## **Review**

# Environmental tobacco smoke: health policy and focus on Italian legislation

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#### Abstract

Worldwide tobacco smoking kills nearly 6 million people each year, including more than 600,000 non-smokers who die from smoke exposure. Environmental tobacco smoke (ETS, also called secondhand smoke, involuntary smoke, or passive smoke) is the combination of sidestream smoke, the smoke given off by a burning tobacco product and mainstream smoke, the smoke exhaled by smokers. People may be exposed to ETS in homes, cars, workplaces, and public places, such as bars, restaurants, and recreational settings. In addition, there is another type of smoke which until now has not been recognized: the so-called thirdhand smoke, that comes from the reaction of mainstream smoke and environmental nitrous acid (HNO<sub>2</sub>) making carcinogenic tobacco-specific nitrosamines (TSNAs). The effects of ETS on human health are well-known, passive smoking is harmful to those who breathe the toxins and it is a serious problem for public health. The smoking ban in Italy had reduced ETS pollution, as in the United States and in other countries all over the world. However, the implementation of comprehensive legislation on smoking policy will necessitate other tobacco control measures for its successful fulfillment: increased media awareness, telephone smoking cessation helplines and smoking cessation support services could be an opportunity to ensure awareness, comprehension and support to those who want to quit smoking. The effectiveness of legislative efforts will also depend on successful enforcement of smoking bans and compliance with the legislation. This review summarizes the evidences about the effect of ETS and provides an overview of smoke-free laws and policies. Clin Ter 2013; 164(5):e429-435. doi: 10.7417/CT.2013.1623

**Key words:** environmental tobacco smoke, health policy, legislation, passive smoke, secondhand smoke, thirdhand smoke

## Introduction

Environmental tobacco smoke (ETS, also called secondhand smoke, involuntary smoke, or passive smoke) is the combination of *sidestream smoke*, the smoke given off by a burning tobacco product and *mainstream smoke*, the smoke exhaled by smokers; it usually refers to a situation where a non-smoker breathes smoke emitted into the environment

by other people smoking. ETS is probably the most important contaminant of indoor air and it is reasonable to expect that ETS exposure would cause the same diseases as active smoking, but at a risk reduced approximately in proportion to the considerable dilution of the smoke. In fact, the ETS was declared to be carcinogenic by the International Agency for Research on Cancer (IARC), a branch of the World Health Organization (1, 2).

People may be exposed to ETS in homes, cars, workplaces, and public places, such as bars, restaurants, and recreational settings. The source of most of ETS is from cigarettes, followed by pipes, cigars, and other tobacco products (3). Smoking bans are a relatively recent phenomenon: in the USA, California became the first state to implement a comprehensive state-wide smoking ban which prohibited smoking in all workplaces including restaurants and bars. Since then, many American states have enacted similar laws (4, 5). In 2004, Ireland became the first European country to impose an outright ban on smoking in workplaces; the Irish legislation made an offence to smoke in workplaces, which had the effect of banning smoking in pubs and restaurants. Following this successful example, other countries, such as Norway, Italy, Britain, Portugal and Sweden, have drafted plans to establish similar laws (6). Italy was one of the first European countries to introduce a comprehensive smoking ban in January 2005. Indeed, on 16 January 2003 Italy passed the so-called "Legge Sirchia", which regulates smoking in public and private premises, open to the public, in order to protect the health of non-smokers (7).

The main reason for introducing smoking bans in many countries seems to be their potential of substantially reduce well-known secondhand smoking related diseases as well as the considerable treatment costs associated (8). In economic terms, the US Center for Disease Control and Prevention (9) estimated that cigarette smoking was responsible for \$193 billion in annual health-related economic losses in the United States (nearly \$96 billion in direct medical costs and additional \$97 billion in lost productivity). Thus, preventing smoking and increasing cessation rates need to remain priorities of public health professionals and declines in smoking-attributable deaths can be achieved by further

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reducing smoking prevalence rates. The present review summarizes the evidence of the effect of ETS and provides an overview of smoke-free laws and policies.

Epidemiological aspects and ETS-related diseases

Worldwide tobacco smoking kills nearly 6 million people each year, including more than 600,000 non-smokers who die from smoke exposure. Up to half of the world's 1 billion smokers will eventually die of a tobacco-related disease and if current trends continue, by 2030 tobacco will kill more than 8 million people worldwide each year (10). Since 1950s, several epidemiological studies and meta-analysis have investigated the relationship between passive smoking and heart failure as well as other diseases in non-smokers.

#### Cardiovascular diseases

Acute cardiovascular disease (ACVD) still remains the leading cause of death in the United States and all industrialized countries (11). The effects of ETS on cardiovascular system are not caused by a single component of the smoke, but rather are caused by the effects of many elements, including carbon monoxide, nicotine, polycyclic aromatic hydrocarbons, and other, not fully specified elements. Nonsmokers exposed to ETS in everyday life exhibit an increased risk of both fatal and non-fatal cardiac events, therefore the American Heart Association's Council on Cardiopulmonary and Critical Care concluded that ETS is a "major preventable cause of cardiovascular disease and death" (12, 13). The ETS contributes to endothelial function impairment and increases the oxidative stress; as demonstrated, significant exposure to the ETS is associated with the presence of an increased level of C-reactive protein which, in turn, explain the relationship between ETS and death due to cardiovascular reasons (14, 15).

It can be estimated (16), on the basis of different study designs and methods, that the exposure to ETS increases the risk of an ACVD event by 25-35%.

He et al. (17) concluded that even if this association is not fully known, it is quite evident that for non-smokers exists an increased risk for ACVD; the risk increases with the number of cigarettes smoked per day by the spouse/partner and with the time of exposure. Given the high prevalence of cigarette smoking, the public health consequences of passive smoking to coronary heart disease may be important. Another study (18) concerning possible cardiovascular effect of ETS, found out that doses to non-smokers are small and difficult to detect, so a strong association with cardiovascular event may be inconclusive: such uncertainties probably were the result of the presence of contrasting protective or aggravating confounders, of which more than 200 have been reported in the literature that could not be adequately controlled by any epidemiological study. The risk of dying for heart disease among non-smoking women exposure to ETS was associated with a 15% increase in the risk compared with non-smoking women not exposed to ETS (19). By all means, there is now strong evidence supporting a reduction in ACVD following the implementation of comprehensive smoke-free legislation, with the effect increasing over time from implementation and with more comprehensive laws associated with greater changes in risk (20, 21). In addition, chronic exposure to ETS doubles the risk of stroke, based on exposure to spousal smoking and it is associated with a 20% increase in the progression of atherosclerosis (22, 23).

#### Cancer and other diseases

Concerning respiratory system, the ETS is a risk factor for chronic obstructive pulmonary disease (24) and population on the whole needs to know its consequences because there is no a threshold dose of exposure and even small amounts can be harmful to people's health. Children, heart patients, asthmatic and bronchitis patients are considered the most susceptible categories.

The IARC showed an increased risk for lung cancer in non-smokers exposed to ETS: the spouses of female smokers are the most exposed (30%), followed by spouses of male smokers (20%) and exposed in the workplace (16-19%) (25, 26). A European Multi-Center study found an increase of 16% in the risk of lung cancer for non-smoking spouses of smokers and a 17% increase in the risk of lung cancer associated with exposure to passive smoking in the workplace; for both exposures, there was a dose-response relationship. Workers who had spent up to 29 years in a smoky environment had a 15% greater chance of developing lung cancer, while people who had worked between 30–38 years in a smoky environment had a 26% greater risk of the disease (27).

Though the dose of carcinogen exposure is less than that from active cigarette smoking, the passive smoking is also correlated with bladder cancer (with a disproportionately large contribution to bladder carcinogenesis) (28), rectal cancer (29), diminished cognitive abilities in children and adolescent aged 6-16 (30), increased rates of lower respiratory illness, asthma, and sudden infant death syndrome (31). It has been confirmed that children born to mothers exposed to ETS attain lower APGAR scale results and it has also been established that women infants exposed during pregnancy had their BMI index at the age of 2 and 3 years higher than their contemporaries, whose mothers were not passive smokers (32).

Besides, a major limitation of epidemiological studies on ETS has been the unreliable estimate of dose, which compound the uncertainties of personal or proxy recall of the intensity, frequency, and duration of exposures over individuals lifetimes (33). Cotinine is the major metabolite of nicotine, and its determination in urine is used as an index of exposure to tobacco smoke, without excluding the possibility of other exposure situations for pharmacological or agricultural reason. Although the ETS is not the only indoor risk factor, epidemiological evidence showed that urinary cotinine significantly decreases in biochemical determinations of ex-smokers spouses and their children; we can apply the same remark for the relatives of smokers who do not smoke at home. Less than a fifth of parents in smoking households ban smoking in the home. Banning smoking was associated with a small but significant reduction in urinary cotinine in infants. Smoking cessation among household members is an effective way to reduce passive smoking among young people; changing smoking practices at home in the presence of young people has been suggested as a means of reducing

exposure to tobacco smoke when cessation is not possible (34-36).

## Health policy and legislation overview

The smoking effects on health has led to implementation of legislative and control measures. Below it has been reported a list of the legislative measures in Italy.

- Royal Decree n. 2316 December 24 1934, banned tobacco sale for children under 16, which is also banned smoking in public places.
- Law n. 1409 December 13 1956, maritime surveillance for smuggling prevention.
- Law n. 165 April 10 1962, banned tobacco products advertising.
- Law n. 248 March 12 1968, banned the sale of loose cigarettes.
- Legislative Decree (LD) n. 870 November 30 1970, modified in law n. 3 - January 27 1971, implementation of the European Union Regulation (EEC) on raw tobacco and abolition of the tobacco growing monopoly, import and sale.
- Law n. 306 June 6 1973, creation of the Institute for Experimental Tobacco.
- Law n. 584 November 11 1975, smoking ban in specific public venues and on public transport.
- Decree of the President of the Republic (DPR) n. 753 -July 11 1980, provided new rules on safety and regularity for railways and other means of transport.
- Ministerial Decree (DM) June 15 1981, creation of the tobacco types register.
- Law n. 52 February 22 1983: "the advertising of any national or international smoke product is forbidden.
  Those who break the ban are subject to administrative sanction from Lire 5 million to Lire 50 million".
- Law n. 76 March 7 1985, price of sale for tobacco brands.
- DM 425 November 30 1991, "it is forbidden television advertising for cigarettes and any other tobacco product, or companies whose main activity is the production and sale of these products".
- DM May 28 1993, obligation of reporting the amount of condensate and nicotine of the cigarettes marketed from May 1 1993.
- DM 581 December 9 1993, banned the TV programs sponsorship by physical or legal persons whose main activity is cigarettes manufacture or sale.
- Law 626 art. 33 1994, "the employer must provide healthy air in adequate quantity to workers".
- Directive of the President of the Council of the Minister (DPCM) December 14 1995, extended smoking ban in all public administrations and companies venues in the management of their functions, as well as by private and public services in charge for management of the related activities, provided they are venues open to the public.
- Law n.3 January 16 2003, it extended smoking ban in all enclosed areas, with the only exception of smoking rooms and strictly private areas. The decree provides the possibility to create smoking areas with ventilation parameters and structural characteristics defined by the

- Decree of the President of the Council of Ministers of December 23, 2003.
- LD 184 June 24 2003, defined the cigarettes highest level of tar, nicotine and carbon monoxide, respectively equal to 10 mg/cigarette, and 1 mg/cigarette, and 10 mg/cigarette. In addition, in order to protect the customers it has been forbidden the use of deceptive texts, images or figurative elements on tobacco packages. The decree had obliged tobacco manufacturers and importers to submit annually to competent authorities a complete list of all ingredients used in the process of production.
- As regards operators of public services (article 7, Law n.584/1975), their tasks are defined by paragraph 20 of the Law 448 December 28 2001, with an exacerbation of administrative sanctions for those who break the ban, and for those who are obliged to ensure the ban. The DPCM of December 14 1995, specify that the individuals in charge for the structure and their delegates are obliged to: formally recall who does not respect smoking ban; report those who break the ban to the competent authorities. These individuals have, moreover, the task to place anti-smoking sign according to the agreement of the State-Region Committee of the December 16, 2004.
- DL 300 December 16 2004, regulated tobacco products advertising and the distribution for free promotional purposes.
- DM January 14 2008, among the diseases for which it is mandatory the reporting, it has been included lung cancer derived from work activities that expose to ETS.

### The Italian situation post-smoking ban

The smoking ban in Italy had drastically reduced ETS pollution, as in the US and in other countries. The application of the smoking ban after Law 3/2003 (7), led to a considerable reduction in exposure to indoor fine and ultrafine particles in public venues with a significant reduction of involuntary exposition. The significant reduction in air pollution is probably the result of the rigorous manner in which the law was enforced and, of the great reduction in the number of venues with smoking sections (37).

The law seems to have produced a reduction in the prevalence of smokers: 20.8% of the Italian population currently smokes compared to the 26.2% of the 2004; among young people aged 15-24, smokers are 18.5% (38).

The study of Federico et al. (39) showed among males, a decrease for smoking prevalence (2.6%) and an increase for smoking cessation (3.3%) shortly after the ban, but both measures tended to return to pre-ban values in the following years. This occurred among both highly and low-educated males. Among low-educated females, the ban was followed by a 1.6% decrease in smoking prevalence and a 4.5% increase in quit ratios. However, these favourable trends reversed over the following years. Among highly educated females, trends in smoking prevalence and cessation were not altered by the ban. Gallus et al. (40-42) evaluating the 2005 Italian law for smoke-free public places, estimated that smoking prevalence decreased by 1.9% between 2004 and 2005; for the same period cigarette consumption decreased

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by 8% and these effects were particularly significant in men and in subjects aged 15-44.

Concerning smoking effect on coronary disease, Cesaroni et al. (43) analyzed hospital admission and out-of-hospital deaths for ACVD events between 2000 and 2005 showing a significant reduction in acute coronary events in 35- to 64-year-olds (11.2%) and in 65- to 74-year-olds (7.9%) after smoking ban. No evidence was found of an effect among the very elderly (over 74 years old), probably because of the scarce attendance of the elderly in public venues. The reduction was greater in men and among lower socioeconomic groups. The study of Barone-Adesi et al. (44) estimated that the observed reduction in active smoking after the introduction of the ban could account for a 0.7% decrease in admissions for ACVD during the study period, suggesting that most of the observed effect (11%) might be due to the reduction of passive smoking.

#### **Discussion and conclusion**

This review found several evidence of the effect of ETS on human health. Passive smoking is harmful to those who breathe the toxins and it is a serious problem for public health: it is considered to be the third leading cause of preventable disease, disability and death (45). Many societies have evolved from a history of rewarding smokers with social esteem to using public health policy to combat smoking through increasing social isolation, thereby denying to the individual the nurturing effects of relationships with others: classic example is the great American actor Humphrey Bogart who smoked cigarettes in the movie Casablanca and earned an Oscar Award, while today smokers are forced to stand alone outside the movie theater (46, 47). Bans and policies can be implemented through public health policies or legislation affecting populations at a national, state or community level. This evolution has been driven by the creation of new science showing harm, including lung cancer in healthy exposed non-smokers, and highlighting the need of protection by public health policies (48). However, society's treatment of smoking is complex and has radically changed over the years in the United States and other Western countries.

Our review showed many associations between ETS, cardiovascular diseases and cancer. There are cases where tobacco industry-funded epidemiological analyses of large data sets were used to argue against epidemiological association between ETS and heart failure, but these analyses all suffered from exposure misclassification problems that eventually even some in the tobacco industry recognized. An example of a controversial study was the research of Enstrom and Kabat (49): the results of this study do not support a causal relation between ETS and tobacco related mortality, although they do not rule out a small effect; for these authors the association between exposure to ETS, heart disease and lung cancer may be considerably weaker than generally believed.

The tobacco industry attempted to undermine the ETS-related diseases to combat smoke-free regulations; the industry interest in preserving corporate viability has affected the design and interpretation of their cardiovascular studies,

indicating the need for great caution in current debates about future tobacco industry regulation and development of reduced-harm tobacco products (50).

The aim of the Action Plan 2008-2013 of the World Health Organization is the promotion of interventions to reduce the main risk factors for chronic diseases: mass media campaigns are giving more and more space to these healthrelated issues regarding nutrition, physical activity, and quitting smoking (51, 52). The last update of the Cochrane Review (53) concerning workplace interventions to reduce smoking habits points out that there is strong evidence on the effectiveness of interventions in the workplace as well as strong evidence that workplace smoking ban may reduce the number of cigarettes smoked per day by workers and the exposure of nonsmokers to ETS. Besides, company policies for prevention, care and control on tobacco smoking may represent effective measures to reduce smoking prevalence, cigarette consumption and exposure to ETS (10). The European Union (EU) and the Luxembourg Declaration on Workplace Health Promotion (54) had formerly defined workplace health promotion as the combined efforts to improve the health and well-being of people at work "Health promotion in the workplace should be a joint effort between employers, employees and society to improve the health and well-being of workers. This can be achieved improving work organization and environment, promoting active participation of the workers and improving personal skills". These evidence were also adopted from the Italian Ministry of Health and the Istituto Superiore di Sanità (ISS) with the "Clinical guidelines to promote smoking cessation" (55).

The Italian National Prevention Plan (PNP), a document of the Italian Ministry of Health undersigned by the State-Region Committee, takes in to account the importance of the promotion of smoke-free strategies. These strategies were implemented from each Italian region with the Regional Prevention Plan (PRP): PRPs should develop specific projects for smoking cessation to improve the well-being of individuals and community (56-58).

Studies (59, 60), recently investigated how individuals react to the introduction of a public smoking ban in Italy concluding that smoking ban can have important benefits on both smokers' and nonsmokers' health since it reduces both participation rate and consumption of cigarettes. A comprehensive set of measures should be put in place together to achieve the best results, including smoking bans, higher taxes, bans on advertising and promotion of all tobacco products, logos and brand names, better consumer information, direct warning labels on cigarette boxes and other tobacco products; these measures may be helpful for smokers who would like to quit. The estimated social savings of quitting smoking appear to be substantial: one of the great benefit of the smoking ban is shown by the cost-effectiveness analysis, with positive implications in terms of costs to the Italian National Health Service.

In addition to ETS inhaled in public spaces and in workplaces, there is another type of smoke which until now has not been considered: the so-called *thirdhand smoke* (Fig. 1), that comes from the rests of active smoking nicotine (*mainstream smoke*) that is laid down on the surfaces of indoor environments (cars, clothes, curtains, wallpaper, etc.) and reacts with environmental nitrous acid (HNO<sub>2</sub>) making

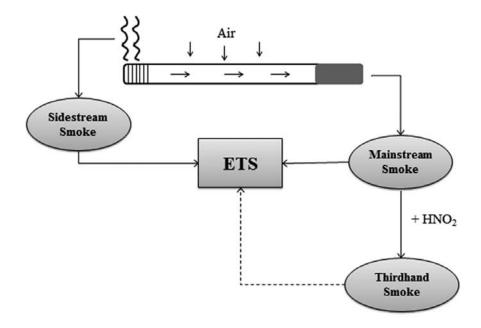


Fig. 1. Mechanism of ETS formation. Sidestream and mainstream smoke originate from cigarette; thirdhand smoke is the reaction of mainstream smoke and the environmental nitrous acid (HNO<sub>2</sub>), it may contribute to ETS.

carcinogenic tobacco-specific nitrosamines (TSNAs). One of the most alarming characteristics of TSNAs is their longevity: they are among the most broadly acting and potent carcinogens present in burned tobacco and tobacco smoke. Removing *thirdhand smoke* in the form of nicotine residue from carpet, for example, especially carpet with long term exposure, would be nearly impossible (61, 62).

In conclusion, we believe according to Callinan et al. (53) that the implementation of comprehensive legislation on smoking policy worldwide will necessitate other tobacco control measures to prepare for its successful fulfillment: increased media awareness, telephone smoking cessation helplines and smoking cessation support services could be an opportunity to ensure awareness, comprehension and support to those who want to quit smoking. The effectiveness of legislative efforts will also depend on successful enforcement of smoking bans and compliance with the legislation. Other tobacco control measures (taxation on tobacco products, limits on advertising and sponsorship and limits on the sale of tobacco products) may vary between jurisdictions. Strategies should be targeted for both individual and population levels, the smoking ban in workplace may be an attempt for a comprehensive approach to tobacco control. Interventions at each of these levels may contribute to the overall goal of improving population health.

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