



Towards a Tobacco Free Society

RCPI Policy Group on Tobacco

March 2014

Executive Summary	4
1. RCPI Policy Group on Tobacco	7
2. Tobacco Harm	8
2.1. Smoking-Related Illness and Death	8
2.2. Smoking Prevalence	11
2.3. <i>Tobacco Free Ireland</i>	14
3. What Works	15
3.1. MPOWER.....	15
3.2. Surgeon General Report (2014)	15
3.3. NICE Guidance	16
RCPI Policy Group on Tobacco: Position and Recommendations.....	17
4. Offering Help to Quit	17
4.1. What RCPI can do	17
4.2. Smoking in pregnancy	19
5. National Policy/Legislative Measures.....	20
5.1. Standardised Packaging	20
5.2. Availability	21
5.3. Taxation	21
5.4. Smoke Free Environments	22
5.5. Smoking in cars.....	22
6. Changing Behaviour through Public Campaigns	23
7. Electronic-cigarettes	23
References.....	25

Members- RCPI Policy Group on Tobacco

Member	Representing
Dr Pat Doorley - Chair	Faculty of Public Health Medicine, RCPI
Prof Tom Clarke	Faculty of Paediatrics, RCPI
Dr Linda Coate	The Irish Society of Medical Oncology
Dr William Flannery	The College of Psychiatry of Ireland
Dr Donal Murray	Irish Cardiac Society
Dr Peter Noone	Faculty of Occupational Medicine, RCPI
Dr Brian Norton	The Irish College of General Practitioners
Dr Anthony O'Regan	The Irish Thoracic Society
Dr Margaret O'Rourke	The Psychological Society of Ireland
Ms Anne O'Shaughnessy	Head of Education and Professional Development, RCPI
Dr. Carmen Regan	Institute of Obstetricians & Gynaecologists, RCPI
Dr Peter Wright	Faculty of Public Health Medicine, RCPI

Additional contributions from Dr Des Cox, Consultant in Paediatric Respiratory Medicine, Our Lady's Children's Hospital Crumlin, and Dr Eve Robinson, Specialist Registrar in Public Health Medicine.

Executive Summary

Tobacco is an addictive drug that kills when used as intended. Tobacco smoke affects virtually every organ in the body and leads to serious and fatal cardiovascular and respiratory disease as well as lung cancer and other cancers. As highlighted in the HSE's successful QUIT campaign, one of every two people who smoke long term will die from a smoking related disease. The health impacts however are not only limited to smokers; exposure to second hand smoke also results in many of the same health risks.

Exposure to second hand smoke from parents compromises the vascular health of children; so much so that the impact is seen up to 25 years later. Despite the health risks, Irish children are frequently exposed to second hand smoke and residual tobacco smoke at home, in the car and in other areas.

Perhaps the greatest risk to children from second hand smoke occurs in prenatal life. Serious adverse effects of fetal exposure to cigarette smoke are well documented. These pose risks not alone within pregnancy, but in the early neonatal period, childhood and later life. Nonetheless, approximately one in eight Irish women will continue to smoke in pregnancy, such is the nature of the addiction.¹

There has been much progress in reducing smoking prevalence in Ireland, and the introduction of the workplace smoking ban a decade ago was a pioneering move which was followed by many countries worldwide. Other measures such as taxation, ban on display at point of sale, and the ban on the sale of cigarettes in packs of less than 20 have been effective, especially in reducing prevalence among children. In order to make tobacco addiction a thing of the past we need sustained commitment not just from the health services and health professionals but also from government and many elements of civil society.

RCPI is supportive of *Tobacco Free Ireland*, the Government's first policy document published under the *Healthy Ireland* framework, and the recommendations in that report. RCPI's policy statement also draws attention to specific recommendations based on an understanding of interventions proven effective internationally. The World Health Organisation, for example, promotes the MPOWER measures to assist in the country-level implementation of effective interventions to reduce the demand for tobacco, as contained in the WHO Framework Convention on Tobacco Control (WHO FCTC). The latest US Surgeon General report also describes the

interventions that work. In addition the UK's National Institute for Health and Care Excellence (NICE) includes in its public health guidance, recommendations on smoking cessation prevention that are based on extensive review of 'what works'.

Every smoker who needs help to quit should be offered support through smoking cessation services. This should include integration of brief interventions at every contact between a smoker and a health professional ('making every contact count'), and in-depth counselling as appropriate. Services offering support to pregnant women in quitting smoking are of particular importance.

Physicians have a duty of care to advise patients and the general public on their health. As a training institution, RCPI is cognisant of its role in educating and training doctors to support smoking cessation. **We urge all doctors to raise the issue of smoking with patients at every opportunity.** To support doctors and other healthcare staff in doing this:

- RCPI has started to offer a Smoking Cessation training course, open to all frontline healthcare staff.
- RCPI will promote smoking cessation as appropriate through current events such as Master classes and Clinical Updates.
- RCPI will also explore options for other methods of delivering training, e.g. online.

RCPI also has an advocacy role, and is committed to advocating for interventions to reduce tobacco related harm in Ireland. Legislative actions have been shown to have a strong impact at the population level. Therefore, we make the following recommendations to the Government on **National Policy/Legislative measures to reduce tobacco related harm:**

- Introduction of standardised packaging for cigarettes in Ireland.
- Introduction of further measures to reduce the availability of tobacco to both adults and children, and stricter enforcement of existing legislation.
- Continue to use taxation as a proven measure to reduce tobacco use.
- Swift introduction of new legislation on smoke free environments, as described in *Tobacco Free Ireland*.
- Introduction of a ban on smoking in cars when children are present.

- We further recommend that the campuses of all publicly funded institutions should be tobacco free, in particular hospitals campuses and academic campuses

Determinants of smoking behaviour may differ according to the individual, and as such different people will respond in different ways to different interventions. Targeted evidence- based campaigns which follow social marketing principles, such as the HSE quit campaign, are effective in getting smokers to quit. **Public Information Campaigns such as the QUIT campaign are effective in changing behaviour and should be continued, with adequate resourcing to allow expansion.**

While preparing this policy statement, this group also considered the question of electronic cigarettes. Undoubtedly the use of and interest in electronic cigarettes is increasing rapidly. While they are likely safer for the individual user with regard to tobacco related morbidity and mortality, they are not risk free products and their potential as a cessation aid is still unclear. There is also concern that they may re-normalise smoking. Our view is that the current lack of regulation is unsatisfactory. Nicotine is a drug of addition that is currently available to children in the form of e-cigarettes. While we welcome the provisions on electronic cigarettes of the EU Tobacco Products Directive, more regulation is needed. The absence of age limits in that directive means that it will continue to be available to children, and there should be a ban the sale of these products to children. Further consideration also needs to be given to the efficacy and safety of these products based on best practice evidence.

1. RCPI Policy Group on Tobacco

As part of its mission, the Royal College of Physicians of Ireland seeks to promote health nationally and internationally and play a leading role in the delivery of high quality patient care by setting and maintaining standards of medical practice and promoting clinical excellence.

While the mission is achieved primarily through training, continuing professional development, professional competence and examination activities, RCPI also has an advocacy role and is at the forefront of improving healthcare and public health. This is achieved by providing evidence-based advice to the profession, policy makers, healthcare providers, and the public and working with government and other agencies to influence health and healthcare policy.

As part of this commitment to improving healthcare and public health, RCPI convenes a number of issue-focused policy groups where medical and other experts can meet to discuss the issues and concerns about a specific health matter with the aim of producing evidence based policy statements that outline the issues, propose specific steps to deal with the issues, and clarify RCPI's position.

In response to the continuing public health consequences associated with tobacco, and building on RCPI's past work on smoking, a policy group on tobacco was established in early 2014. The overall aim of the policy group is to influence national tobacco policy and legislation, particularly in support of the *Tobacco Free Ireland* plan launched by the Minister for Health in 2013. The policy group comprises representatives from a range of medical specialties from within RCPI's own Faculties and Institute, and from other external bodies such as the Irish College of General Practitioners, the Irish Thoracic Society and the Psychological Society of Ireland.

2. Tobacco Harm

2.1. Smoking-Related Illness and Death

Tobacco is an addictive drug that kills when it is used as intended and tobacco use remains the leading cause of preventable death worldwide. The World Health Organisation (WHO) estimates that tobacco use is currently responsible for six million deaths each year², equating to one death every six seconds. This figure is predicted to rise to eight million deaths per year by 2030, while in the European region it is estimated that smoking is a leading risk factor for premature mortality, accounting for 1.6 million deaths per year.³

Tobacco smoke affects virtually every organ in the body, and it has been found that tobacco use and exposure to second hand smoke (SHS) leads to serious and often fatal diseases, including cardiovascular and respiratory disease as well as lung cancer and other cancers.

It is also known that one out of every two people who smoke long term will die from a smoking related disease⁴ and that an average smoker loses about 10 quality years of life because of smoking³.

Surgeon General's Report (2014)

In addition to the above harms, the most recent report⁵ from the US Surgeon General cites a number of new findings that expand on the disease risks highlighted in previous reports by that office, spanning a period of 50 years. These new findings include:

- Liver cancer and colorectal cancer are added to the long list of cancers caused by smoking;
- Exposure to second hand smoke is a cause of stroke;
- Smoking increases the risk of dying from cancer and other diseases in cancer patients and survivors;
- Smoking is a cause of diabetes mellitus; and
- Smoking causes general adverse effects on the body including inflammation and impaired immune function.
- The evidence is sufficient to infer a causal relationship between cigarette smoking and rheumatoid arthritis.

Irish Data

Data presented by RCPI Faculty of Public Health Medicine at its Winter Scientific Meeting in 2011, and referenced in *Tobacco Free Ireland* (TFI)⁶ highlights the following Irish statistics:

- Tobacco use is the leading cause of preventable death in Ireland.
- Each year at least 5,200 people die from diseases caused by tobacco use, representing approximately 19% of all deaths. These deaths are caused by Cancers (44%), Circulatory Diseases (30%), Respiratory Diseases, (25%) and Digestive Diseases (1%).

In addition, 2005 figures show that the percentage of all mortality attributable to tobacco use in Ireland was 20% for men and 16% for women. This is more than double the EU average for women (7%), but slightly lower than the EU average for men of 23%. The Irish Heart Foundation also reports that smoking causes up to 2,500 strokes and 500 stroke related deaths per year.³

Economic Cost

In addition to the health costs, which are experienced by both smokers and by exposure to second hand smoke, the high societal cost of smoking is also an imperative for action. TFI highlights that the cost of treating an inpatient for a smoking related disease in Ireland amounts to €7,700. An EU report, also referenced in TFI³ estimated that Ireland spent €500 million of its health expenditure on tobacco related diseases in 2009. The same study also estimated that productivity losses and long-term incapacity due to smoking-related diseases cost the Irish state over €160 million annually and the cost of premature mortality was estimated at €3.5 million in the same year.

Second hand smoke (SHS)

Secondhand tobacco smoke is exhaled smoke, the smoke from burning tobacco, and smoke from the filter or mouthpiece end of a cigarette, pipe, or cigar. It contains many poisons, including nicotine (a pesticide), carbon monoxide, ammonia, formaldehyde, hydrogen cyanide, nitrogen oxides, phenol, sulfur dioxide, and

others.⁷ Evidence shows that exposure to second-hand smoke increases the risk of serious medical conditions, such as lung cancer, cardiovascular disease, respiratory disease and sudden infant death syndrome³. The WHO⁸ estimated that this exposure contributed to 1% of worldwide mortality in 2004. This can be broken down as follows:

- 379,000 deaths from ischaemic heart disease
- 165,000 from lower respiratory infections
- 36,900 from asthma
- 21,400 from lung cancer.

A recent study⁹, published in the *European Heart Journal* in early 2014, which measured the effects of parental smoking on children, found that children who were exposed to SHS had worse arterial health in adulthood. The difference between exposure to both parents smoking and no exposure was found to be the equivalent of 3.3 additional years of vascular ageing.

In Ireland, the study¹⁰ *A Tobacco Free Future*, by the Institute of Public Health and the TobaccoFree Research Institute found that Irish children's exposure to SHS is quite common. Close to a quarter (22%) of primary caregivers of 9 year olds reported that smoking occurs in the same room as their child, while more than 1 in 10 (14.8%) of children aged 13-14 years reported exposure to smoking in cars in 2007. In addition, the prevalence of severe asthma among children exposed to SHS was consistently higher than the prevalence of severe asthma among non-exposed children.

Residual Tobacco Smoke

Residual tobacco smoke consists of pollutants that remain on surfaces and in the dust after tobacco has been smoked. There is emerging evidence that residual tobacco smoke has a significant health impact on the people exposed to it, especially children¹¹. A 2009 study, found that children exposed to residual tobacco smoke have increased respiratory symptoms when compared with children of non-smoking parents¹². In addition, the nicotine level in the hair and serum is high not only in children whose parents smoke inside but also in children whose parents smoke outside¹³.

Smoking in Pregnancy

Maternal smoking in pregnancy is hugely concerning and poses significant risks for the fetus throughout pregnancy¹⁴. Pregnant women who smoke place their fetus at risk of miscarriage, low birth weight, preterm delivery and placental abruption. The latest data from the US¹⁵ indicate that smoking is associated with stillbirth in a dose-dependent fashion. Sudden infant death syndrome and respiratory diseases during infancy occur with increased frequency in offspring of smoking mothers. Antenatal exposure to cigarette smoke may increase the risk of certain birth defects¹⁶ and there is accumulating evidence suggesting that prenatal tobacco exposure is related to altered brain development and childhood behavioral disorders¹⁷.

Smoking is causally linked to intrauterine growth restriction, and accounts for approximately one third of all cases. The degree of growth restriction is shown to be proportional to the number of cigarettes smoked and results in a global restriction in fetal growth with reduced head circumference.

Despite known causal associations between smoking, growth restriction in pregnancy, prematurity and sudden infant death syndrome, 12% of Irish mothers will continue to smoke¹. These mothers are more likely to be socially disadvantaged, to be younger, to continue to consume alcohol during pregnancy and to have used illicit drugs in the past. Mothers who quit prior to pregnancy or in the first trimester are likely to be older and are largely self-motivated. Mothers who fail to quit utilize a variety of aids including nicotine replacement therapy (NRT)¹.

2.2. Smoking Prevalence

We know from statistics gathered by the National Tobacco Control Office and SLAN surveys that smoking prevalence among adults has decreased over time. In 1998, 33% of people reported being current smokers¹⁸; however this had reduced to 22% in 2012³. This decrease in smoking prevalence is key evidence that more stringent tobacco control policies have worked. Figure 1 shows the smoking prevalence from June 2003 to December 2012. Figure 2 shows tobacco consumption trends from 1987 to 2011, and highlights the legislative measures taken over that period.

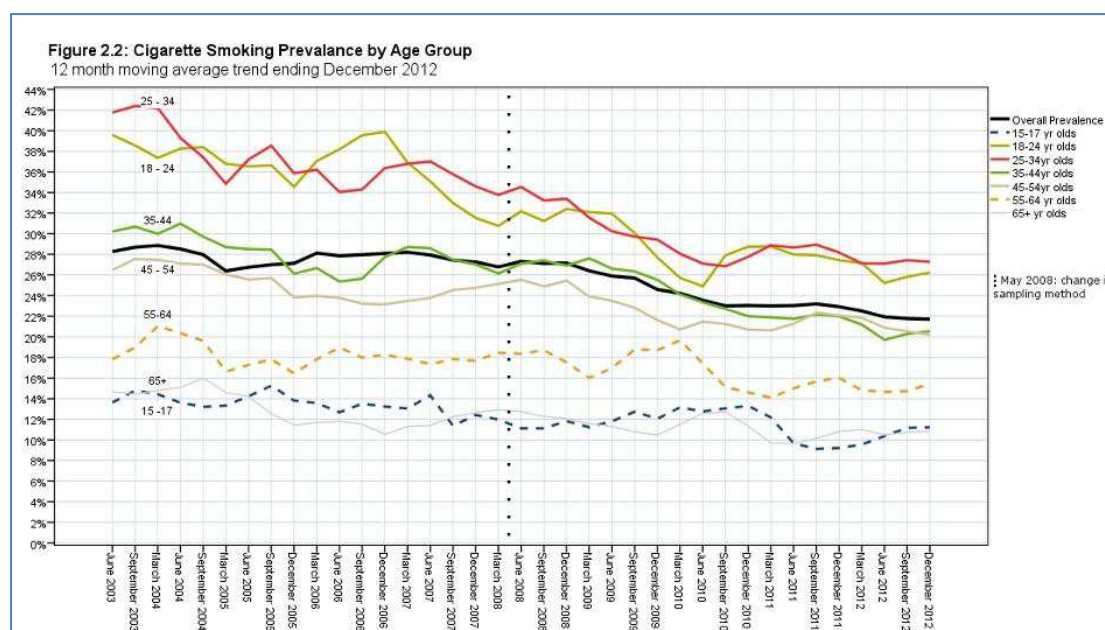


Figure 1: Smoking Prevalence by age group

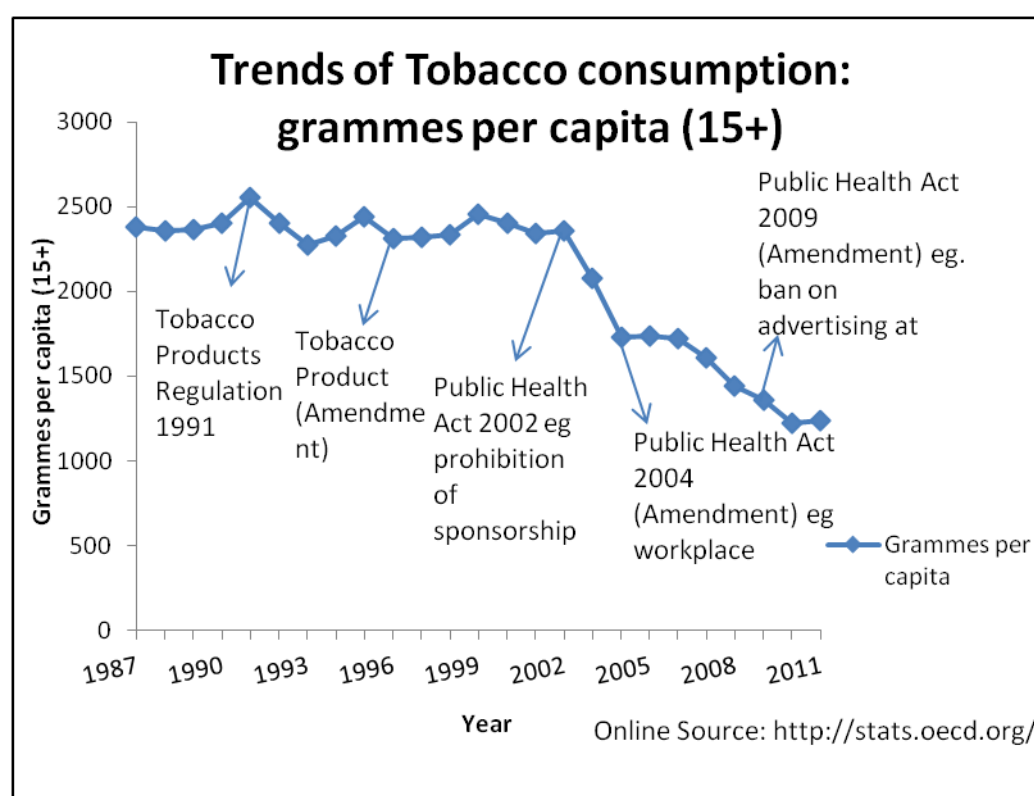


Figure 2: Tobacco Consumption and Legislative Measures

Smoking prevalence among Irish children has also decreased, from 21% to 12% between 1998 and 2010³. It is reasonable to attribute this substantial decrease to policies such as the ban on sale of packs of less than 20 cigarettes and the ban on

display at point of sale. Strong tobacco control policies do work, especially for children. This point has recently been reiterated by the German Cancer Research Centre¹⁹ (DKFZ), which attributes the decline of smoking among young people in Germany to a number of legal measures that the German Government has introduced since 2002. They specifically attribute the decrease in young smokers to the increases in tax between 2002 and 2005, and the introduction of non-smoker protection legislation between 2007 and 2010. They also refute the tobacco industry's assertion that smoking among young people in Germany is mainly attributable to health education. Rather, their findings confirm the broad international scientific consensus about the effectiveness of considerable tobacco tax increases in changing smoking behaviour among young people.

Lower socio-economic groups bear a disproportionate burden of ill health. Health inequalities among lower socio economic groups are frequently exacerbated as a result of lifestyle risk factors such as alcohol, smoking and obesity. In Ireland,

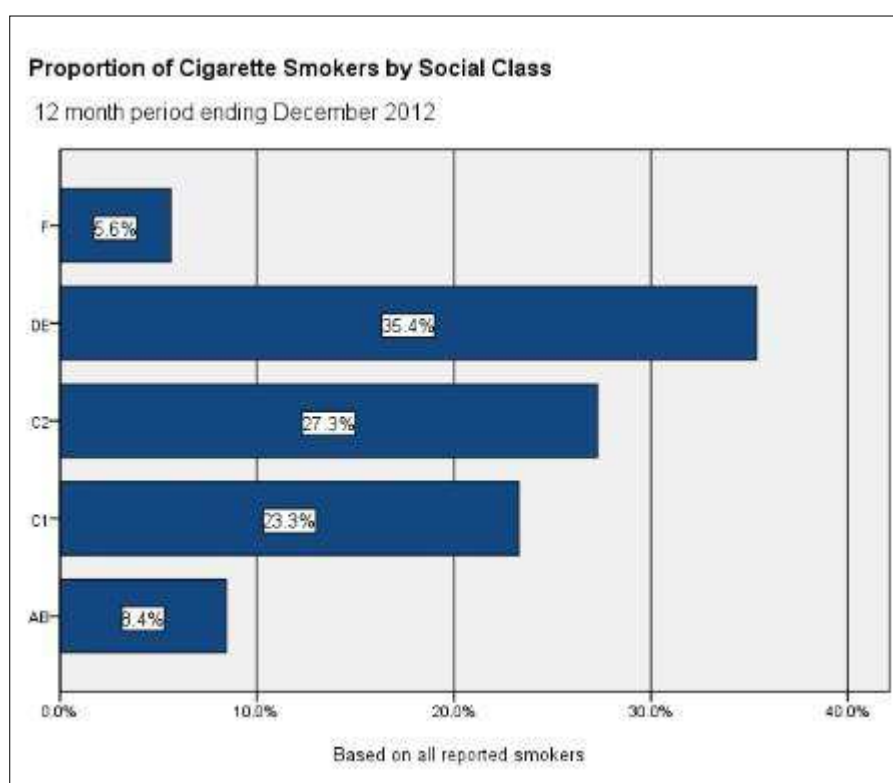


Figure 3: Smokers by Social Class in Ireland

smoking prevalence is highest among lower socio economic groups²⁰, as illustrated in figure 3.

In addition, the 2013 *Tobacco Free Future* study¹⁰ found that smoking prevalence among young people is significantly higher in less affluent areas. The results revealed that among school-children in social class 1-2 (high social class), 6.3% reported that they smoked 6 or more cigarettes during the last 30 days compared to 10% in social class 5-6 (low social class). Furthermore, the analysis found that the highest smoking rate was 15-17 year old girls in social class 5-6 (low social class).

A disproportionate number of people with severe mental illness are regular smokers and die from smoking related diseases. A study in the US²¹ has found that people with mental health issues were about twice as likely to smoke compared to people with no mental health illness. This indicates that tobacco should be treated as a care issue for people with mental illness.

2.3. *Tobacco Free Ireland*

While we have made much progress in tobacco control in this country in recent years, the toll of tobacco related deaths, disease and disability is still unacceptably high. *Tobacco Free Ireland*, the first policy document under *Healthy Ireland*, the new national framework for health and wellbeing from the Department of Health (DOH) - recognises this, and has set a target smoking prevalence of 5% or less for adults in Ireland by 2025. Achieving this target will require a rate of progress greater than we have been achieving to date and it will require a shared commitment and action from the Government, the DOH, NGO's and all members of society.

3. What Works

Recommendations presented here are based on evidence of best practice and ‘what works’ from the WHO, the US Surgeon General’s report (2014), and the UK’s National Institute for Health and Care Excellence. Appendix A provides a detailed table of the positions and recommendations of this policy statement and indicates the corresponding international intervention or recommendation.

3.1. MPOWER

The WHO Framework Convention on Tobacco Control and its guidelines provide the foundation for countries to implement and manage tobacco control. WHO introduced the MPOWER measures, which correspond to one or more articles of the Framework Convention, to assist in reducing the demand for tobacco products at country-level. These measures are as follows:

- Monitor Tobacco Use and Prevention Policies
- Protect People from Tobacco Smoke
- Offer Help to Quit Tobacco Use
- Warn about the Dangers of Tobacco
- Enforce Bans on Tobacco Advertising, Promotion and Sponsorship
- Raise Taxes on Tobacco Products

3.2. Surgeon General Report (2014)

The review of evidence as to ‘what works’, as published in the latest Surgeon General report of March 2014⁵ states the following:

- The evidence is sufficient to conclude that there are diverse tobacco control measures of proven efficacy at the population and individual levels.
- The evidence is sufficient to conclude that advertising and promotional activities by the tobacco companies cause the onset and continuation of smoking among adolescents and young adults.

- Tobacco product regulation has the potential to contribute to public health through reductions in tobacco product addictiveness and harmfulness, and by preventing false or misleading claims by the tobacco industry of reduced risk.
- The evidence is sufficient to conclude that litigation against tobacco companies has reduced tobacco use in the United States by leading to increased product prices, restrictions on marketing methods, and making available industry documents for scientific analysis and strategic awareness.
- The evidence is sufficient to conclude that increases in the prices of tobacco products, including those resulting from excise tax increases, prevent initiation of tobacco use, promote cessation, and reduce the prevalence and intensity of tobacco use among youth and adults.
- The evidence is sufficient to conclude that smoke free indoor air policies are effective in reducing exposure to secondhand smoke and lead to less smoking among covered individuals.
- The evidence is sufficient to conclude that mass media campaigns, comprehensive community programs, and comprehensive statewide tobacco control programs prevent initiation of tobacco use and reduce the prevalence of tobacco use among youth and adults.
- The evidence is sufficient to conclude that tobacco cessation treatments are effective across a wide population of smokers, including those with significant mental and physical co-morbidity.

3.3. NICE Guidance

The UK National Institute for Health and Care Excellence (NICE) includes in its public health guidance²² recommendations on smoking cessation prevention that are based on extensive review of ‘what works’. For example, under *Preventing the uptake of smoking by children and young people* (PH 14), NICE recommends mass media campaigns and point of sales interventions especially aimed at deterring retailers from making illegal sales. NICE (PH10) also recommends brief Interventions as effective and cost effective for all smokers (including pregnant women- PH26).

Brief Interventions²³

“Brief interventions involve opportunistic advice, discussion, negotiation or encouragement. They are commonly used in many areas of health promotion and are delivered by a range of primary and community care professionals. For smoking cessation, brief interventions typically take between 5 and 10 minutes and may include one or more of the following:

- simple opportunistic advice to stop
- assessment of the patient's commitment to quit
- an offer of pharmacotherapy and/or behavioural support
- provision of self-help material and referral to more intensive support
- The particular package that is provided will depend on a number of factors, including the individual's willingness to quit, how acceptable they find the intervention on offer and the previous ways they have tried to quit.”

RCPI Policy Group on Tobacco: Position and Recommendations

Tobacco related diseases have a serious impact on the well-being of society from a health and economic perspective. These impacts are avoidable, and there are solutions which if implemented can further reduce the negative impacts which tobacco has on Irish society. These solutions are outlined in the following sections, covering offering help to quit, national policy/legislative measures and public campaigns.

4. Offering Help to Quit

4.1. What RCPI can do

RCPI urges all doctors to raise the issue of smoking with patients at every opportunity.

As a training institution, RCPI is committed to offering training that furthers use of Brief Interventions and the 5As approach.

Brief Interventions are evidence based psychological techniques and practices aimed at facilitating lifestyle and behavior change practices. Brief interventions for tobacco use focus on enhancing tobacco users' motivation to change and connecting them with evidence-based resources to help make the next quit attempt a success²⁴.

To support doctors in this:

- RCPI has started to offer a Smoking Cessation training course, open to all frontline healthcare staff.
- RCPI will promote smoking cessation as appropriate through current events such as Master classes and Clinical Updates.
- RCPI will also explore options for other methods of delivering training, e.g. online.

The 5As approach: This approach is developed by the US Clinical Practice Guidelines and is a useful framework for approaching a brief intervention. The elements of this approach are:

Ask: Regularly ask all patients if they smoke and record the information in the medical record.

Advise: Advise all smokers to quit in a clear, unambiguous way such as “the best thing you can do for your health is to stop smoking”

Assess: Assessment of interest in quitting helps to tailor advice to each smoker's needs and stage of change. Nicotine dependence should also be assessed and helps to guide treatment. Assessment of other relevant problems such as mental health conditions, other drug dependencies, and co morbidities is necessary to develop a comprehensive treatment plan

Assist: All smokers should be offered help to quit

Arrange: Follow-up visits have been shown to increase the likelihood of long term abstinence and are especially useful in the first few weeks after quitting.

Figure 4: the 5A's Approach

4.2. Smoking in pregnancy

Expectant mothers should be offered comprehensive, structured support to quit smoking.

We recommend that health care professionals, particularly those involved in the care of pregnant women, are trained in brief intervention therapies. Research has shown that cognitive behavioural therapy, motivational intervention and structured self help support from stop smoking services is effective in reducing smoking behavior. Women who have received brief interventions were approximately 30% more likely to not smoke late in pregnancy (WHO)². In a recent Cochrane Review psychosocial interventions to support women to stop smoking in pregnancy were seen to increase the proportion of women who stopped smoking in late pregnancy and to reduce the rate of preterm birth and low birthweight infants²⁵. We recommend the use of Brief Interventions in the practice of health care professionals in general, with specific emphasis on those in contact with women who are pregnant or actively trying to become pregnant.

We recommend funding of further research into interventions which may be effective in stopping smoking in pregnancy.

Combining behavioural and pharmacological treatments may increase quitting success particularly for heavy smokers because they address both the physiological and psychological aspects of tobacco addiction. Nicotine replacement therapy is the only pharmacotherapy for smoking cessation that has been tested in RCTs conducted in pregnancy. At present there is insufficient evidence to determine whether or not NRT is effective or safe when used to promote smoking cessation in pregnancy or to determine whether or not using NRT has positive or negative impacts on birth outcomes²⁶. Promotion of further research evidence of efficacy and safety is needed, ideally from placebo-controlled randomized controlled trials.

We recommend the development of a national guideline to manage smoking during pregnancy.

Giving up smoking is extremely difficult with 90% or more of those who try, failing to remain abstinent over one year²⁷. Many of the mothers who smoke are younger

and more socially disadvantaged and this population is less likely to quit smoking. The inequality in cessation rates among women of different socioeconomic groups demonstrates a need to create specific approaches targeting these women who often lack strong support systems and must cope with stressful or difficult living circumstances on a daily basis.

The WHO has highlighted the lack of national pregnancy guidelines as a major concern in reducing tobacco use. A national guideline for management of smoking in pregnancy will help to ensure that women understand the effects of tobacco use and are given the appropriate support on how to stop.

We recommend the provision of a structured “Stop Smoking Service”¹ to pregnant women for initial and ongoing support.

In addition, further support in the form of access to structured smoking cessation services is required to provide initial and ongoing support. There is also an urgent need to tackle the problem of smoking during pregnancy and to protect women from SHS. Healthcare providers should try and educate partners and other household members about the risks of SHS exposure to pregnant women.

5. National Policy/Legislative Measures

5.1. Standardised Packaging

We strongly support the Government’s plan to introduce standardised packaging for cigarettes in Ireland.

A more detailed discussion of standardised packaging and its potential benefits can be found in a separate report produced by RCPI in Jan 2014²⁸. All recommendations in that report are evidence based, with particular reference to research carried out by the University of Stirling²⁹, the Norwegian Institute for Alcohol and Drug Research,³⁰ and the WHO³¹. This research shows that both package size and colouring have an impact on people’s perceptions of cigarettes, and that standardised packaging would reduce the attractiveness and appeal of tobacco

¹ A ‘Stop Smoking Service’ goes beyond brief interventions, and would include ongoing sustained support including cognitive behavioural therapy and motivational interventions

products. It would also enhance salience of health warnings on packs and would address the use of packaging elements that mislead smokers about products.

5.2. Availability

We support measures to reduce the availability of tobacco to both adults and children.

We support the Government's proposals of implementing tighter regulations on the "Tobacco Retail Environment", as outlined in *Tobacco Free Ireland*. Specifically, we support the introduction of a licensing system for sale of Tobacco products, similar to the licensing system that exists for sale of alcohol.

Stricter regulations will reduce the easy availability of tobacco products and lead to a reduction in tobacco use.

We also recommend stricter enforcement of tobacco legislation and tougher penalties for retailers who break tobacco laws. The current penalties outlined in the Public Health (Tobacco) Act, 2002 are inadequate to deter retailers from breaking legislation. Enhanced resources should also be made available to Environmental Health Officers to ensure enforcement.

We also call for the introduction of legislation to enable the HSE to publish the details of all retailer outlets who break tobacco sale legislation, as is currently the case with FSAI closure orders, for example.

5.3. Taxation

We recommend that the Government increases taxes annually as a method to reduce and denormalise tobacco use

Taxation of tobacco products has been proven to be the most effective way to reduce tobacco consumption.

Implementation of this measure should be assisted by harmonisation of tobacco pricing between the Republic of Ireland and Northern Ireland. We recommend that the pricing between the two countries is kept at a high level in order to deter consumers from purchasing cheap tobacco from either side of the border.

To address the issue of illicit selling and smuggling, more severe penalties are needed to be enforced. At present, the penalties enforced are inadequate and do

not deter illegal activity. For example a group representing retailers have noted, that the maximum fine for cigarette smuggling was increased in the Finance Act 2009 to just over €126,000. However, fines for cigarette smuggling in the second quarter of 2011 were an average of €1,200³².

5.4. Smoke Free Environments

Every individual, particularly children should be able to enjoy a completely smoke free environment.

We support the Government's plan as outlined in *Tobacco Free Ireland*, to enact new legislation requiring all schools, and child care facilities to be tobacco free.

We further recommend that the campuses of all publicly funded institutions should be tobacco free, in particular hospitals and academic campuses.

In addition, smoke free areas should be provided in mental health facilities.

The benefits will be twofold. These measures will lead to the further denormalisation of tobacco use. In addition a smoke free environment in schools, campuses, workplaces, and other public areas will assist in protecting individuals from the harms of second hand smoke.

5.5. Smoking in cars

We call on the Government to introduce a complete smoking ban in cars whenever a child is present

As outlined previously, there is significant international evidence that SHS is very dangerous to the health of any individual, while a recent study showed that exposure to SHS from parents' smoking had an impact on vascular health up to 25 years later⁹.

Irish research reveals that high numbers of Irish children are exposed to SHS in cars. On that basis, we call for the swift implementation of a ban on smoking in cars where children are present. Such a measure will reduce the levels of SHS children are exposed to and increase their quality of life, and will simultaneously help to denormalise smoking.

There are precedents for legislation to influence behaviour while driving, most notably laws requiring the wearing of seatbelts and the use of child car-seats, as well as the ban on mobile phone use while driving. Ireland should follow the example of other jurisdictions such as California, parts of Canada and Australia where smoking in cars where children are present has been banned.

6. Changing Behaviour through Public Campaigns

Information and public campaigns continue to be vital in warning people on the dangers of tobacco use

We support measures to educate people on the dangers of tobacco smoke, including SHS, and residual tobacco smoke, through media, social media and print media campaigns.

The current QUIT campaign run by the HSE is very effective; **we recommend greater investment in public campaigns like this in order to further reduce tobacco use. We also recommend that the QUIT campaign be expanded to help the public understand how the policy measures outlined in TFI respond to the dangers of smoking, including passive smoking.** A particular area of focus may be to educate parents on the lesser known dangers of SHS and residual tobacco smoke and the impact on the health of their children.

7. Electronic-cigarettes

While preparing this policy statement, this group also considered the question of electronic cigarettes. Undoubtedly the use of and interest in electronic cigarettes is increasing rapidly. While they are likely safer for the individual user with regard to tobacco related morbidity and mortality, they are not risk free products and their potential as a cessation aid is still unclear. There is also concern that they may re-normalise smoking.

Our view is that the current lack of regulation is unsatisfactory. Nicotine is a drug of addiction that is currently available to children in the form of e-cigarettes. While

we welcome the provisions on electronic cigarettes of the EU Tobacco Products Directive, more regulation is needed. The absence of age limits in that directive means that it will continue to be available to children, and there should be a ban the sale of these products to children. Further consideration also needs to be given to the efficacy and safety of these products based on best practice evidence.

(See appendix B for a topic review of electronic-cigarettes.)

References

- ¹ Deirdre J Murphy, Clare Dunney, Aoife Mullally, Nita Adnan, Richard Deane. Population-Based Study of Smoking Behaviour throughout Pregnancy and Adverse Perinatal Outcomes. *Int J Environ. Res. Public Health* 2013, 10,3855-3867.
- ² World Health Organization. (2013) “WHO Recommendations for the Prevention and Management of Tobacco use and Second-Hand Smoke Exposure During Pregnancy”, *World Health Organization*, Online Source, Available at: <http://www.who.int/tobacco/publications/en/>.
- ³ DOH. (2013) *Tobacco Free Ireland*.
- ⁴ The Doctors Study” (Doll R, Peto R, Wheatley K, Gray R, Sutherland I. Mortality in relation to smoking: 40 years observations on male British doctors. *British Medical Journal* 1994; 309:901-911).
- ⁵ U.S. Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.
- ⁶ Howell FR, Shelley E (2011). *Mortality attributable to tobacco use in Ireland*. The Faculty of Public Health Medicine RCPI Winter meeting; Dublin.
- ⁷ Best, Dana. “Secondhand and Prenatal Tobacco Smoke Exposure.” *Pediatrics* 124, no. 5 (November 1, 2009): e1017-e1044. doi:10.1542/peds.2009-2120.
- ⁸ WHO Report on the Global Tobacco Epidemic, 2009: Implementing smoke free environments. Geneva, World Health Organisation, 2009
- ⁹ Gall, S. Long Huynh, Q. Magnussin, C.G. Junonala, M. Viikari, J.S.A. Kahonen, M. Dwyer, T. Raitakari, O.T. and Venn, A. (2014) “Exposure to parental smoking in childhood or adolescents is associated with increased carotid intima-media thickness in young adults: Evidence from Cardiovascular Risk in Young Finns study and the Childhood Detriments of Adult Health Study”, *European Heart Journal*, pp1-8.

¹⁰ The Institute of Public Health in Ireland (IPH) and the TobaccoFree Research Institute Ireland (TFRI), (2013), *A Tobacco Free Future: An All Ireland Report on Tobacco Inequalities and Childhood*, pp37-38.

¹¹ Matt GE, Quintana PJ, Destailats H, *et al.* Third hand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environ Health Perspect* 2011; 119: 1218-26.

¹² Roberts JW, Wallace LA, Camann DE, Dickey P, Gilbert SG, Lewis RG, *et al.* 2009. Monitoring and reducing exposure of infants to pollutants in house dust. *Rev Environ Contam Toxicol* 201;1-39.

¹³ Nelson R. Smoking outside still causes second-hand smoke exposure to children. *Lancet* 2002;359:1675.

¹⁴ Cnattingius S, Haglund B, Meirik O. Cigarette smoking as risk factor for late fetal and early neonatal death. *BMJ*. 1998 Jul23;397(6643):258-61.

¹⁵ Varner *et al* Association between stillbirth and illicit drug use and smoking during pregnancy. *Obstet Gynecol* 2014;123:113-25

¹⁶ Alan Hackshaw, Charles Rodeck, Sadie Boniface. Maternal smoking in pregnancy and birth defects: a systematic review based on 173 687 malformed cases and 11.7 million controls. *Hum Reprod Update*.2011 Sep-Oct; 17 (5):589-604.

¹⁷ Hanan El Maroun, Marcus N Schmidt, Ingmar HA Franken, Vincent WV Jaddoe, Albert Hoffman, Aad van der Lugt, Frank C Verhulst, Henning Tiemeier and Tonya White. Prenatal Tobacco Exposure and Brain Morphology: A Prospective Study in Young Children. *Neuropsychopharmacology* (2014) 39, 792-800.

¹⁸ Friel, S. Nic Gabhainn, S. and Kelleher, C. (1999), *The National Health and Lifestyle Surveys: Survey of Lifestyle, Attitudes and Nutrition, (SLÁN) & The Irish Health Behaviour in School-Aged children survey (HBSC)*, Main report: Health Promotion Unit, Department of Health and Children, Dublin and Centre for Health Promotion Studies, National University of Ireland, Galway.

¹⁹ German Cancer Research Center (Feb 12, 2014), "What is the most effective way to prevent smoking in youth?", Available online at: <https://www.dkfz.de/en/presse/pressemitteilungen/2014/dkfz-pm-14-07-What-is-the-most-effective-way-to-prevent-smoking-in-youth.php> [Accessed on: 10/03/2014]

-
- ²⁰ http://www.hse.ie/eng/about/Who/TobaccoControl/Research/Chart_1_3.html
- ²¹ Lasser, K, J W Boyd, S Woolhandler, D U Himmelstein, D McCormick, and D H Bor. "Smoking and Mental Illness: A Population-Based Prevalence Study." *JAMA: The Journal of the American Medical Association* 284, no. 20 (November 22, 2000): 2606-2610.
- ²² National Institute for Health and Care Excellence <http://guidance.nice.org.uk/PHG/Published>
- ²³ National Institute for Health and Care Excellence. Smoking cessation services. Issued: February 2008 last modified: November 2013. NICE public health guidance 10 guidance.nice.org.uk/ph10
- ²⁴ Maryland's Tobacco Resource Center, "Brief Interventions & 5As", Available online at: <http://mdquit.org/cessation-programs/brief-interventions-5> [Accessed on 10/03/2014].
- ²⁵ Cochrane Database Syst Rev. Chamberlain C, Omara-Eyes A, Oliver S, Caird JR, Perlen SM, Eades SJ, Thomas J. Psychological interventions for supporting women to stop smoking in pregnancy. 2013 Oct 23;10:CD001055.
- ²⁶ Cochrane Database Syst Rev Tim Coleman, Catherine Chamberlain, Mary-Ann Davey, Sue E Cooper, Jo Leonardi-Bee. Pharmacological interventions for promoting smoking cessation during pregnancy. 2012 Sept 12;10 CD010078.
- ²⁷ Cahill K, Stevens S, Lancaster T. Pharmacological treatments for smoking cessation *JAMA* 2014;311:193-4.
- ²⁸ http://www.rcpi.ie/content/docs/000001/1620_5_media.pdf?1392208577
- ²⁹ Moodie, C. Agnus, K. and Stead, M. and Bauld, L. (2013) "Plain Tobacco Packaging Research: An Update", *Institute for Social Marketing and Stirling University*, pp1-50.
- ³⁰ Scheffels, Janne, and Ingeborg Lund. "The Impact of Cigarette Branding and Plain Packaging on Perceptions of Product Appeal and Risk among Young Adults in Norway: A between-Subjects Experimental Survey." *BMJ Open* 3, no. 12 (December 1, 2013): e003732. doi:10.1136/bmjopen-2013-003732.
- ³¹ World Health Organization. (2013) "WHO Report on the Global Tobacco Epidemic: Enforcing bans on tobacco advertising, promotion and sponsorship", *World Health*

Organization,	Online	Source,	Available	at:
				http://www.who.int/tobacco/publications/en/

³² Retailers Against Smuggling, “Minimum Fines for Cigarette Smugglers and Illegal Cigarette Sellers”, Available online at: <http://www.retailersagainstmuggling.ie/>

Appendix A: International Recommendations and Interventions

RCPI Policy Recommendation /Position	WHO MPOWER Model Recommendation	US Surgeon General's Report (2014) Recommendation	National Institute for Care and Excellence Recommendation (NICE)
RCPI is committed to offering training that furthers use of Brief Interventions	Offer Help to Quit Tobacco Use: The WHO recommends the use of smoking cessation as a means to offer people help to quit tobacco use. They state, "that cessation support and medication can increase the likelihood that a smoker will quit successfully".	The Surgeon General's Report states, that "the evidence is sufficient to conclude that tobacco cessation treatments are effective across a wide population of smokers, including those with significant mental and physical co-morbidity".	The NICE guidelines recommend the use of Brief Interventions to "everyone who smokes should be advised to quit, unless there are exceptional circumstances [18]. People who are not ready to quit should be asked to consider the possibility and encouraged to seek help in the future"
RCPI recommends the introduction of plain packaging	Warn about the Dangers of Tobacco, Enforce Bans on Tobacco Advertising, Promotion and Sponsorship The WHO recommends the implementation of plain tobacco product packaging. They state that this "would eliminate the tobacco	Not Specified	The NICE guidelines suggest that "plain packaging might be considered to reduce the attractiveness of cigarettes to young people", as a means to prevent the uptake of smoking among young people.

RCPI Policy Recommendation /Position	WHO MPOWER Model Recommendation	US Surgeon General's Report (2014) Recommendation	National Institute for Care and Excellence Recommendation (NICE)
	industry's ability to place targeted messages and designs on the packages of its products, would increase the impact of health warnings, reduce false and misleading messages that deceive customers into believing that some tobacco products are safer than others, and reduce the attractiveness of products to segments of the population specifically targeted by tobacco companies".		

RCPI Policy Recommendation /Position	WHO MPOWER Model Recommendation	US Surgeon General's Report (2014) Recommendation	National Institute for Care and Excellence Recommendation (NICE)
<p>RCPI recommends measures to reduce the availability of Tobacco</p>	<p>MPOWER refers to monitoring of tobacco control policies:</p> <p>Monitor Tobacco Use and Prevention Policies</p> <p>Tobacco Control Policies and regulation needs to be monitored by Government enforcement and societal compliance with tobacco control policies, including tax collection and tax evasion, smoke-free places, and advertising and marketing bans</p>	<p>Tobacco product regulation has the potential to contribute to public health through reductions in tobacco product addictiveness and harmfulness,</p>	<p>The NICE guidelines recommend, "prosecuting retailers who persistently break the law and ensure efforts to reduce illegal tobacco sales by retailers are sustained" as a means to reduce the easy availability of tobacco products.</p>

RCPI Policy Recommendation /Position	WHO MPOWER Model Recommendation	US Surgeon General's Report (2014) Recommendation	National Institute for Care and Excellence Recommendation (NICE)
RCPI recommends increased taxation on tobacco products	Raise Taxes on Tobacco Products: The WHO recommends, that "increasing the price of tobacco through higher taxes is the single most effective way to decrease consumption and encourage tobacco users to quit".	The Surgeon General's Report states, "the evidence is sufficient to conclude that increases in the prices of tobacco products, including those resulting from excise tax increases, prevent initiation of tobacco use, promote cessation, and reduce the prevalence and intensity of tobacco use among youth and adults".	The NICE guidelines state, "there is review-level evidence that increasing the unit price of cigarettes is effective at stopping tobacco use, and this remains true for vulnerable groups, women and men, low-income groups and people with lower educational achievement".
RCPI recommends the introduction of smoke free environments	Protect People from Tobacco Smoke: The WHO states, that the "elimination of indoor smoking through the creation of 100% smoke-free environments is the only effective science-based measure to protect the population from the harmful effects of exposure to SHS, according to Article 8	The Surgeon General's Report states, that "the evidence is sufficient to conclude that smoke-free indoor air policies are effective in reducing exposure to second-hand smoke and lead to less smoking among covered individuals."	The NICE guidelines recommend that secondary healthcare facilities "develop a policy for smoke free grounds in collaboration with staff and people who use secondary care services or their representatives". This is aimed at initiating smoking cessation in secondary care: acute, maternity and

RCPI Policy Recommendation /Position	WHO MPOWER Model Recommendation	US Surgeon General's Report (2014) Recommendation	National Institute for Care and Excellence Recommendation (NICE)
	of the WHO Framework Convention on Tobacco Control (WHO FCTC) and its guidelines".		mental health services.

RCPI Policy Recommendation /Position	WHO MPOWER Model Recommendation	US Surgeon General's Report (2014) Recommendation	National Institute for Care and Excellence Recommendation (NICE)
RCPI recommends a complete smoking ban in cars whenever a child is present	<p>Protect People from Tobacco Smoke:</p> <p>The WHO states, that the "elimination of indoor smoking through the creation of 100% smoke-free environments is the only effective science-based measure to protect the population from the harmful effects of exposure to SHS, according to Article 8 of the WHO Framework Convention on Tobacco Control (WHO FCTC) and its guidelines".</p>	<p>The Surgeon General's Report states, that the "evidence is sufficient to conclude that smoke free indoor air policies are effective in reducing exposure to second-hand smoke and lead to less smoking among covered individuals".</p>	Not Specified
Smoking in Pregnancy (To be completed based on IOG rep input)	<p>Offer Help to Quit Tobacco Use: The WHO recommends the introduction of a national guideline for smoking</p>	Not Specified	The Nice guidelines recommends a number of different steps to help pregnant women who smoke during

RCPI Policy Recommendation /Position	WHO MPOWER Model Recommendation	US Surgeon General's Report (2014) Recommendation	National Institute for Care and Excellence Recommendation (NICE)
	during pregnancy to provide advice on how to manage smoking during pregnancy and to address the dangers that women and their foetuses face from exposure to second hand smoke		pregnancy such as, "identifying pregnant women who smoke and referring them to NHS Stop Smoking Services – action for midwives; Identifying pregnant women who smoke and referring them to NHS Stop Smoking Services – action for others in the public, community and voluntary sectors; Use of NRT and other pharmacological support; educate partners and others in the household who smoke and training to deliver interventions". For more recommendations go to: http://publications.nice.org.uk/quitting-smoking-in-pregnancy-and-following-childbirth-ph26/recommendations

RCPI Policy Recommendation /Position	WHO MPOWER Model Recommendation	US Surgeon General's Report (2014) Recommendation	National Institute for Care and Excellence Recommendation (NICE)
<p>RCPI recommends that the QUIT campaign is continued and expanded</p>	<p>Warn about the Dangers of Tobacco: The WHO states that, "mass-media counter-advertising campaigns have been consistently found to reduce overall tobacco consumption. Mass-media campaigns are a cost-effective way to educate large population groups about the full extent of the risks of tobacco use and exposure to second-hand smoke. Media campaigns can also motivate and inform people on how to quit. Well-executed campaigns can also increase public support for key policy changes such as smoke-free public places".</p>	<p>The US Surgeon General's Report states, that "the evidence is sufficient to conclude that mass media campaigns, comprehensive community programs, and comprehensive state-wide tobacco control programs prevent initiation of tobacco use and reduce the prevalence of tobacco use among youth and adults".</p>	<p>The NICE guidelines recommend that a "mass-media and point-of-sales measures should be combined with other prevention activities as part of a comprehensive tobacco control strategy. Such a strategy is defined by the US Surgeon General, World Health Organization and others as encompassing price and regulation policies, education programmes, cessation support services and community programmes. It should be sufficiently extensive and sustained to have a reasonable chance of success".</p>

“Towards a Tobacco Free Society”

Appendix B: Topic Review- Electronic Cigarettes

1. Electronic Cigarettes

1.1. What are Electronic Cigarettes?

Electronic cigarettes, termed electronic nicotine delivery systems (ENDS) by the WHO, are also commonly called e-cigarettes or vapors.

While there are different designs, generally electronic cigarettes consist of a battery, a heating element, and a cartridge filled with a humectant, often propylene glycol, and nicotine solution. They are available in a range of nicotine concentrations and may also contain flavouring. They can be disposable, rechargeable or refillable. They usually resemble combustible cigarettes in size, shape and colour. Some have a LED tip which glows to further resemble a combustible cigarette.

Upon activation by puffing, the liquid in the cartridge passes across the heating element, is vaporised, and then inhaled through the tube.

1.2. Current Use and Awareness of Electronic Cigarettes

There is increasing interest in electronic cigarettes in the medical literature and the general media.

Awareness of electronic cigarettes amongst the public is increasing; with awareness being highest amongst smokers (1). They are used most commonly by current or former smokers. In the US and UK, around 20% of current smokers report having used electronic cigarettes (1). Common reasons for using electronic cigarettes amongst smokers are to decrease their smoking, to help quit smoking, and because they consider them to be less harmful (2). Some individuals use electronic cigarettes to avoid smoking restrictions.

2. Possible Benefits of Electronic Cigarettes

2.1. Use in Cessation

There is some limited evidence suggesting electronic cigarettes may assist in smoking cessation. In one randomised control trial (RCT) comparing nicotine containing electronic cigarettes with nicotine patches and nicotine free electronic cigarettes - similar abstinence rates were seen in all groups (3). However, the difference in cessation between groups was not statistically significant. In a study amongst smokers not intending to quit - the use of electronic cigarettes with or without nicotine led to decreased cigarette consumption and abstinence (4). This study did not include an alternative cessation aid, or the use of no aid, as a comparator.

2.2. Role in Tobacco Harm Reduction

Harm reduction is an approach to a risk behaviour which focuses on minimising potential damage/ danger rather than eliminating the behaviour. It is likely that electronic cigarettes are less harmful to the individual smoker than combustible cigarettes or other tobacco products and using them instead of tobacco products may reduce tobacco related morbidity and mortality. Advocates of the harm reduction approach believe that those who are unwilling or unable to quit combustible cigarettes should be encouraged to at least switch to electronic cigarettes.

To date the public health and health promotion approach to tobacco has been one of avoidance and cessation. There is concern that shifting to a focus on harm reduction will blur the picture, and undermine the message of avoidance and cessation as the ultimate goal in tobacco control.

3. Possible Harms of E-Cigarettes

The possible harms of electronic cigarettes include possible harms to the individual and possible population level harms.

3.1. Possible Harms to the Individual

Health Effects of Nicotine

Nicotine at high concentrations can lead to both local adverse effects and acute and chronic toxicity if systemically absorbed. Systemic absorption occurs through

inhalation, ingestion and skin or mucous membrane contact. Both nicotine cartridges used in reusable cigarettes and the bottles of nicotine solution used with refillable products contain high concentrations of nicotine. There is a potential for accidental spillage in the process of replacing or refilling cartridges. If products are not child tamper proof, there is a potential risk of accidental spillage or ingestion by a child. The estimated lethal dose of nicotine for a child is 10 mg (5); and 30-60mg for an adult. Electronic cigarette cartridges can contain over 20mg/ml of nicotine.

Nicotine has a number of physiological effects and the use of electronic cigarettes in hospital patients has raised concerns. Due to smoking restrictions in hospitals many patients would have previously abstained completely from smoking during the perioperative period or would use medicinal nicotine replacement therapy where the dosage of nicotine is regulated. Some patients are now turning to electronic cigarettes. Anaesthetists have expressed concern that acute nicotine toxicity due to the use of electronic cigarettes prior to surgery may have negative consequences in the perioperative period (6). Additionally, surgeons have expressed concern that the physiological effects of nicotine may impact on wound healing and surgical outcomes (7).

Long term nicotine use may be associated with increased risk of cardiovascular disease (CVD). A review of the biochemical mechanisms of smoking, nicotine, and cardiovascular disease by The American Heart Association concluded that while other components of combustible cigarette smoke are more important contributors to smoking related CVD, nicotine may also be a contributing factor (8).

Nicotine is a recognised teratogen¹.

Nicotine Addiction

The use of nicotine-containing electronic cigarettes does not address the underlying nicotine addiction of current smokers. Their use in non smokers may lead to the development of a nicotine addiction, or reestablishment of addiction in former smokers.

¹ An agent or factor which causes malformation of an embryo.

Health Effects of Other Components of Electronic Cigarettes

Some concern has been expressed over the effects of inhalation of propyl glycol, the humectant used in electronic cigarettes. A case of lipoid pneumonia due to glycerine in the vapour has been attributed to electronic cigarette use (9).

Quality of Electronic Cigarettes

The quality of electronic cigarettes has been questioned - both the content of the solutions and their ability to deliver nicotine to the user.

In an analysis of various cartridges from two different brands of electronic cigarettes by the Food and Drug Administration in the United States tobacco specific nitrosamines and tobacco specific impurities (diethylene glycol, cotinine, anabasine, myosmine and β -nicotyrine) were found in a number of products (10). A study evaluating the vapour from 12 brands of electronic cigarettes found potentially toxic and carcinogenic substances, but at levels 9 to 450 times lower than those found in combustible cigarette smoke (11).

There have also been variations from stated nicotine content, including nicotine in supposed nicotine free products (10, 12).

Inter and intramanufacture variability in nicotine delivery has been demonstrated between products containing the same amount of nicotine. There is also variability in the amount of nicotine aerosolised by each puff (13).

Delay or Decrease in Cessation

The efficacy of electronic cigarettes as cessation aids is not well established. In addition the evidence on their efficacy in relieving nicotine withdrawal symptoms is inconsistent (1).

When used in smoking cessation electronic cigarettes may not treat the underlying nicotine addiction. In one study of electronic cigarettes as a cessation aid - participants allocated to electronic cigarettes were more likely to continue to use the nicotine replacement product after achieving abstinence compared to those allocated to the nicotine patch (3). Also amongst those who did not achieve

abstinence dual use of combustible cigarettes and the nicotine replacement product was higher in the electronic cigarette group.

Due to their similarity to combustible cigarettes in look and feel, their easy availability and their marketing, there is concern that smokers wishing to quit will choose electronic cigarettes above cessation aids/devices which have been proven to work therefore delaying and/or decreasing successful cessation.

3.2. Possible harms at a population level

Appeal to young people

Data from the US show that the use of electronic cigarettes is increasing rapidly amongst school children in the US (14). Analysis of the National Youth Tobacco Surveys (NYTS) showed that both current electronic cigarette use and ever electronic cigarette use doubled among middle and high school students between 2011 and 2012. It is estimated that 1.78 million students have ever used electronic cigarettes as of 2012. The 2012 survey showed that, an estimated 160,000 students who reported ever using electronic cigarettes had never used conventional cigarettes.

Among Polish high school students aged 15 to 19 years, 23.5% had ever used electronic cigarettes and 8.2% had done so within the previous 30 days (15). In Hungary the Global Youth Tobacco Survey of 2012 showed that 13% of 13-15 year old schoolchildren reported having used electronic cigarettes in the previous 30 days; and 4.7 % of those reporting never smoking tobacco products used an electronic cigarette in the previous 30 days (16). The use of electronic cigarettes amongst students in Paris has doubled between 2011 and 2012.

The exposure of young people to nicotine through the use of electronic cigarettes is in itself a concern. In addition the establishment of a nicotine addiction in young people may lead to an easier transition to the use of combustible cigarettes and other tobacco products.

Their availability in a range of flavours may appeal to young people.

Re-Introduce Former Smokers

There is concern that former smokers may be attracted to electronic cigarettes. This may re-establish a nicotine addiction and lead to a transition back to combustible cigarettes or other tobacco products.

Normalisation of Smoking Behaviour

The introduction of legislation for smoke free environments such as public buildings and workplaces has been a significant achievement in tobacco control.

The public health objectives of such policies include protecting non-smokers from the effects of second hand smoke (SHS), limiting opportunities for smoking thus decreasing smoking and promoting cessation amongst smokers, and denormalising smoking leading to less initiation and promoting cessation. However it is the first objective which gained the support required to introduce such legislation and the continued voluntary implementation of smoke free environments. Protection from SHS is the legal backbone behind smoke free legislation and regulations. The use of electronic cigarettes may not be precluded under current smoke free legislation. The opportunity to use electronic cigarettes in smoke free environments may mean that current smokers will have less incentive to quit. Also, the use of electronic cigarettes in environments where smoking is either prohibited or where it is no longer considered appropriate to smoke will increase young people's exposure to adult role models' smoking behaviour.

4. Advertising and Marketing

The advertising and marketing of tobacco products is not permitted in Ireland. Even if licenced as medicinal products or devices electronic cigarettes can be advertised.

They have already featured on UK television broadcast in Ireland, in TV dramas and advertisements. The revision to the EU Directive stipulates that the advertising of nicotine containing electronic cigarettes licensed as consumer products comply with existing rules for cross-border advertising and promotion of tobacco products. However the Directive does not cover advertising without a cross border effect or electronic cigarettes licenced as medicinal products or devices.

Exposure to electronic cigarettes, which by design imitate combustible cigarettes, in advertisements and TV/ film has the potential of renormalising smoking behaviour.

5. Regulation of Electronic Cigarettes

The classification of a product as a general product, medicinal product, medicinal device or tobacco product determines the regulatory framework for the product's sale, advertising, marketing, and monitoring. At present in Ireland, electronic cigarettes are classed as a consumer product and therefore are considered under general product safety legislation. There are no regulations on their sale, use or advertising (beyond general advertising standards) and they do not fall under the tobacco legislation.

An orientation note on electronic cigarettes and European Commission(EC) legislation prepared by the Health and Consumer Protection Directorate-General provides a comprehensive overview of the classification of products based on EC legislation, the implications for products and how electronic cigarettes fit into the legislation ([available here](#)) (17).

5.1. Regulation in other countries

The regulation of electronic cigarettes varies within Europe and internationally. Some EU member states consider them medicinal products; some have included them in smoke free environments legislation; some have banned their advertising; Lithuania has banned them as imitation tobacco products; and Norway has banned their sale and import (18).

5.2. EU Tobacco Products Directive

The revised EU Tobacco Products Directive, was formally approved by the European Parliament on 26 February 2014, and contains some provisions relating to electronic cigarettes. The Directive applies to nicotine containing electronic cigarettes classed as consumer products.

The following regulations are contained in the Directive:

Safety and quality:

- There will be a maximum nicotine concentration level for electronic cigarettes and maximum volumes for cartridges, tanks and containers of nicotine liquids.
- These will have to be child and tamper-proof and protected against leakage to limit the risk of exposing consumers - in particular children - to the risks of handling or ingestion.
- Only ingredients of high purity may be used in the nicotine-containing liquid, and electronic cigarettes will be required to deliver the nicotine doses at consistent levels under normal conditions of use.

Packaging and labelling requirements:

Health warnings on electronic cigarette packs will be mandatory, as will instructions for their use, information on addictiveness and toxicity, a list of all substances contained in the product and information on the product's nicotine content. No promotional elements will be allowed on packs.

Member State authorities and the Commission will be able to act in cases of justified safety concerns relating to these products. Authorities will monitor the market for any evidence that electronic cigarettes lead to nicotine addiction or to traditional tobacco consumption, especially in young people and non-smokers, and the Commission will report on safety concerns and market developments.

Manufacturers will be required to:

- **Notify Member States before placing new products on the market:** notification will include information on the manufacturer, the ingredients used and emissions, nicotine dose and uptake, product and production process and a declaration that the manufacturer takes full responsibility for the quality and safety of the product under normal use.
- **Report annually to Member States** on the sales volumes of the products, types of users and their preferences and trends.
- **Comply with** existing rules for cross-border advertising and promotion of tobacco products

While the EU Directive is welcome, it does not cover electronic cigarettes licenced as medicinal, or non-nicotine containing electronic cigarettes. It also does not

cover the regulation of flavours, advertising without cross border effects, and age limits.

Specific legislation to address these and other issues concerning electronic cigarettes is required.

6. Conclusion

Undoubtedly the use of, and interest in electronic cigarettes is increasing rapidly. While they are likely safer for the individual user with regard to tobacco related morbidity and mortality, they are not risk free products. Their potential role as a cessation aid or in harm reduction is still unclear. Also, the dangers of long-term use are not known. Further research is needed to determine their utility in harm reduction and smoking cessation, and any long-term adverse effects. In addition their potential population level effect on tobacco use is not known. Given the morbidity and mortality associated with tobacco use, and the achievements made to date in reducing smoking prevalence, it would be prudent to introduce regulations to mitigate against any potential negative impacts of electronic cigarettes.

References

1. Pepper JK, Brewer NT. Electronic nicotine delivery system (electronic cigarette) awareness, use, reactions and beliefs: a systematic review. *Tob Control*. 2013.
2. Adkison SE, O'Connor RJ, Bansal-Travers M, Hyland A, Borland R, Yong HH, et al. Electronic nicotine delivery systems: international tobacco control four-country survey. *Am J Prev Med*. 2013;44(3):207-15.
3. Bullen C, Howe C, Laugesen M, McRobbie H, Parag V, Williman J, et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet*. 2013;382(9905):1629-37.
4. Caponnetto P, Campagna D, Cibella F, Morjaria JB, Caruso M, Russo C, et al. Efficiency and Safety of an eElectronic cigAreTte (ECLAT) as tobacco cigarettes substitute: a prospective 12-month randomized control design study. *PLoS One*. 2013;8(6):e66317.
5. Cobb NK, Abrams DB. E-cigarette or drug-delivery device? Regulating novel nicotine products. *N Engl J Med*. 2011;365(3):193-5.
6. Roberts M, Davies M. Dangers of using e-cigarettes before anaesthesia. *Bmj*. 2014;348:g1310.
7. Holmes WJ, Southern SJ. Detrimental effects of e-cigarettes on surgical outcomes. *Bmj*. 2014;348:g1156.
8. Piano MR, Benowitz NL, Fitzgerald GA, Corbridge S, Heath J, Hahn E, et al. Impact of smokeless tobacco products on cardiovascular disease: implications for policy, prevention, and treatment: a policy statement from the American Heart Association. *Circulation*. 122. United States 2010. p. 1520-44.
9. McCauley L, Markin C, Hosmer D. An unexpected consequence of electronic cigarette use. *Chest*. 2012;141(4):1110-3.
10. Westenberger BJ. Evaluation of e-cigarettes. Division of Pharmaceutical Analysis, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, ; 2009.
11. Goniewicz ML, Knysak J, Gawron M, Kosmider L, Sobczak A, Kurek J, et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tob Control*. 2014;23(2):133-9.
12. Palazzolo DL. Electronic Cigarettes and Vaping: A New Challenge in Clinical Medicine and Public Health. A Literature Review. *Front Public Health*. 2013;1:56.

13. Trtchounian A, Williams M, Talbot P. Conventional and electronic cigarettes (e-cigarettes) have different smoking characteristics. *Nicotine Tob Res.* 2010;12(9):905-12.
14. Notes from the field: electronic cigarette use among middle and high school students - United States, 2011-2012. *MMWR Morb Mortal Wkly Rep.* 2013;62(35):729-30.
15. Goniewicz ML, Zielinska-Danch W. Electronic cigarette use among teenagers and young adults in Poland. *Pediatrics.* 2012;130(4):e879-85.
16. Hungarian Focal Point for Tobacco Control. Global Youth Tobacco Survey; Hungary (13-15), Factsheet [cited 2014 9 March]. Available from: <http://www.fokuszpont.dohanyzasvisszaszoritasa.hu/en/content/hungarian-and-foreign-data-statistics>.
17. Orientation Note Electronic Cigarettes and the EC Legislation. Brussels: 2008.
18. de Andrade M, Hastings G. Tobacco Harm Reduction and Nicotine Containing Products Research Priorities and Policy Directions. Cancer Research UK; 2013.