacco Products Directive obliged EU countries to introduce pictorial health warnings. Nine countries in this survey (UK, France, Ireland, Hungary, Norway, Slovenia, Turkey, Israel and Belgium) adopted plain packaging legislation, although Israel and Hungary had not yet implemented their legislation on 1 January 2020. (Israel 8/1/2020 and Hungary 1/1/2022)

Table 5. The EU Tobacco Products Directive

KEY PROVISIONS

The Directive states that all EU countries will have to put in place a series of tough legal measures to curb smoking and tobacco use, including the following key elements:

- Mandatory pictorial health warnings covering 65% of both main surfaces, at the top of the pack.
- Countries can go further by introducing standardised packaging.
- A ban on "characterising flavours" in cigarettes, such as fruit or chocolate, from 2016, with menthol banned from 2020.
- Minimum packet dimensions to ensure greater visibility of health warnings and rule out the possibility of 'lipstick' style packs popular amongst young people.
- A regulatory framework for electronic cigarettes.
- Provisions for setting up a **tracking and tracing** system for tobacco products to help fight illicit trade from 2019.

Since 2013, 13 countries have introduced a smoking ban in private cars when minors are present. (Ireland, UK, France, Finland, Italy, Malta, Cyprus, Lithuania, Slovenia, Luxembourg, Austria, Greece and Belgium)

All countries in this survey (with the exception of Switzerland) have ratified the WHO Framework Convention on Tobacco Control and nineteen countries have ratified the WHO FCTC Protocol to Eliminate the Illicit Trade in Tobacco Products.

Were this a test requiring a minimum score of 50 to pass, then 14 countries, or 39 % of the field, would fail. Their end-of-term report would undoubtedly say: "Must do better." They urgently need to improve their tobacco control score in the next few years.

A major concern is the lack of funding for tobacco control. No country spends €2 per capita on tobacco control, with only Iceland coming close. The TCS scores for spending are extremely low and we are seeing reduced funding in several countries.

COMMENTS ON INDIVIDUAL COUNTRIES

Here, in slightly end-of-term report style, we comment briefly on individual countries, in reverse order of their 2019 ranking (with, in brackets, the 2016 ranking and up or down movement on the scale).

36.	Germany (33 ▼3).	The lowest TCS score. No new tobacco control policies introduced since 2010 except for the transposition of the 2014 EU Tobacco Products Directive and the ratification of the WHO FCTC Illicit Trade Protocol. Germany is the only EU country which still allows tobacco advertising on billboards. There are initiatives to ban billboard tobacco advertising, but still with long transition periods.
35.	Switzerland (21 ▼14).	Switzerland is the homeland for international tobacco companies, has very weak tobacco advertising legislation and is the only country in this survey which has not ratified the WHO Framework Convention on Tobacco Control. Since 2017, the Federal Council (cabinet) has no more the competence to increase cigarette taxes. The last time the Federal Council increased the tax by 10 cents was in 2013. A price increase is only possible when tobacco companies increase their price and thus their profits (16). Switzerland seems to be more interested in the well-being of the tobacco companies than in the health of its citizens (17).
34.	Luxembourg (33 ▼1).	Luxembourg is the richest country in the EU and has very low taxes on tobacco products, in order to attract cross border shopping from neighbouring countries. Luxembourg banned smoking in private cars when minors are present and ratified the WHO FCTC Illicit Trade Protocol.
33.	Serbia (23 ▼10).	No major new initiatives since 2013. The biggest priority should be to introduce smoke free legislation in bars and restaurants. Serbia ratified the WHO FCTC Illicit Trade Protocol.
32.	Slovakia (30 ▼2).	No progress to report since 2010. Slovakia ratified the WHO FCTC Illicit Trade Protocol.
29.	Lithuania (28 ▼1).	Lithuania ratified the WHO FCTC Illicit Trade Protocol. Fear of illicit supply of cig- arettes from neighbouring countries and tobacco industry pressure contribute to tax levels remaining low.
29.	Denmark (23 ▼6).	Denmark is not doing well on 1 January 2020 but plans to do much better in 2020 with increased taxes, a display ban and plain packaging (including for heated tobacco products and e-cigarettes).
29.	Russian Federation (17 ▼12).	The Russian Federation has introduced comprehensive advertising and smoke free legislation in 2014. The score attributed to prices is low to some extent as result of the weak value of its currency.
27.	Cyprus (26 ▼1).	Compliance with their smoke free legislation is a huge problem. Cyprus banned smoking in private cars when minors are present and ratified the WHO FCTC Illicit Trade Protocol.
27.	Bulgaria (19 ▼8).	Bulgaria had introduced comprehensive smoke free legislation in 2012 with improved, but still unsatisfactory result of compliance.
23.	Estonia (21 ▼2).	Similar comment as for Lithuania. Estonia ratified the WHO FCTC Illicit Trade Protocol

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23.	Czechia (31 ▲8).	Despite a strong tobacco industry presence in the country, Czechia adopted com prehensive smoke free legislation in February 2017. Czechia ratified the WHC FCTC Illicit Trade Protocol.
23.	Latvia (26 ▲3).	Latvia ratified the WHO FCTC Illicit Trade Protocol.
23.	Poland (15 ▼8).	Tobacco control policy in Poland has stagnated over the last three years, but in early 2020 a tax increase was introduced, which is not reflected in its score.
20.	Austria (35 ▲15).	A positive development in Austria with comprehensive and enforced smoke free legislation since 1 November 2019. Austria had the lowest TCS ranking since 2007 but moved from the lowest ranking to number 20 of the list now. Austria was the first European country to ratify the WHO FCTC Illicit Trade Protocol. Price and tax levels remain low.
20.	Ukraine (17 ▼3)	Ukraine introduced comprehensive smoke free legislation, advertising bans and pictorial health warnings.
20.	Portugal (15 ▼5).	Portugal has ratified the WHO FCTC Illicit Trade Protocol but should intensify its tobacco control policies. In particular, efforts should be made to introduce smoke free legislation as soon as possible.
17.	Croatia (23 ▲6).	Croatia improved its TCS score by implementing the Tobacco Products Directive and ratifying the WHO FCTC Illicit Trade Protocol.
17.	Malta (13 ▼4).	Banned smoking in private cars, but the enforcement of its smoke free legislation could be better. Malta ratified the WHO FCTC Illicit Trade Protocol
17.	Turkey (9 ▼8).	Turkey adopted plain packaging and has the largest health warnings in Europe (85% of the surface). It has now the best health warning score. Turkey introduced in 2009 comprehensive smoke free legislation (no exceptions, no smoking rooms) but experienced serious enforcement problems in bars and tea houses. Turkey los points as result of the weak value of its currency. Turkey ratified the WHO FCTC Illicit Trade Protocol.
15.	ltaly (13 ▼2).	No real progress to report since 2005 except for the smoking ban in private cars when minors are present.
15.	Sweden (9 ▼6).	Sweden banned smoking in some outdoor premises (e.g. restaurants) but is slow to tackle tobacco advertising at the point of sales or implement a display ban Sweden ratified the WHO FCTC Illicit Trade Protocol.
14.	Netherlands (9 ▼5).	The Netherlands will be the first EU country to host the Conference of the Parties (COP) of the WHO FCTC and the 2nd Meeting of the Parties (MOP) of the FCTC Protocol in November 2020. An impressive list of measures (including plain pack aging and display bans) is planned but has not been introduced yet as of 1 January 2020. A tax increase of €1 per pack is planned for April 2020, likely to be followed by significant increases the years ahead.
13.	Greece (31 ▲18).	Like in Austria a positive development. New legislation was adopted in 2019 to enforce the 2010 smoke free legislation and it works. Greece moved from ranking 31 in 2016 to ranking 13 now.
11.	Romania (7 ▼4).	Romania adopted comprehensive smoke free legislation in 2016 which is well enforced according to the 2017 Eurobarometer survey. The Parliament is currently debating a comprehensive Tobacco Advertising, Promotion and Sponsorship bill for all tobacco products, including heated tobacco products.

10.	Belgium (17 ▲7).	Belgium made progress and adopted plain packaging legislation, banned smoking in cars in the presence of minors and ratified the WHO FCTC Illicit Trade Protocol. Discussions to ban the display of tobacco products and an advertising ban at the point of sales are still ongoing in the Parliament.
10.	Spain (8 ▼2).	Spain ratified the WHO FCTC Illicit Trade Protocol but has not undertaken any new initiatives since 2010.
8.	Hungary (9 ▲1).	Hungary has well enforced, comprehensive smoke free legislation and will intro- duce plain packaging in 2022.
8.	Slovenia (28 ▲20).	Slovenia has introduced an impressive list of tobacco control measures which includes plain packaging, advertising ban at the point of sales, display ban and smoking ban in private cars when minors are present. The ranking of Slovenia improved from 28 in 2016 to 8 in 2019.
7.	Israel (new).	Israel has the highest score on prices and implemented plain packaging legisla- tion for cigarettes and e-cigarettes on 8 January 2020 (although without pictorial warnings) which is not reflected in its score. Israel belongs to the group of the best seven countries, but still allows tobacco advertising in the print media.
6.	Finland (6).	Finland adopted an ambitious plan to make the country tobacco free by 2040. Finland increased tobacco taxes and made progress but has not yet introduced plain packaging legislation. Finland banned smoking in cars when minors are present.
5.	Norway (5).	Norway remains one of the strong leaders in tobacco control in Europe since the 1960s and adopted plain packaging legislation. Norway ratified the WHO FCTC Illicit Trade Protocol.
4.	lceland (3 ▼1).	Iceland has by far the highest spending on tobacco control per capita in Europe. The law obliges the government to spend at least 0.9% of the total amount spent on tobacco, on tobacco control.
3.	Ireland (2 ▼1).	Ireland adopted plain packaging legislation and banned smoking in cars when minors are present. The nominal value of cigarettes prices is the highest in Europe (€13,50 a pack in 2020) but as result of the increase in affordability, Ireland lost points in the price scoring. The Gross Domestic Product (GDP) in Power Purchasing Standards per capita was 187 in 2018 compared to 145 in 2015 (+30%).
2.	France (4 ▲2).	A pack of Marlboro costed €9,30 in 2019 compared to €7 in 2016 (+33%). France is the third country in the world which adopted plain packaging. In addition, France ratified the WHO FCTC Illicit Trade Protocol, organised media campaigns "a month without tobacco", banned advertising at the point of sales and smoking in private cars when minors are present. The French Tobacco Fund (Fonds de lutte contre le tabac) had a budget of 100 million euro in 2018.
1.	United Kingdom (1).	The UK remains number one but is not doing well on funding (zero points) and is no longer the leader on prices (due to some extent to the weakness of the Pound). The UK is the second country in the world to adopt plain packaging legislation. England, Scotland, Wales and Northern Ireland banned smoking in cars when minors are present. The UK ratified the WHO FCTC Illicit Trade Protocol.

RECOMMENDATIONS

Before the Ninth European Conference on Tobacco and Health (ECToH) in 2023, countries should:

- Implement at least the six World Bank priority measures; a comprehensive tobacco control policy is an obligation under Article 4 of the WHO Framework Convention on Tobacco Control (FCTC).
- 2. Spend a minimum of €2 per capita per year on tobacco control.
- 3. Address tobacco industry interference in public health policy making, in accordance with the quidelines on Article 5.3 of the WHO FCTC.
- 4. Implement the FCTC Article 6 guidelines on tobacco taxation and revise the EU Tobacco Tax Directive in 2020, which should result in significant tax increases and smaller tax differences between cigarettes and hand rolled tobacco.
- 5. Introduce comprehensive smoke free legislation in line with the FCTC Article 8 guidelines, including a ban on smoking in private cars when minors are present.
- 6. Introduce standardised/plain packaging for all tobacco products.
- 7. Ban the display of tobacco products at the point of sale.
- 8. Accelerate the implementation of tobacco cessation support in line with Article 14 of the WHO FCTC and its guidelines.
- 9. Ratify the WHO FCTC Protocol to eliminate the illicit trade in tobacco products and adopt tracking and tracing standards in line with the Protocol.
- 10. Invest in research to monitor and measure the effect of tobacco control policies in line with Article 20 of the WHO FCTC.

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ANNEXES

APPENDIX 1

HISTORY OF THE TOBACCO CONTROL SCALE

In 2004, the European Network for Smoking Prevention (ENSP) provided a grant to Luk Joossens for a project to measure tobacco control activity at country level in Europe. A questionnaire was drafted then finalised with feedback from a panel of ten experts, international tobacco control researchers and specialists. In 2004 the questionnaire was sent to correspondents in 28 European countries who had agreed to fill in their country data.

Although the original intention of the project was simply to describe current tobacco control policies in Europe, it seemed worthwhile trying to quantify these policies, in order to be able to compare countries systematically. However, while we have evidence which tells us broadly which tobacco control measures are effective, it is not easy to decide what weight should be given to each policy measure in a scale. Ideally this would be decided by the size of the effect of a policy measure, but relatively little rigorous research on the effectiveness of tobacco control policy exists, and such research that does exist is not precise enough to permit easy comparisons between countries. Therefore, in order to score the questionnaire and create the scale we had to assign scores to each tobacco control policy. To do this we convened an international panel of ten experts to agree the allocation of points to the scale.

In 2005, Martin Raw joined in the scoring project of tobacco control policies. The objective was to repeat the collection of data, but to do it in a more systematic and scientific manner with the intention to have the methodology published in and approved by a scientific journal. In the summer of 2005, the questionnaire survey was repeated, this time with 30 European countries: the previous 28 plus two accession countries, Bulgaria and Romania. Data were collected using the 2004 questionnaire, but stricter definitions were applied in the scale to smoke free places and smoking treatment systems. The report was submitted by Luk Joossens and Martin Raw to the Tobacco Control journal which published the article in May 2006 (1). Joossens and Raw remained the authors of 2007, 2010, 2013 and 2016 editions. In 2018, Ariadna Feliu and Esteve Fernandez of the Catalan Institute of Oncology joined the project. The authors for the 2019 edition were Luk Joossens, Ariadna Feliu and Esteve Fernandez.

In 2007 the Swiss Cancer League financed and published the 2007 edition, the 2010, 2013 and 2016 editions of the Tobacco Control Scale (TCS) were published by the Association of European Cancer Leagues. These research results were presented each time at the European Conferences on Tobacco or Health (ECToH), which are organized by ECL members under the auspices of ECL. Previous ECToHs (www.ECToH.org) took place in Basel (2007), Amsterdam (2011), Istanbul (2014), Porto (2017) and Berlin in 2020.

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DATA TABLES TOBACCO CONTROL SCALE, 2019

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Appendix 1: Smoke free public places - score on	1 January 2020 in 36 European countries
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Country	Bars and restaurants (max=8 points)	Public transport (max=2 points)	Public places (max=1 point)	Private cars (max=1 point)	Work place (max=10 points)	Total (max=22 points)
Ireland	8	2	1	1	10	22
United Kingdom	8	2	1	1	10	22
Hungary	8	2	1	0	10	21
Romania	8	2	1	0	10	21
Spain	8	2	1	0	10	21
Greece	8 (1)	2	1	1	8	20
Austria	8 (2)	2	1	1	8	20
Finland	6	2	1	1	8	18
France	6	2	1	1	8	18
Iceland	8	2	1	0	6	17
Norway	8	2	1	0	6	17
Belgium	6	2	1	1	6	16
Italy	6	2	1	1	6	16
Luxembourg	6	2	1	1	6	16
Slovenia	6	2	1	1	6	16
Ukraine	6	2	1	0	6	15
Russia	6 (3)	2	1	0	6	15
Sweden	6	2	1	0	6	15
Netherlands	6 (4)	2	1	0	6	15
Turkey	4 (5)	2	1	0	8	15
Czechia	6 (6)	2	1	0	6	15
Israel	6	2	1	0	6	15
Estonia	6	1	1	0	6	14
Lithuania	6	1	1	1	4	13
Latvia	6	1	1	0	4	12
Slovakia	4	1	1	0	6	12
Malta	4	2	1	1	4	12
Poland	4 (7)	2	1	0	4	11
Switzerland	4 (8)	2	1	0	4	11
Bulgaria	4 (9)	2	1	0	4	11
Portugal	4 (10)	2	1	0	4	11
Croatia	4	2	1	0	4	11
Serbia	2	2	1	0	6	11
Denmark	4	2	1	0	4	11
Germany	4 (11)	2	1	0	4	11
Cyprus	2 (12)	2	1	1	4	10

- (1) Greece adopted in 2010 comprehensive smoke free legislation in bars and restaurants, but compliance was rather problematic. In November 2019, legislation was adopted to make enforcement stronger. The new government, including the Prime Minister, was strongly in favour of the new law. Several press articles report that the smoking ban is now well implemented.
- (2 New smoke free legislation in bars and restaurants came into force on 1st November 2019. 3981 bars and restaurants in Vienna were controlled in November 2019 and 98% were compliant.
- (3) The Russian Federation introduced comprehensive smoke free legislation in June 2014, but compliance remains a problem, according to the WHO tobacco control country profile 2019.
- (4) Smoking rooms will be banned in 2020.
- (5) Compliance is very weak in cafés, coffee or teahouses according to the WHO tobacco control country profile 2019.
- (6) The Czech Republic adopted in February 2017 comprehensive smoke free legislation which came into force on 31st May 2017. Surveys indicate that the ban is well respected. Surprisingly, the use of waterpipes is still authorized in bars and restaurants.
- (7) The Polish law allows exceptions, for instance for drinking and eating establishments with two or more rooms.
- (8) Legislation of smoking in bars of restaurants is a split competence of the cantons and the federal legislator. A majority of the cantons apply smoke free legislation in bars and restaurants.
- (9) Comprehensive smoke free legislation in public spaces (including bars and restaurants) came into in June 2012. Compliance with the legislation has improved but remains insufficient (see Eurobarometer survey, 2017).

(10) Until 2020 smoking areas are still allowed in workplaces, restaurants, pubs bars etc.

- (11) Legislation of smoking in bars and restaurants is a competence of the regions (länder). Most länder ban smoking in bars and restaurants but may allow smoking rooms or some exceptions.
- (12) Cyprus has comprehensive smoke free legislation in bars and restaurants (no smoking rooms, no exemptions) since 2010, but compliance remains a major concern.

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Appendix 2: Compliance of smoke free legislation at the workplace based on Eurobarometer 429 (fieldwork November- December 2014)¹

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Country	Workplace: Never or almost never exposed to tobacco smoke at your workplace (November-December 2014)
Sweden	95%
Finland	92%
Denmark	90%
United Kingdom	89%
Ireland	87%
Luxembourg	87%
Netherlands	84%
Slovenia	82%
Germany	80%
Belgium	79%
Spain	78%
France	77%
Portugal	77%
Estonia	76%
Slovakia	74%
Hungary	70%
Latvia	68%
Bulgaria	67%
Malta	66%
Czechia (1)	65%
Lithuania	63%
Croatia	61%
Italy	56%
Austria (2)	55%
Poland	46%
Cyprus	45%
Romania (3)	42%
Greece (4)	41%

(1) Czechia has introduced comprehensive smoke free legislation in 2017.
 (2) Austria has introduced comprehensive smoke free legislation in 2019.
 (3) Romania has introduced comprehensive smoke free legislation in 2016.
 (4) Greece reinforced its smoke free legislation in 2019.

¹ European Commission. Special Eurobarometer 429. Attitudes of Europeans towards tobacco and electronic cigarettes. Brussels: European Commission; 2015.

Appendix 3: Compliance of smoke free legislation in bars and restaurants based on Eurobarometer 458 (fieldwork March 2017)²

Country	Bars: People smoking inside during the last visit in the last 6 months (March 2017)	Restaurants: People smoking inside during the last visit in the last 6 months (March 2017)
Sweden	2%	1%
United Kingdom	5%	3%
Slovenia	6%	1%
Ireland	6%	4%
Finland	7%	2%
Hungary	7%	4%
Luxembourg	11%	2%
Estonia	11%	5%
Lithuania	11%	6%
Romania	11%	6%
Spain	12%	3%
Poland	14%	6%
Italy	15%	9%
France	16%	8%
Belgium	18%	4%
Netherlands	20%	6%
Germany	22%	5%
Latvia	22%	9%
Portugal	38%	11%
Denmark	39%	3%
Malta	39%	13%
Bulgaria	42%	25%
Slovakia	50%	18%
Austria (1)	57%	32%
Cyprus	65%	51%
Czechia (2)	73%	49%
Croatia	77%	17%
Greece (3)	87%	78%

Austria has introduced comprehensive smoke free legislation in 2019.
 Czechia has introduced comprehensive smoke free legislation in 2017.
 Greece reinforced its smoke free legislation in 2019.

² European Commission. Special Eurobarometer 458. Attitudes of Europeans towards tobacco and electronic cigarettes. Brussels: European Commission ; 2017.

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Appendix 4: Tobacco advertising ban - score on 1/1/ 2020 in 36 European countries

Country	Tv / Radio	Cin- ema	Out- door	Print	Point of sales	Dis- play	Sponsor nat.	Sponsor inter.	Inter- net	In- direct	Total
Max points	2	1	2	1,5	2	2	0,5	0,5	0,5	1	13
Finland	2	1	2	1,5	2	2	0,5	0,5	?	1	13
Iceland	2	1	2	1,5	2	2	0,5	0,5	?	1	13
Norway	2	1	2	1,5	2	2	0,5	0,5	?	1	13
Russia	2	1	2	1,5	2	2	0,5	0,5	?	1	13
Slovenia	2	1	2	1,5	2	2	0,5	0,5	?	1	13
Ireland	2	1	2	1,5	2	2	0,5	0,5	?	1	13
United Kingdom	2	1	2	1,5	1 (1)	2	0,5	0,5	?	1	12
Croatia	2	1	2	1,5	2	2	0	0	?	1	12
Hungary	2	1	2	1,5	2	0	0,5	0,5	?	0	11
Malta	2	1	2	1,5	2	0	0,5	0,5	?	1	11
Poland	2	1	2	1,5	2	0	0,5	0,5	?	1	11
France	2	1	2	1,5	2	0	0,5	0,5	?	1	11
Estonia	2	1	2	1,5	2	0	0,5	0,5	?	1	11
Cyprus	2	1	2	1,5	2	0	0,5	0,5	?	1	11
Bulgaria	2	1	2	1,5	2	0	0,5	0,5	?	1	11
Ukraine	2	1	2	1,5	2	-	0,5	0,5	?	1	11
Israel	2	1	2	0	2	2	0,5	0,5	?	1	11
Portugal	2	1	2	1,5	2	0	0,5	0,5	?	0	10
Latvia	2	1	2	1,5	2	0	0,5	0,5	?	0	10
Lithuania	2	1	2	1,5	2	0	0	0,5	?	1	10
Spain	2	1	2	1,5	0	0	0,5	0,5	?	1	9
Slovakia	2	1	2	1,5	0	0	0,5	0,5	?	1	9
Serbia	2	1	2	1,5	0	0	0,5	0,5	?	1	9
Italy	2	1	2	1,5	2	0	0	0,5	?	0	9
Luxembourg	2	1	2	1,5	0	0	0,5	0,5	?	1	9
Netherlands	2	1	2	1,5	0	0	0,5	0,5	?	1	9
Sweden	2	1	2	1,5	0	0	0,5	0,5	?	1	9
Czechia	2	1	2	1,5	0	0	0,5	0,5	?	0	8
Belgium	2	1	2	1,5	0	0	0,5	0,5	?	0	8
Denmark	2	1	2	1,5	0	0	0,5	0,5	?	0	8
Romania	2	1	2	1,5	0	0	0	0,5	?	1	8
Turkey	2	1	2	1,5	1 (2)	0	0	0,5	?	0	8
Greece	2	1	2	1,5	0	0	0	0,5	?	0	7
Austria	2	1	2	1,5	0	0	0	0,5	?	0	7
Germany	2	0	0	1,5	0	0	0	0,5	?	0	4
Switzerland	2	0	0	0	0	0	0	0	?	0	2

"?" means that there are no data to verify whether the ban was enforced or not.

- Advertising and display at points of sale is banned in the UK except in specialized retail outlets for tobacco products only.
- (2) Turkey has a ban on advertising at the point of sales, but weak enforcement according to the WHO country profile 2018.

Appendix 5: Label score on 1 January 2020 in 36 European countries

Country	Size (max= 3 points)	Pictorial health warings (max= 3 points)	Plain packaging (1) (4 points if implemented)	Total (max=10 points)
Turkey	3	3	4	10
France	2	3	4	9
Ireland	2	3	4	9
United Kingdom	2	3	4	9
Slovenia	2	3	4	9
Belgium	2	3	4	9
Norway	1	3	4	8
Croatia	2	3	0	5
Denmark	2	3	0	5
Germany	2	3	0	5
Greece	2	3	0	5
Spain	2	3	0	5
Italy	2	3	0	5
Luxembourg	2	3	0	5
Netherlands	2	3	0	5
Austria	2	3	0	5
Portugal	2	3	0	5
Finland	2	3	0	5
Sweden	2	3	0	5
Czechia	2	3	0	5
Estonia	2	3	0	5
Cyprus	2	3	0	5
Latvia	2	3	0	5
Lithuania	2	3	0	5
Hungary (1)	2	3	0	5
Malta	2	3	0	5
Poland	2	3	0	5
Slovakia	2	3	0	5
Switzerland	2	3	0	5
Bulgaria	2	3	0	5
Romania	2	3	0	5
Iceland	1	3	0	4
Ukraine	1	3	0	4
Russia	1	3	0	4
Serbia	1	0	0	1
Israel (1)	1	0	0	1

 Hungary (2018) and Israel (2019) have adopted plain packaging legislation but not yet into force on 1 January 2020. The Israeli legislation came into force on 8 January 2020 and the Hungarian legislation will come into force on 1 January 2022.

Appendix 6: Tobacco Control Budget (TCB) score in 2018 in 36 European countries

TCB

score

Max=

15

9

4

4

2

2

2

1

1

1

1

1

1

1

1

0

0

0

0

0

0

0

0

0

-

0

-

-

0

0

0

0

0,008 0

points

TCB

capita

PPS

2018

1,83

0.78

0.74

0.40

0.33

0,31

0.30

0.29

0,25

0.24

0.20

0.19

0,13

0,13

0,13

0.08

0,07

0,07

0.01

0,01 0.08

0.07

0,004 0

0,04

0.03

0.008 0

0,03

0,01

0,009

0.01

-

Per

GDP

FU=

100

2018

133

104

157

110

87

70

126

91

81

115

150

187

91

129

81

121

98

104

95

64

254

127

76

90

87

70

71

-

123

68

50

65

58

40

20

63

1.96

5,37

7.38

118

24

73.4

-

0,005

0,008

0,003

0.006

-

372 439 €

32 300€

25 424 €

925 000

In PPS

Country	Popula- tion 1000s 1 Jan. 2019	TCB in national Currency 2018	TCB € 2018	Exchange rate Euro 2 July 2018	TCB 2018 per Capita €
Iceland	349	105 000 000 ISK	846 774 €	124	2,43
France (1)	66 926	54 200 000 €	54 200 000€	1	0.81
Switzerland (2)	8 484	11 400 000 CHF (2)	9 827 586€	1.16	1,16
Finland	5 513	2 433 000 €	2 433 000 €		0.44
Slovenia	2067	600 000€	600 000€	1	0,29
Latvia	1 934	425 048 €	425 048 €	1	0,22
Denmark	5 781	16 500 000 DKK	2 214 765€	7.45	0.38
Israel	8 972	10 000 000 ILS	2 347 418€	4,26	0.26
Estonia	1 319	263 000€	263 000€	1	0.2
Belgium	11 399	3 174 000 €	3 174 000 €	1	0.28
Norway	5 296	15 000 000 NOK	1 579 000€	9.50	0.30
Ireland	4 830	1 740 000 €	1 740 000 €	1	0.36
Spain	46 658	5 400 000 €	5 400 000 €	1	0,11
Netherlands	17 181	2 900 000 €	2 900 000 €	1	0,17
Lithuania	2 809	285 000 €	285 000 €	1	0,10
Sweden	10 120	10 000 000 SEK	9 57 €	10.45	0.09
Malta	476	32 347 €	32 347 €	1	0,07
United Kingdom (3)	66 274	4 447 905 GBP (1)	4 997 646 067 €	0.89	0,08
Italy	60 484	636 000 €	636 000€	1	0.01
Romania	19 531	583 000 RON	125 000€	4.66	0,006
Luxembourg	602	120 000 €	120 000 €	1	0.19
Austria	8 822	600 000 -940 000€	600 000-940 000 €	1	0.09
Portugal	10 291	-	-	1	-
Czechia	10 610	962 785 CZK	37 030 €	25.99	0,003
Cyprus	864	33 965 €	33 965 €	1	0,04
Hungary	9 778	70 000 000 HUF	212 121€	330	0,02
Poland	37 977	1 000 000 PLN	227 790	4.39	0,006
Slovakia	5 443	-		1	-
Germany	82792	2 900 000 €	2 900 000 €	1	0,04
Greece	10 741	-	-	1	-

- (1) The French Tobacco Fund (Fonds de lutte contre le tabac) has a total budget of 100 million euro. Tobacco control budgets in the TCS focus on media campaigns and tobacco control projects and do not take into account expenditures for reimbursement of medicines, research and management. Tobacco control projects financed by the Tobacco Fund were 53 750 000 million euro in 2018. https://www.legifrance.gouv.fr/affichTexte. do?cidTexte=JORFTEXT000037111835&categorieLien=id In addition, there was 450 000 € support for 3 NGOs.
- (2) The Swiss Prevention Fund against Tobacco spends some 12 million CHF on projects. 5% of the spending are research projects. Tobacco control projects represented 11,4 million CHF in 2018. https://www.tpf.admin.ch/tpf/fr/home/fonds/tabakpraeventionsfonds.html
- (3) This includes spending on media campaigns and tobacco control projects by Public Health England, ASH (UK), Fresh, Breathe2025 and ASH Scotland (UK).

29

Bulgaria

Turkey

Croatia

Serbia

Ukraine

Russia

7 050

4 106

7 001

42 154

144 439

80 811

2 000 000 TRY

239 000 HRK

3000 000 RSD

67 886 399 RUB

(2010)

(2016)

30

Appendix 7: Cigarette price score 2018 in 36 European countries

Country	Retail price cigarettes weighted average price 2018 €	Price premium brand -10% in 2018 €	2018 PPS per capita EU =100	Price in € to PPS per capita	Score prices (Max= 30 points)
Israel		8,08	91	8,88	27
United Kingdom	8,77		104	8,43	25
Iceland	-	10,27	133	7,72	23
France	7,78		104	7,48	22
Norway	÷	11,16	150	7,44	22
Serbia	·	2,52	40	6,30	19
Ireland	11,37		187	6,08	18
Finland	6,70		110	6,07	18
Portugal	4,49		76	5,90	18
Greece	4,18		68	6,15	18
Ukraine		1,12	20	5,60	17
Malta	5,25		98	5,36	16
Croatia	3,35		63	5,32	16
Romania	3,40		64	5,31	16
Belgium	6,10		115	5,30	16
Italy	4,90		95	5,16	15
Bulgaria	2,57		50	5,14	15
Cyprus	4,33		87	4,98	15
Spain	4,52		91	4,97	15
Hungary	3,46		70	4,94	15
Netherlands	6,19		129	4,69	14
Sweden	5,60		121	4,63	14
Germany	5,64		123	4,59	14
Poland	3,26		71	4,59	14
Latvia	3,18		70	4,54	14
Estonia	3,55		81	4,38	13
Denmark	5,39		126	4,28	13
Switzerland		6,70	157	4,27	13
Slovenia	3,51		87	4,03	12
Slovakia	3,06		78	3,92	12
Lithuania	2,77		81	3,91	12
Czechia	3,48		90	3,87	12
Austria	4,76		127	3,75	11
Turkey	-	2,12	65	3,26	10
Russian Federation		1,78	63	2,83	8
Luxembourg	4,64		254	1,83	5
9					

Appendix 8: Treatment - score in 2019 in 36 European countries

Country	Recording Smoking Status (Max= 1 point)	Brief advice (Max= 1 point)	Quitline (Max= 2 points)	Network Cessation Support (Max= 4 points)	Reimburse- ment (Max= 2 points)	Total (Max= 10 points)
United Kingdom	1	1	2	4	1	9
Ireland	-	-	2	4	2	8
Denmark	0	0	2	4	1	7
France	0	0	2	3	2	7
Luxembourg	0	1	2	3	1	7
Netherlands	0	1	2	3	1	7
Sweden	0	0	2	3	2	7
Czechia	0	0	2	4	1	7
Switzerland	0	1	2	3	1	7
Poland	1	1	2	3	0	7
Belgium	0	1	1	3	1	6
Israel	1	0	0	4	1	6
Italy	0	0	2	3	1	6
Slovenia	0	0	2	4	0	6
Slovakia	0	0	2	3	1	6
Romania	1	0	2	2	1	6
Turkey	0	0	2	3	1 (2)	6
Russia	1	0	2	3	0	6
Hungary	0	0	2	4	0	6
Malta	-	-	2	3	0	5
Spain	0	1	1	3	0	5
Austria	0	0	2	3	0	5
Finland	0	0	1	3	1	5
Cyprus	-	-	0	3	2	5
Bulgaria	0	0	2	3	0	5
Croatia	-	-	2	3	0	5
Latvia	0	0	2	2 (1)	0	4
Lithuania	0	0	2	2	0	4
Germany	0	0	2	2	0	4
Portugal	0	0	0	3	1	4
Iceland	0	0	2	2	0	4
Norway	0	1	0	3	0	4
Serbia	1	1	0	2	0	4
Estonia	0	-	0	3	0	3
Ukraine	0	0	0	3	0	3
Greece	0	0	0	3	0	3
		-			-	

 Smoking cessation consultations are provided by narcologists and family doctors as part of a healthy life-style consultation (brief interventions).

(2) Nicotine replacement products have been reimbursed in Turkey at specifics periods, but not on a permanent basis.

32

Appendix 9: Illicit trade - score in 2019 in 36 European countries

Country	Ratification FCTC Illicit trade Protocol (Max= 1 point)	Track and Trace system (Max= 2 points)	Total (Max= 3 points)
Austria	1	1	2
Belgium	1	1	2
Germany	1	1	2
Luxembourg	1	1	2
Spain	1	1	2
France	1	1	2
Sweden	1	1	2
United Kingdom	1	1	2
Czechia	1	1	2
Estonia	1	1	2
Cyprus	1	1	2
Latvia	1	1	2
Portugal	1	1	2
Turkey	1	1	2
Croatia	1	1	2
Malta	1	1	2
Slovakia	1	1	2
Norway	1	0	1
Serbia	1	0	1
Finland	0	1	1
Russia	0	1	1
Greece	0	1	1
Denmark	0	1	1
Ireland	0	1	1
Italy	0	1	1
Hungary	0	1	1
Netherlands	0	1	1
Poland	0	1	1
Slovenia	0	1	1
Bulgaria	0	1	1
Romania	0	1	1
Switzerland	0	0	0
Ukraine	0	0	0
Iceland	0	0	0
Israel	0	0	0

Appendix 10: Tobacco Industry Interference Score in 2019 in 36 European countries

Country	Maximum score = 2 points	Country	Maximum score = 2 points	Country	Maximum score = 2 points
France (1)	1	Portugal	0	Slovakia	0
Ireland (2)	1	Finland	0	Iceland	0
Netherlands (3)	1	Sweden	0	Norway	0
United Kingdom (4)	1	Czechia	0	Switzerland	0
Denmark	0	Estonia	0	Bulgaria	0
Belgium	0	Cyprus	-	Romania	0
Germany	0	Latvia	0	Turkey	0
Greece	0	Lithuania	0	Croatia	-
Spain	0	Hungary	0	Serbia	0
Italy	0	Malta	-	Ukraine	0
Luxembourg	0	Poland	0	Russia	-
Austria	0	Slovenia	0	Israel	0

- (1) The French government disallows the acceptance of all forms of contributions/ gifts from the tobacco industry including offers of assistance, policy drafts, or study visit invitations given or offered to the government, its agencies, officials and their relatives. In addition, French legislation prevents former ministers, former presidents of local councils as well as former members of independent administrative or public authorities entering the private sector. (Source: STOP, Global Tobacco Industry Interference Index 2019)
- (2) In Ireland, the whole government strictly enforces a policy or code of conduct on tobacco industry interference (Article 5.3 of the WHO FCTC), and violations are being monitored and sanctioned. The minister of Health, other ministers and their officials do not meet representatives of the tobacco industry.
- (3) The Dutch government's position is that there should be and are no contacts with the tobacco sector, unless such contacts are necessary (technical matters arising in relation to the implementation of already approved or adopted legislation or policies). These may include public consultations.
- (4) The Department for Health & Social Care in its 2017 Tobacco Control Plan for England formulates the need to limit 'direct contact with the tobacco industry to that necessary to discuss the implementation of regulatory provisions or operational matters', and encourages tobacco companies to engage with government in writing rather than face to face. (Source: Mateusz Zatoński and Anna Gilmore. 2019 UK Tobacco Industry Interference Index. Tobacco Control Research Group, University of Bath. October 2019.)
 - The Tobacco Control Plan for England specifies "To ensure further transparency, the government commits to publishing the details of all policy-related meetings between the tobacco industry and government departments."
 - The Department of Health requires that any individual or organisation responding to Department of Health consultations must declare whether they have any links with or receive funding from the tobacco industry. In addition, the UK Government has issued guidelines for diplomatic posts on dealings with the tobacco industry.

Appendix 11: Tobacco Control Scale Ranking from 2005 to 2019

Country	TCS Ranking 2005 (30 countries)	TCS Ranking 2007 (30 countries)	TCS Ranking 2010 (31 countries)	TCS Ranking 2013 (34 countries)	TCS Ranking 2016 (35 countries)	TCS Ranking 2019 (36 countries)
United Kingdom	2	1	1	1	1	1
Ireland	1	2	2	2	2	3
Iceland	4	2	4	3	3	4
Norway	3	4	3	4	5	5
Turkey	-	-	4	5	9	17
France	9	7	6	5	4	2
Spain	26	12	13	7	8	10
Malta	5	5	7	7	13	17
Finland	7	8	7	9	6	б
Ukraine	-	-	-	10	17	20
Sweden	6	6	9	11	9	15
Hungary	15	22	27	11	9	8
Netherlands	10	14	13	13	9	14
Belgium	12	8	10	13	17	10
Italy	8	10	12	15	13	15
Denmark	17	20	13	15	23	29
Bulgaria	16	13	24	15	19	27
Switzerland	24	18	11	18	21	35
Romania	29	14	16	19	7	12
Slovenia	22	25	17	20	28	8
Estonia	17	11	19	20	21	23
Poland	12	14	19	20	15	23
Serbia	-	-	-	23	23	33
Latvia	28	24	17	24	26	23
Portugal	19	23	19	24	15	20
Croatia	-	-	-	26	23	17
Slovakia	14	17	22	27	30	32
Luxembourg	30	28	29	28	33	34
Lithuania	25	21	22	29	28	29
Greece	20	28	30	29	31	13
Czechia	20	25	27	31	31	23
Cyprus	11	19	24	32	26	27
Germany	22	27	26	33	33	36
Austria	26	30	30	34	35	20
Russian Federation	-	-	-	-	17	29
Israel	-	-	-	-	-	7



Association of European Cancer Leagues (ECL)

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Belgian Foundation against Cancer

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German Cancer Aid

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German Cancer Society

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The Tobacco Control Scale website was launched in 2017 at the 7th ECToH as a joint initiative of the Association of European Cancer Leagues and the Tobacco Control Unit of the Catalan Institute of Oncology, a WHO Collaborating Centre for Tobacco Control. The website provides a brief history of the Tobacco Control Scale, the original reports of each edition since the Tobacco Control Scale's first publication in 2005, interactive data visualizations, and a repository of publications related to the Tobacco Control Scale.

www.tobaccocontrolscale.org

Annex 7 Curriculum vitae and list of main publications

7.1. Curriculum vitae

The author of this PhD thesis, Ariadna Feliu, was born in Barcelona in 1993. In 2015, she obtained a degree in Biomedical Sciences at Universitat de Barcelona and, in 2017, she obtained a MSc in Public Health (MPH) from the Universitat Pompeu Fabra and Universitat Autònoma de Barcelona. She also holds a degree in Law by the University of Barcelona (January 2021).

Right after graduating, in November 2015, she started collaborating with the Tobacco Control Unit of the Institut Català d'Oncologia, a WHO Collaborating Centre for Tobacco Control conducting fieldwork from a project funded by Instituto de Salud Carlos III. In January 2017, after conducting an internship at the Environment Health Unit at the Health Department of the Generalitat de Catalunya, she joined the Tobacco Control Unit as a junior researcher. Since then, she has participated in six funded projects at national and international level (**ACT-ATAC**, **QUIT-MENTAL**, **E-PISCIS**, ImaginTAB-tv, **ISCI-SEC**, and **INSTrUCT**). During her PhD, she has conducted a Predoctoral International Stay at the Public Health Policy Evaluation Unit, Primary Care and Public Health Department, a WHO collaborating Centre for Public Health Education and Training, at the Imperial College of London, under the supervision of Dr. Filippos T. Filippidis.

In 2018, she started collaborating as an Associate Lecturer in Ethics, legislation, and digital reputation, in the Master in e-Health, Universitat Oberta de Catalunya (UOC).

7.2. List of main publications

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