Answer from the Norwegian Institute of Public Health to point 1 in addition to letter of allocation from Norwegian Ministry of Health and Care Services of 22.06.2017

Evaluation of harm reduction as a strategic element in tobacco work

13 December 2017

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Preface

In the public health context, harm reduction aims to offer substitutes to people who already practice, or are at risk of beginning with, health threatening activities or consumption. The substitutes are not risk free but less hazardous than the behaviour or the consumption they replace. In the tobacco area, the nicotine containing medicines, snuff, e-cigarettes and combustion-free cigarettes product group right now can be classified as harm reducing replacement products for cigarettes. It is expected that several new nicotine products will be included in this the group in the years ahead.

A harm reduction policy can in practice be based on i) letting (some or a number of) these products compete against cigarettes in the nicotine market, ii) granting these a competitive advantage in relationship to cigarettes so that consumption by the risk groups (smokers and potential smokers) is channelled to the least hazardous products, iii) to inform of the continuum of nicotine product health risks (harm difference of cigarettes).

This policy can have a number of unfortunate side effects. The availability of substitutes can make it easier for smokers to continue smoking, because the substitutes meet smokers' nicotine needs in situations where smoking is not permitted. They can therefore undermine the effects of measures which, in the absence of the substitutes, will get smokers to stop. The products can mean that those with a nicotine dependency, which in itself is a highly negative state, is maintained for people who otherwise would have stopped all nicotine consumption. The products can lead to nicotine dependency in young people who otherwise would have been completely abstinent, and in the worst case act as the entry point for tobacco smoking.

In political decisions on substitution products in the tobacco area, expected health benefits for smokers who choose substitution are weighed against the above risk factors. We must know how many smokers are expected to obtain a benefit from the harm reduction policy. We must know how many people can be expected to end up with one or a number of the unfortunate side effects. We must have good estimates of the degree of harm from snuff use, vaping and aerosol inhalation in relationship to tobacco smoking. We should also have estimates of how serious the nicotine dependency should be considered to be in relation to tobacco related health harm, including lung and heart disease and a shorter life.

Based on such numerical estimates, it is possible to form a picture of whether a specific policy (i.e. liberal) for a substitution product overall gives a disease burden or a welfare benefit for the population in the short and long term compared with an alternative policy (i.e. restrictive). Tobacco preventative measures have, to a small extent, been the object for such weighing.

The assignment of the letter of allocation

In 2018 the Norwegian Ministry of Health and Care Services is to start work on creating a new strategy plan for its tobacco preventative work. In association with this, The Norwegian Institute of Public Health has, in addition to the letter of allocation dated 22 June 2017, received this assignment:

> ***Evaluation of harm reduction as a strategic element in tobacco work, particularly in the light of e- cigarettes and new hybrid and nicotine products' entry into the Norwegian market***
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> *The Department has asked The Norwegian Institute of Public Health to illuminate different perspectives on 'tobacco harm reduction' in a way which reflects the international discourse in the area, and will briefly reflect on which implications this can have on the tobacco strategy's goals and instruments. We request that the knowledge which is available so far on the use of harm reducing products is briefly summarised, both with respect to scope, recruitment of non-smokers in different countries, the products' role in stopping smoking and, if possible, that it is discussed how different political choices will be able to affect current and future generations' dependency on tobacco and nicotine products. The deadline for answering the assignment is set to 30 September 2017. (The deadline was later extended to 1 December).*

In part I, The Norwegian Institute of Public Health will illuminate different perspectives on 'tobacco harm reduction' in a way which reflects the international discourse in the area, and will briefly reflect on which implications this can have on the tobacco strategies' goals and instruments.

In part II, The Norwegian Institute of Public Health will summarise the research into the scope of harm reducing nicotine products, the products' user groups, their role in stopping smoking etc.

In part III, The Norwegian Institute of Public Health briefly discusses how different political choices can affect current and future generations' dependency on tobacco and nicotine products.

Delimitation

Epidemiological and biomedical literature which can form the basis for clarifying the different nicotine products' absolute degree of harm (in relation to non-use) and relative degree of harm (in relation to tobacco smoking) are described only to a minor extent. We have taken as the start point that the different nicotine products can be placed along a risk continuum where the combustion-free products have a significantly lower degree of harm than conventional cigarettes, but have not attempted to estimate health risks.

Declaration

The memorandum is written by Karl Erik Lund, research leader for tobacco at The Norwegian Institute of Public Health. 13 researchers from different departments at FHI and with different views on the harm reduction concept, have given more or less extensive responses during the preparation. Feedback has been very conflicting, challenging to summarize and demonstrates

that the internal staff at FHI adhere to ‘a wide range of perspectives’ on harm reduction in the tobacco area. A nearly completed version of the memorandum has been reviewed by the area management for Physical & Mental Health (20 November) and the top management at FHI (21 November).

The main author has worked for 10 years with problems particularly associated with harm reduction, both in his day-to-day research work but also as a member of international study groups and research forums. It should be declared that the main author, in the course of this period of time, developed a conditional sympathy for harm reduction in the tobacco area. The aim has however been to try to give a balanced presentation which can be a framework for the future evaluation of harm reduction which is to be adopted as an element in the strategy to reduce smoking related diseases and death.

Summary

PART I. Different perspectives on harm reduction and their implications for the tobacco strategy's goals and instruments

In the strategy plan for the tobacco preventive work for 2013-2016 ‘A future without tobacco’, harm reduction was not considered to be a strategic supplement to reduce tobacco related sickness and mortality. A vision is expressed in the plan of a tobacco free society. A strict interpretation of such a goal means a total cessation of recreational use of products which contain tobacco or nicotine derived from the tobacco plant.

Harm reduction however aims to move users of nicotine along a nicotine continuum from the most hazardous products to the less hazardous products, without the end goal necessarily being cessation of all use of tobacco or nicotine. Harm reduction therefore apparently has no role in a statutory 0-vision of nicotine use, in any case not as a long term strategy.

A harm reduction policy can in practice be based on i) letting (some or a number of) these products compete against cigarettes in the nicotine market, ii) granting these a competitive advantage in relationship to cigarettes so that consumption by the risk groups (smokers and potential smokers) is channelled to the least hazardous products, iii) to inform of the continuum of nicotine product health risks (harm difference of cigarettes).

Harm reduction can be topical in a strategy plan if the authorities introduce the additional goal of reducing tobacco related harm while working to achieve a tobacco free society. In December 2016, Parliament adopted permitting nicotine containing e-cigarettes to be sold in Norway. This indicates that the Norwegian authorities in practice do not aim to achieve a strict 0-vision for use of tobacco and nicotine. In any case not just now. Under the long term vision of a tobacco free society, there appears to be an acceptance for opening up for (temporary?) use of harm reducing nicotine products.

Disagreement on harm reduction

Disagreement on harm reduction in a tobacco history context is unusually large and the fronts are uncommonly sharp. Harm reduction has, for a long time, been an accepted strategy for a great deal of other risk behaviour such as sexual behaviour in vulnerable groups (free condom distribution to homosexual men), opiate use (substitution treatment, syringe distribution, injection rooms), road use behaviour (helmets, seat belts), alcohol consumption (blood alcohol limits, moderation advice) etc. The frameworks for harm reduction measures in the different areas will however have to be able to vary.
Substitution treatment for opiate dependency is via prescription medicines and with individual medical follow up. Harm reduction in tobacco use is dominated by substitution mechanisms which to a great extent are controlled by a commercial market.

The need for harm reduction is justified by its supporters by the argument that almost 50 years of information activity, sales restrictions, behaviour limitations, duty increases and therapeutic measures have not given the desired reduction in smoking related sickness and mortality. Around 600 000 people still smoke and projections indicate that the proportion of smokers will remain above 10% also for the next decade. Annually 5 000 people die from smoking

related diseases and these diseases will increasingly impact different social groups to different extents. It is claimed that today's smokers have help requirements that differ from those the health authorities addressed in the 1970s and 1980s. Around 25% of smokers must be categorized as 'hard-core smokers' with strong nicotine dependency and no plans to stop.

Those who support harm reduction are inclined to accept a continued widespread nicotine dependency, providing it is not related to cigarette smoking. They believe that the size of tax duties and the strength of market and use restrictions should reflect the product's capacity to harm. Furthermore, the health authorities should inform about risk differences between the nicotine products, let risk from cigarette smoking be the reference point for comparisons and encourage smokers to change product through information campaigns. They base the need for innovative products on the extensive sickness and mortality from cigarettes and believe that use of a precautionary principle which prevents market access, can result in the nicotine market 'freezing' in favour of the most hazardous product – cigarettes. The proponents are also prepared to cooperate with the nicotine industry to make harm reducing nicotine products attractive, available and as safe as possible.

The opponents, on the other side, believe that the goal of tobacco policy should be to eliminate all use of nicotine for recreational purposes. They believe the disadvantages of granting a competitive advantage to the assumed least harmful products are greater than the benefits and are not in favour of the proportionality principle of taxation. The opponents claim that the evidence for the effect of these on stopping smoking is not robust and that such products will be able to delay stopping smoking and lead to dual usage. The opponents also fear that the products will recruit non-smokers and in the worst case act as an entry point for youth starting tobacco smoking who otherwise would not have begun using nicotine. They fear the products' similarities with cigarettes and its similar means of use as smoking will be able to renormalize smoking and undermine the work to de-normalize cigarettes. They believe that the risk of a harm reducing product cannot be clarified before documentation from long term use is available, and that risk should, even so, not be compared with the risks of cigarette smoking but instead be contrasted with total abstinence from nicotine use (the normal state). The opponents invoke the precautionary principle whilst waiting for longer observation periods of any health effects to be completed and in the light of the swift rate of innovation of the development of new product generations. Any development of harm reducing products should not take place in cooperation with the tobacco industry or other branches of the nicotine industry, except for the pharmaceutical industry which the opponents consider to be an ally in the work to reduce tobacco related morbidity.

International practice

The world Health Organization has preliminarily taken an abeyant and conditional position on the harm reduction concept. The UK health authorities have adopted harm reduction principles in tobacco policy. The USA health authorities have traditionally been sceptical to harm reduction. New signals have, however, in recent years come from the FDA.

The EU tobacco directive provides, for the first time, a joint harmonized regulation for e-cigarettes. The implementation of article 20 in the tobacco directive resulted in a number of member states and EEA states, including Norway, changing their e-cigarette legislation.

The directive does not prevent countries which practiced total prohibition from continuing with this scheme. Most country's authorities however found it most appropriate to regulate e-cigarettes in accordance with the new EU rules. Implementation for countries such as Sweden and Norway represented a liberalisation, while for other countries such as Cyprus and The UK the directive represents an intensification of regulations.

Part II. The scope of harm reducing nicotine products, the products' user groups and their role in stopping smoking

The international discourse on harm reduction in the tobacco area relates primarily to the use of four types of products. These are nicotine containing medicines, nicotine containing snuff with or without tobacco, nicotine containing e-cigarettes and combustion-free cigarettes (HnB). Common to these is that nicotine uptake takes place without a burn phase of the tobacco, which leads to less exposure to known health threatening substances.

Nicotine containing medicines and tobacco containing snuff have been on the market for a long time, and both have been subject to investigations on health hazards, dependency potential, therapeutic effect, appeal, usage patterns etc. A great deal of knowledge has been established which is relevant to a discussion of the products' advantages and disadvantages in the harm reduction context. Knowledge of this kind is not available for the other products.

Nicotine containing medicines

The nicotine containing medicines, nicotine chewing gum, nicotine patches and nicotine inhalers have been on sale since 1986 in Norway. These were, up until 2003, prescription products. They subsequently have been made over the counter products and for sale in grocery stores. The original design of nicotine medicines as a therapeutic product was that they should exclusively appeal to being used to help stop smoking. Product presentations have gradually become 'more nuanced'. The range of nicotine containing medicines has gradually increased to include mouth spray, lozenges and mouth powder in dose pads (so called nicopads) all available in a number of flavours. The nicotine in medicines is derived from tobacco leaves. Most products are produced by the pharmaceutical industry or are supplied by pharmaceutical companies which are owned by the cigarette industry. A common aspect is that they are marketed with therapeutic claims with respect to stopping smoking and that they have been subject to tests for tolerance and side effects. Given the products' status as non-prescription medicines, the producer has the opportunity to advertise to the public within the limitations set by pharmaceutical legislation and regulations.

Users

Nicotine chewing gum, nicotine patches and nicotine inhalers, the classic nicotine medicines are exclusively used by smokers or former smokers. Use among non-smokers has not been a topic of research or represented a concern in the tobacco control community. Among smokers, the medicines have three functions, i) a method for stopping using cigarettes, ii)a method for reducing nicotine abstinence when in no-smoking arenas and iii) a method for preventing a relapse to cigarettes by former smokers. The two first functions may mean a shorter or longer period of dual use of nicotine medicines and cigarettes. Dual use has, however, not been used

as a significant objection to nicotine medicines. The last function, medicines involve a risk of extended nicotine use. This has not trigged any particular concern in the tobacco control movement.

Stopping smoking

Systematic summaries of the research literature show that around 16% of smokers manage to remain non-smokers after one year's of use of nicotine medicines. This means that around 84% relapse to smoking in the course of the observation period, most after a short period of time. There are for each smoker who 'is cured', between 5 and 6 who are not 'cured'. The stop rate is better than the results in the control groups, relapse being 90% in the group with placebo and 92% in the group without medicines. Investigations show that a great deal of the effect disappears when the medicines are used outside the experimental setting, in smokers' natural contexts. This can, to a certain extent, be due to smokers not following the recommendations for use when administrating intake and therefore not utilizing the full potential for effect. Another cause can be that the experimental studies are carried out under conditions which promote good results.

At the population level, a weak effect of a nicotine medicine can be significant if sufficiently many chose to use the products. The nicotine medicines were, however, designed to be less attractive and provide small and perhaps unsatisfactory nicotine doses to smokers. Most smokers do not consider their smoking to be an illness which should be medicated. This means that even though nicotine medicines have helped a number of smokers to stop smoking cigarettes, the moderate effect of stopping smoking in combination with the low prevalence of reductions in smoking in Norway must predominantly be attributed to other factors.

Snuff

Use of Scandinavian snuff types is low outside of Norway and Sweden. However, as a potential harm reducing product, snuff has received international attention. In 2007, snuff was included in the portfolio of harm reducing products by the Royal College of Physicians. In addition to emphasizing the harm difference between snuff and cigarettes, snuff was considered to be a part of a possible solution of smoking as a public health problem. The extraordinary low occurrence of tobacco related deaths among Swedish men who have consumed as much tobacco as the average in Europe but where most of the tobacco has been consumed as snuff, was referred to.

Snuff, unlike nicotine containing medicines and e-cigarettes, is a tobacco product and the snuff producers are consequently, even though they do not produce cigarettes, viewed as being a branch of the general tobacco industry. This industry has incurred a justified reputation problem. The snuff industry has therefore, in principle, low credibility as dispatchers of a message on the use of snuff as an alternative product to cigarettes in a harm reduction policy. In 2009, the harm reduction potential of snuff was however discussed in a separate report from SIRUS. A publicly appointed expert committee proposed in February 2013 that snuff should be prohibited in Norway within the next three years.

Users

Despite the proportion of smokers falling, most users of snuff come from the smoking part of the population. Among men who in the period 2011-15 stated that they used snuff or had used snuff previously, 63% were either former (36%) or current smokers (27%). From 2003, the proportion of people without previous smoking experience had however increased from 21 to 37 per cent in this group.

When the most important reservoir of potential snuff users (smokers) is in the process of shrivelling, this is likely to result in fewer snuff users in the future. It is unlikely that the extent of snuff use will reach the same epidemic proportions as cigarette smoking for men at the beginning of 1960s. Another consequence of the reduction in smoking is that it also will distort the relationship between smokers and non-smokers among snuff users. We must expect that the proportion of prior smoking experience will become increasingly less among new snuff users.

Growth in snuff use took place in parallel with a reduction in cigarette use. This inverse relationship was particularly clear among the young. Among men in the age group 16-24, daily use of snuff increased from 5% in 1985 to a peak of 25% in 2011 and then fell to 20% in 2015. Occasional use rose from 8% to 16% in 2005 but is now back at 8%. The same flattening out is not observed for women in the same age group. For young women, the proportion of daily users has increased from 1% to 17% while the proportion of occasional users has increased from 3% to 8%.

The increase in snuff use among youth arises i) partly because young smokers also use snuff to stop or cut down on cigarettes, ii) partly because potential smokers chose snuff instead of cigarettes and iii) partly because youth who otherwise never would have started to smoke begin using snuff. The increase in snuff use takes place therefore as a result of the increasing inflow of people from all these three segments. The empirical challenge is to filter them from each other.

Stopping smoking

Snuff, unlike nicotine containing medicines, is not presented with therapeutic claims on the effect in stopping smoking. There are therefore very few experimental studies of snuff in stopping smoking.

The results from the few studies found vary from finding the same effect as nicotine medicines, beneficial effects on biomarkers for smoking, reduced cigarette consumption and increased motivation to stop smoking, reduced alcohol-related smoking, better effect than NRT and reduced urge to smoke.

Despite snuff not primarily being considered to be a product for stopping smoking, snuff has (after unassisted attempts to stop) however become the most used method in stopping smoking in Norway. Observational studies show that stopping smoking is a widespread motivation for increasing the use of snuff. The intention of not smoking five years into the future is more widespread among dual users than among smokers who do not use snuff. The smoking cessation rate among snuff users is higher than for those who do not use snuff and

smokers who had used snuff as a method for stopping more often become non-smokers than smokers who had used nicotine containing medicines.

The use of one conventional method for stopping (nicotine chewing gum, patch and inhaler, Zyban, Champix, assistance from health services, self-help materials) increases the probability of the use of other recommended methods. The use of snuff however appears to be negatively correlated with the use of the above mentioned conventional methods. This can be an indication that snuff attracts those who want to stop smoking who, for different reasons, do not want to make use of the recommended methods.

Snuff, unlike nicotine medicines, appeals also to smokers who are not trying to stop smoking. Smokers who experiment with an alternative nicotine product for other reasons than stopping smoking, but who as a result of this experimentation end up stopping smoking, are called ‘accidental quitters'. There are no certain reference points as to how many stop smoking after accidental experimentation with snuff.

E-cigarettes

It was the growth in e-cigarettes which in earnest activated an interest in harm reduction in the tobacco area. E-cigarettes were patented in 2003 and have been on sale internationally since 2007. Many countries, including Norway, have practiced a prohibition of the sale of nicotine containing e- cigarettes. Norwegian vapers have been able buy the vaporizers in Norway while they primarily have bought the nicotine containing fluid in other countries. The forthcoming cessation of the prohibition of domestic sale of nicotine containing products (in the course of 2018) will, depending on the Norwegian tax system, probably contribute to the displacement of supply to Norwegian sales outlets.

Product development for e-cigarettes has taken place outside health control, approval and blessing. The majority of the product portfolio was originally produced by consumer controlled small companies without any links with the tobacco industry. The target group for these products was exclusively smokers. The tobacco industry launched its products first from 2012, and has now a significant share of the market for the e-cigarettes, which resemble ordinary cigarettes, the so called cig-a-likes. Most vapers however prefer tank systems and modified versions.

Users

It is possible to calculate from Norwegian investigations that around 50,000 people (1.1%) use e-cigarettes daily and further 120 000 people (2.4%) use e-cigarettes occasionally. Only 3.6% of current users and 4.7% of former users of e-cigarettes had not previously been smokers. Vapers consist primarily of people who either smoke daily or occasionally, or who have stopped smoking. This is a result which can be also found in systematic summaries of the international literature.

The average age for current and former vapers was 42 years and 41 years respectively. These were approximately the same as for smokers, while snuff users on average were around 7 years younger. Only just under 15% of vapers belonged to the age group under 25 years.

The longest time series in the USA shows that the proportion of 12-18 year olds who reported use of e-cigarettes last month had increased from 1.5% in 2011 to 16% in 2015, but then fell to 11.3% in 2016. Daily use of e-cigarettes in this age group was only 1.1% in 2016. Nine out of ten youth who had experimented with e-cigarettes, had not used the product in the course of the last month. Only 0.2% of those who had tried e-cigarettes stated that they used the product every day. This illustrates that the majority of experimentation with e-cigarettes among youth does not result in regular use.

Two of three American youth who have used e-cigarettes stated that they had used nicotine free versions. It appears that the taste is, for youth, more important than nicotine supply in selecting a product.

A summarized presentation of five investigations carried out in The UK shows that the use of e-cigarettes among non-smoking youth was very limited. However, between 4% and 14% of non-smoking youth had tried e-cigarettes, but only between 0.1% and 0.5% used e-cigarettes weekly or more often.

A recurrent finding in the literature on youth and risk behaviour is that involvement in one type risk behaviour increases the probability of subsequently starting another type of risk behaviour. A number of investigations show, in line with this, that non-smoking youth who experiment with e-cigarettes and also with snuff, have greater inclination to begin to smoke compared with youth who refrain from the use of e-cigarettes. It is however very difficult and maybe it is impossible to determine how much of this association can ultimately be attributed to the product per se. After having reported the methodical challenges by identifying a causal effect of e-cigarettes on smoking, Public Health England wrote in its 2015 rapport: *"we strongly suggest that use of the gateway terminology be abandoned until it is clear how the theory can be tested in this field"*. The topic continues, however, to be the object of a heated international debate.

Stopping smoking

In England, e-cigarettes were the preferred method for stopping smoking in 2013. Also in Norway there has been an increase in the use of e-cigarettes as a method for stopping smoking. How great an effect do e-cigarettes have on stopping smoking is, however, a heated debate topic. There is a great deal of anecdotal evidence from vapers who report that e-cigarettes reduce abstinence symptoms, act satisfactorily as a replacement for conventional cigarettes and function well in attempts to stop smoking. Such data is given little weight in questions on the effect of a product in stopping smoking.

Very few randomized controlled trials have been carried out on the use of e-cigarettes in stopping smoking. The products are not presented using therapeutic claims, as such messages would categorize e-cigarettes as a medicine and make them subject to pharmaceutical legislation. Producers present e-cigarettes as an alternative to tobacco cigarettes and not as a product for stopping smoking. The swift product development of e-cigarettes also removes the incentive for producers to carry out effect studies. The differences between the different generations is great.

Carrying out experimental studies is time-consuming. The type of e-cigarettes which are investigated will most likely no longer be on the market when the results are available. In addition, most producers are small and do not have the ability to administrate expensive and long term trials, which they furthermore do not need to access the market and will be able to utilize in marketing.

There are however some experimental studies. A summary article from 2017 summarized the results as follows:

> *Four RCTs show that ENDS are effective in helping some adult smokers to quit or to reduce their cigarette consumption. In the studies that assessed smoking cessation, rates of cessation in the ENDS study groups were similar to or higher than rates of cessation seen in previous clinical trials of nicotine-replacement therapy (NRT).*

There are however more than 100 articles (as at 1 Nov 2017) on studies that use longitudinal data or cross sectional studies. Many of these have shortcomings which make it difficult to conclude any certain level of effect. A group of researchers who recently reviewed this portfolio concluded that those of best quality achieved the same results as from the experimental studies:

> *The few observational studies meeting some of the criteria (duration, type, use for cessation) triangulated with findings from three randomized trials to suggest that e-cigarettes can help adult smokers quit or reduce cigarette smoking. Only a small proportion of studies seeking to address the effect of e-cigarettes on smoking cessation or reduction meet a set of proposed quality standards. Those that do are consistent with randomized controlled trial evidence in suggesting that e-cigarettes can help with smoking cessation or reduction.*

E-cigarettes also attract users who have no plans to stop smoking. The product therefore has, as does snuff, the potential to produce ‘accidental quitters’. These are smokers who experiment with an alternative nicotine product for other reasons than stopping smoking, but who as a result of this experimentation end up stopping smoking.

Combustion-free

Scandinavian snuff types are supplied by tobacco producers that do not themselves make cigarettes. The combustion-free cigarettes are, however, developed by companies which primarily produce cigarettes or by producers who cooperate with these companies. The mechanisms for heating tobacco vary between the products and can result in different temperatures.

HnB products have been tested, as at November 2017, in the nicotine market for example in Japan, South Korea, Switzerland, Italy, Canada and Russia. WHO however notifies of industry plans to apply for market access for HnB cigarettes in a number of countries including Norway.

Market analysts have predicted that HnB can be expected to capture 30 % of the American nicotine market in 2025. Philip Morris has applied to the FDA to market iQOS in the USA as a ‘Modified Risk Tobacco Product'.

Today‘s combustion-free cigarettes consist of finely cut tobacco packed in paper sleeves with a filter (and resembles a mini-cigarette). They are also called Heets or HeatSticks and are inserted into a rechargeable battery driven unit which, when inhaling, heats up the tobacco to around 350 degrees. This produces an inhalable aerosol. Unlike e-cigarettes, HnB products contain tobacco and taste more like ordinary cigarettes.

A certain amount of chemical, toxicological and clinical research is being carried out into the levels of harmful compounds in combustion-free cigarettes. Most of this research is carried out by the tobacco industry itself which, unlike many of the producers of e-cigarettes, have advanced laboratories and high levels of resources for research. The results from some non-industry financed studies indicate that HnB can supply the same concentrations of nicotine as smoking conventional cigarettes. Concentrations of nitrosamines (TSNA), formaldehyde, carbon monoxide and a number of other poisonous substances are far lower.

No studies have been published on user configuration or effect of stopping smoking.

Tobacco free snuff

In Sweden, Zyn (a type of tobacco free but nicotine containing snuff) was launched for sale in a selection of shops from December 2016. The product had been tested in a number of sates in the USA from 2014. Swedish Match has notified that they also want to sell Zyn in Norway.

Nicopads (nicotine containing mouth powder) do not, as for e-cigarettes, contain any plant materials from the tobacco plant. The product consists of a white, dry powder packed into small pads as for tobacco containing snuff pouches. The powder contains nicotine salts leached from tobacco leaves, to which is added aroma (lemon/mint), acid regulators, sweeteners, stabilisers and fillers.

Zyn comes from the snuff industry. The almost identical product Zonnic however comes from the pharmaceutical industry. It was launched in 2008 and released onto the Norwegian market a few years later.

Zonnic is sold as a non-prescription product and can be bought at pharmacies and in kiosks and grocery stores. With status as medicine, the producer can advertise the product.

Nicipad products illustrate how challenging it gradually has become to subdivide the nicotine market by the products' use (therapy v recreation) and producers (pharmaceutical industry, snuff industry, other industry). This, much like product risk, is regulated by a number of different legislations and regulations (The Pharmaceutics Act vs. The Tobacco Act).

Part III. How will different political choices affect current and future generations’ dependency on tobacco and nicotine products?

A potential dilemma can arise for harm reducing nicotine products where market access, competitive advantage and information on a reduced degree of harm creates an enticement pressure in groups in the population who, where there was no harm reduction policy, would not have been tempted to use these products. Examples of such groups are youth who do not view smoking as a real alternative or former smokers who easily could have stopped all nicotine consumption but who instead extended their period of use with one or a number of the new nicotine products.

Decision makers should also try to weigh up the estimated benefits against the estimated disadvantages before any harm reduction is adopted as a supplementary element in tobacco policy. The net benefit in the target group for the harm reduction policy (smokers and potential smokers – high risk group) should be compared with the unintended negative consequences for those that are not in the target group (low risk group)?

Two components will primarily be included in this weighing up. The number of people who are influenced by the harm reduction policy (the so called group transition) and the health consequences for those influenced in one or other direction.

More precisely, this means that decision makers must have clear perceptions of how many in the high risk group are influenced by the harm reduction policy in directions that benefit their health and how many in the low risk group are influenced in directions that harm their health. Decision makers must also have perceptions of how great the health benefit is for smokers and potential smokers who chose a harm reducing product instead of cigarettes. They similarly must know the size of the health deterioration of those influenced in the low risk group who instead of being nicotine free are tempted to use a nicotine containing harm reducing product.

It is possible to model the net effect of a harm reduction policy at the public health level by inserting estimates for the different group transitions and estimates for the health outcomes for those who change user status. Briefly summarised, user configuration and relative degree of harm determines the effect of a harm reducing product on public health.

Research today cannot provide the authorities with certain and consistent information on degree of harm and user configuration. This uncertainty can be used, and is used, as an argument for delaying the decision that authorities include harm reduction as a supplement in the illness prevention work in the tobacco area. Whilst awaiting a greater number of certain and more consistent answers, it can be legitimate for decision makers to invoke the precautionary principle as a normative leitmotiv.

Decision theorists emphasise that necessary care must not be rooted in moralism, emotions, political direction or social mood, but that the precautionary principle can ultimately be applied after having weighed up the estimated benefits against estimated disadvantages. The precautionary principle can be misused and be a pretext for resistance to harm reduction which is more ideologically founded.

This precaution can also result in costs. Applied to the tobacco area, costs from not applying a harm reduction policy can be that smokers and potential smokers (high risk groups) are prevented access to harm reducing forms of nicotine uptake. The precautionary principle can paradoxically come to entrench the position of the most hazardous product, cigarettes, and protect the cigarette industry from competition in the nicotine market.

SECTION I. Various perspectives on harm reduction, the implications these have for the objectives and tools of the tobacco strategy

1. A tobacco free society, harm reduction or both?

In the previous national strategy plan for tobacco control for 2013-2016 – 'A tobacco free future' – harm reduction is not considered as a strategic supplement to help in reducing tobacco-related illnesses and deaths (apart from that non-prescription medicinal products containing nicotine are recommended as an aid when giving up smoking). The term 'harm reduction' is not used in the document. The plan puts forward a vision of a tobacco free society. This vision was later written into law in the introduction to Act No. 14 of 9 March 1973 relating to Prevention of the Harmful Effects of Tobacco in May 2013, where the stated objective of the Act is "*to limit the damage to health caused by the use of tobacco products* ***by reducing consumption with a view to eventually achieving a tobacco-free society"***.

A strict interpretation of this objective means the total cessation of the recreational use[1] of products that contain tobacco or nicotine extracted from tobacco plants – so-called tobacco derivatives. Harm reduction on the other hand is about persuading nicotine users to take a path along a risk continuum away from the most dangerous products to the less dangerous products without the end game necessarily being the cessation of all use of tobacco or nicotine. It would thus seem that harm reduction has no place in a 0-vision for tobacco use incorporated in law – at least not as a long term strategy.

Harm reduction can however form part of a strategy plan if the authorities introduce an additional aim *to reduce tobacco-related harm* while still working towards achieving a tobacco free society. It appears that in practice this is what the authorities are working towards with this additional objective. In the Government White Paper 19 (2014-2015) 'Mastering and Possibilities' for example the door was quite explicitly opened for harm reduction in the area of tobacco use.

> *The emergence of electronic cigarettes has intensified the debate on whether harm reduction should be a supplement to the traditional tobacco policy. Smokers who have not been able to stop smoking will be able to reduce their own health risk by switching to e-cigarettes, although they are not necessarily completely harmless. Harm reduction as a political strategy so far has had no place in Norwegian tobacco policy. The Government is open to new thinking in this area with regard to e-cigarettes, without reaching any conclusions as to how the products should be regulated (page 72).*

In December 2016, Storting (the Norwegian Parliament) adopted by a large majority that e-cigarettes containing nicotine should be permitted for sale in Norway. It is also signalled that the 1989 regulation, which banned the entry of new nicotine products, will be lifted. The regulation will instead be replaced with an approval scheme for new nicotine products. This indicates that in practice Norwegian authorities do not operate under a strict 0 vision for tobacco and nicotine use, or at least not at this point in time. Under the long-term vision of a

[1] We presume that tobacco use for therapeutic purposes is not encompassed under this vision.

tobacco free society, there appears to be acceptance to allow (temporarily) the use of harm-reducing nicotine products.

2. The origins of harm reduction in tobacco usage

On the Internet pages of the organisation Harm Reduction International harm reduction is defined as follows:

> *Harm reduction refers to policies, programs and practices that aim to reduce the harms associated with the use of psychoactive drugs in people unable or unwilling to stop. The defining features are the focus on the prevention of harm, rather than on the prevention of drug use itself, and the focus on people who continue to use drugs.*
>
> *Harm reduction complements approaches that seek to prevent or reduce the overall level of drug consumption. It is based on the recognition that many people throughout the world continue to use psychoactive drugs despite even the strongest efforts to prevent the initiation or continued use of drugs*[2].

2.1 Michael Russell

In the field of tobacco usage the South African psychiatrist Michael Russell is recognised as the father of the harm reduction concept. In a much-quoted article in British Medical Journal from 1976 Russell wrote *„People smoke for nicotine but they die from the tar"*[3] and claimed that smokers did not need to risk their lives to get their nicotine dose if the method of taking the drug could be changed.

It is however Russell's article from Addiction from 1991 – The future of nicotine replacement – that is considered to be the origin of harm reduction in tobacco usage. It was here that Russell wrote amongst other things:

> *A case is advanced for selected nicotine replacement products to be made as palatable and acceptable as possible and actively promoted on the open market to enable them to compete with tobacco products. They will also need health authority endorsement, tax advantages and support from the anti-smoking movement if tobacco use is to be gradually phased out altogether.*
>
> *It is essential for policy makers to understand and accept that people would not use tobacco unless it contained nicotine, and that they are more likely to give it up if a reasonably pleasant and less harmful alternative source of nicotine is available. It is nicotine that people cannot easily do without, not tobacco.*
>
> *It will be assumed throughout that our main concern is to reduce tobacco-related diseases and that moral objections to the recreational and even addictive use of a drug can be discounted provided it is not physically, psychologically or socially harmful to the user or to others.*

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[2] https://www.hri.global/what-is-harm-reduction

[3] Russell M. Br Med J. 1976 Jun 12; 1(6023): 1430–1433. Low-tar medium-nicotine cigarettes: a new approach to safer smoking. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1640397/

2.2 The Committee for Smoking Research

In Norway the influential "Committee for Smoking Research" has as early as in 1967 written that *"direct change to the harmful products seems to be one of the decidedly most promising methods to combat harm caused by cigarette smoking"*.

The Committee also wrote that the authorities should "take advantage of the possibility to guide consumption towards the least harmful products through the conscious use of taxes and tithes and regulative policies". (Ministry of Social Services Information Secretariat 1967, page 125-126)[4].

In the current climate this statement would have placed the committee amongst the followers of the harm reduction concept. However, the committee never used the term 'harm reduction' in its recommendation. The committee – consisting of experts from medicine, criminology, social psychology, economics and education – was tasked with forming Norway's first systematic programme for preventive measures against the harmful effects of tobacco.

Harm reduction would however not be adopted as a supplementary element for the resulting tobacco policy in Norway. It was only in 2009 that a report from SIRUS – A tobacco-free society or tobacco harm reduction? Which objective is best for the remaining smokers in Scandinavia? – initiated a public debate on whether harm reduction could be a strategy in addition to traditional tobacco prevention measures[5]. In 2014, the Solberg government signalled that it was open to new thinking about harm reduction[6], and in 2016, the Storting therefore decided to lift the ban on amongst other things e-cigarettes containing nicotine, quoting amongst other reasons harm reduction as the justification.

2.3 Harm reduction now

The need for harm reduction is justified by its supporters by that nearly 50 years of information activities, sales restrictions, behavioural constraints, tax increases and therapeutic measures have not resulted in the desired reduction in smoking-related illnesses and deaths. In the region of 600,000 people are still smoking, projections indicate that the proportion of smokers will remain above 10% in the next decades[7], 5,000 people die of smoking-related diseases every year, and these diseases will increasingly affect the socially disadvantaged. It is claimed that today's smokers have different needs than the smokers the health authorities

[4] The Committee was established in February 1965 by Landsforeningen mot Kreft – The Norwegian Cancer Society – at the request of Chief Medical Officer Karl Evang and was led by Chief Physician Kjell Bjartveit, who would go on to head The State Committee on the Harmful Effects of Tobacco for more than 20 years

[5] Lund KE. A tobacco-free society or tobacco harm reduction? Which objective is best for the remaining smokers in Scandinavia? 85 s. SIRUS rapport 6/2009, Oslo 2009. http://snusforumet.se/wp-content/uploads/sites/7/2017/05/26-2009-karl-erik-lund-a-tobacco-free-society-or-harm-reduction-in-english-p-engelska.pdf

[6] Green paper. St. 19 (2014-2015). Public Health report – Mastering and Possibilities. Advice from the Ministry of Health and Care Services 27th March 2015, approved by the Council of State on the same date. https://www.regjeringen.no/no/dokumenter/meld.-st.-19-2014-2015/id2402807/

[7] Gartner CE, Lund KE, Barendregt JJ et al. (2016). Projecting the future smoking prevalence in Norway. Eur J Public Health. 2017 Feb 1;27(1):139-144. https://brage.bibsys.no/xmlui/handle/11250/2427158

addressed in the 1970s and 80s, and that about 25% of smokers must be categorised as hard-core smokers[8] with strong nicotine dependence and with no intention to stop smoking.

2.4 International scientific disagreement

At the 2017 conference of Society for Research on Nicotine and Tobacco (SRNT) The American health economist and tobacco researcher Ken Warner presented an overview of some of the themes in connection with harm reduction that had in his opinion split the international community for the control of tobacco (table 1).

2.4.1 Proponents

According to Warner, harm reductionists are inclined to accept continued widespread nicotine dependence as long as this is not related to cigarette smoking. They believe the level of taxation and the robustness of market and usage restrictions should be in accordance with ability of the product to cause harm. Furthermore, that health authorities should disclose risk differences between nicotine products, let the risks inherent in cigarette smoking be the reference for the comparison and encourage smokers to change to safer products through information campaigns. They justify the need for innovative products by referring to the many illnesses and deaths caused by cigarettes and believe that the application of a precautionary principle that prevents market access could result in the nicotine market being a status quo situation weighted towards the most dangerous product – cigarettes. Proponents are also no stranger to collaborating with the nicotine industry in making harm-reducing nicotine products attractive, available and as safe as possible

2.4.2 Opponents

On the other hand, according to Warner, the opponents believe that the purpose of the tobacco policy should be to eliminate any use of nicotine for recreational purposes. They think the disadvantages are greater than the benefits of granting competitive advantages for the supposedly least harmful products and do not subscribe to the proportionality principle of taxation. Opponents claim that the evidence base for the effect when giving up smoking is not robust and that such products will be able to delay smokers quitting and lead to double use. The opponents also fear that the products will recruit non-smokers and, at worst, act as a gateway to the subsequent launch of tobacco smoking for young people who would otherwise not have started to use nicotine. They fear that the product's similarity to cigarettes and that a mode of use similar to smoking could renormalize smoking and undermine the work of de-normalizing cigarettes. They believe that the risk of using harm-reducing products cannot be clarified before there is documented evidence based on long-term use, and that risk should not be compared to the risk of cigarette smoking, but instead with the non-use of tobacco products. In anticipation of a longer observation period to study possible effects on health and in light of the rapid rate of innovation for the development of ever-new generations of products, the opponents strongly endorse the precautionary principle. The possible

[8] Lund M, Lund KE, Kvaavik E. Hardcore smokers in Norway 1996-2009. Nicotine Tob Res. 2011 Nov; 13(11): 1132–1139. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3203137/

development of harm-reducing products should not take place in conjunction with the tobacco industry or other branches of the nicotine industry, with the exception of the pharmaceutical industry that opponents regard as an ally in the work to reduce tobacco-related illness.

Table 1. Areas of difference between proponents and opponents of tobacco harm-reduction (THR). Source: Ken Warner. SRNT, Florence, March 2017

Issue	Proponents	Opponents
Long-term nicotine addiction	Acceptable if eliminate smoking (switch)	Not acceptable (quit)
Regulation, taxation	Should be proportionate to harm potential	Should be restrictive for all nicotine products
Impact on smoking cessation	Potential to help millions switch	May delay/reduce quitting
Primary information dissemination	To inform smokers on safer alternatives	Fears about gateway effects, dual use, renormalisation of smoking
Risk perspective	Should be contrasted to cigarettes	Risk from the product itself (do-no-harm principle)
Degree of risk reduction	Huge (> 95%)	Unknown, no safe lower limit
Innovation perspective	Death toll requires novel products	Precautionary principle
Tobacco/e-cig companies	Open to work with them It's the product that matters	Not to be trusted The manufacturer matters
Product attractiveness	Should create high likeability among smokers	Should be made dissuasive to never-smokers

Ken Warner is venerated in tobacco research, a winner of the Luther Terry Award and has been an important contributor to several of the leading reports on tobacco from the US Surgeon General. Based on his knowledge of what he called 'the international tobacco control community' he divided this into an academic camp and a more active-oriented camp. His view was that the academic camp was divided roughly in the middle between proponents and opponents, placing the bulk of the active-oriented camp on the opponent side. In tobacco history, Warner claimed that the disagreement about harm reduction was rare and that the frontiers were unusually sharp. He emphasized, however, that the vast majority of the tobacco control community was not polarized into homogeneous groups, but that the most common condition was an interposition[9].

[9] Warner KE. How to think – not feel – about tobacco-harm-reduction. Plenary Thursday March 9, 2017. SRNT, Florence, Italy. Warner gave a similar address with the same title on 17th October 2017 at a conference arranged by The University of California, San Francisco (UCSF) School of Medicine. His slides are here: https://smokingcessationleadership.ucsf.edu/sites/smokingcessationleadership.ucsf.edu/files/Documents/Webinars/FinalWebinar73Harmreduction.pdf

3. Harm reduction in current international tobacco policy

The government's signals that they are considering opening the way for harm reduction as an additional element in the tobacco policy are in line with the signals that have come from authoritative government agencies in for example England, USA and New Zealand. These are countries that have been at the forefront of action against the harm caused by tobacco, and the signals from these countries have traditionally had a major influence on Norwegian tobacco policy. Other leading countries in international tobacco policy, like Finland and Australia, have not adopted the harm reduction ideology. The health authorities in these countries do not look at new, supposedly less harmful nicotine products as part of the solution to the remaining tobacco problem. Rather, these substitution products are perceived as part of the tobacco problem as a whole.

3.1 England

The science branch of the British Medical Association – The Royal College of Physicians (RCP) – released a report as early as in 2007 – „*Harm reduction in nicotine addiction*"[10] – which argued that harm reduction should be adopted as a supplement to the policy to limit the major damage caused by cigarette smoking.

> *We suggested (in 2007) that making effective, affordable, socially acceptable, low-hazard nicotine products available to smokers as a market alternative to cigarettes could generate significant health gains by allowing smokers to stop smoking tobacco without having to stop using nicotine to which they are addicted» "As most of the harm caused by smoking arises not from nicotine but from other components of tobacco smoke, the health and life expectancy of today's smokers could radically be improved by encouraging as many as possible to switch to a smoke-free source of nicotine (RCP 2016 p XI & p 2).*

Harm reduction was then accepted and integrated into National Strategy Plans from the Labour Government (Department of Health 2010) and the subsequent coalition government (Department of Health 2011), and affirmed in publications by the Medicines and Healthcare Products Regulatory Agency (2010) and National Institute for Health and Care Excellence (2013).

In 2007, only nicotine-containing drugs (NRT) and *snus* (low-nitrosamine smokeless-tobacco Swedish style – soft pellets of tobacco placed in the mouth from which nicotine leaches) were considered by RCP as potential substitute products for cigarettes. There was however a ban on the sale of *Snus* in the EU and thus in England, and RCP claimed that the nicotine drugs did not have the necessary appeal to the smokers in order to compete with cigarettes. However, at about the same time, e-cigarettes were launched and the product transformed the UK nicotine market as it soon became the most preferred substitute for people intending to stop or cut down on smoking[11].

[10] The Royal College of Physicians. Harm reduction in nicotine addiction (2007). https://shop.rcplondon.ac.uk/products/harm-reduction-in-nicotine-addiction-helping-people-who-cant-quit?variant=6509405637

[11] http://www.smokinginengland.info/latest-statistics/

RCP published a new benchmark report in 2016 – "*Nicotine without smoke. Tobacco Harm Reduction"* – with its focus on e-cigarettes. The press release about the publications said[12]:

> ***Promote e-cigarettes widely as substitute for smoking says new RCP report.***
>
> *The Royal College of Physicians' new report, 'Nicotine without smoke: tobacco harm reduction', has concluded that e-cigarettes are likely to be beneficial to UK public health. ... Where users have a range of options to similar functional effects, regulation should facilitate transitions to nicotine options with reduced risk. ... In the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK. (Royal College of Physicians UK 2016)*

On publication of the report the President of RCP, Professor Jane Dacre said:

> *Since the RCP's first report on tobacco, 'Smoking and health', in 1962, we have argued consistently for more and better policies and services to prevent people from taking up smoking, and help existing smokers to quit. This new report builds on that work and concludes that, for all the potential risks involved, harm reduction has huge potential to prevent death and disability from tobacco use, and to hasten our progress to a tobacco-free society. With careful management and proportionate regulation, harm reduction provides an opportunity to improve the lives of millions of people. It is an opportunity that, with care, we should take.*

Theresa May's government in England became the third in the series of British governments that adopted the principle of harm reduction in a national strategy plan to combat the smoke-related injuries. In July 2017, the Department of Public Health issued the strategy paper "*Towards a smoke-free generation: tobacco control plan for England" in which it said*[13]:

> *We will help people quit smoking by permitting innovative technologies that minimise the risk of harm. We will maximise the availability of safer alternatives to smoking" (UK Department of Health 2017).*

In information campaigns by the health authorities (for example the annual "Stoptober" from Public Health, England[14]) and in the national guidelines for advice on giving up smoking[15] the use of e-cigarettes is amongst the methods recommended to be used when giving up smoking. Action on Smoking and Health (ASH), which is a tobacco political advisory organ established in 1971 by the Royal College of Physicians, has advised against a general ban on the use of e-cigarettes indoors[16]. The British Medical Association[17] has also adopted the same position:

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[12] https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0

[13] https://www.gov.uk/government/publications/towards-a-smoke-free-generation-tobacco-control-plan-for-england

[14] https://www.youtube.com/watch?v=28aIsV4ya5A

[15] National Centre for Smoking Cessation and Training. Electronic cigarettes: A briefing for stop smoking services http://www.ncsct.co.uk/publicationelectroniccigarettebriefing.php

[16] Arnott DA. Chief Executive. Action on Smoking and Health. Regulation of electronic cigarettes. BMJ 2014; 349 http://www.bmj.com/content/349/bmj.g5484/rr/764176

[17] British Medical Association. E-cigarettes: balancing risks and opportunities (side 11). https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-health/tobacco/e-cigarettes

> *In response to the rapid emergence of e-cigarettes, coupled with the lack of knowledge about the risk of inhaling vapour, the BMA initially supported a precautionary approach of restricting their use in all enclosed public places and workplaces (side 10). Current evidence indicates that exposure to e-cigarette vapour does not pose specific health risks – unlike exposure to second hand smoke – and that their widespread use in public places has not had unintended consequences on re-normalising smoking or on compliance with smoke-free laws. It would therefore be reasonable to support a softer regulatory approach than exists for smoking in public (side 11).*

A notable and key critic of Public Health England's embrace of e-cigarettes has been Professor Martin McKee at the London School of Hygiene and Tropical Medicine. McKee claims that there is minimal evidence that the e-cigarettes have an effect on quitting the smoking habit, that it cannot be ruled out that e-cigarettes may be a gateway to the subsequent start of tobacco smoking and that, in anticipation of better evidence, the principle of better safe than sorry should be the basis for strategy plans for tobacco prevention work[18]. McKee has received support for his view from many other influential actors, including from former editor of Tobacco Control Simon Chapman at the University of Sydney and Stan Glantz at the University of California, San Francisco. On its web pages the British Medical Journal has published an overview of the items it has published about harm reduction / e-cigarettes from proponents and opponents over a longer period of time[19].

The British Medical Association (BMA) did not initially show the same enthusiasm for harm reduction and e-cigarettes as the Royal College of Physicians. On November 29, 2017, however, BMA published its new 'position paper' – 'E cigarettes: Balancing risks and opportunities'[20]. Here it says that the BMA concludes about harm reduction using e-cigarettes:

> *The BMA's ambition is to achieve a tobacco-free society, where there is significantly reduced mortality from tobacco-related diseases. Given that e-cigarettes are now the most popular device used in attempts to quit smoking, and that many people have used them to successfully quit tobacco use, they have significant potential to support this ambition, and help reduce tobacco-related harm.*

3.2 USA

While health authorities, most (but not all) health organizations and most (but not all) leading researchers in England adopted a positive attitude towards harm reduction early on, the idea has increasingly caused division amongst similar actors in the United States. Until recently, US government agencies have been fairly reserved. The measured attitude has been expressed in connection with the FDA's original (now abandoned) draft market regulation of e-

[18] McKee M, Capewell S. Evidence about electronic cigarettes: a foundation built on rock or sand? BMJ 2015;351:h4863 http://www.bmj.com/content/351/bmj.h4863

[19] http://www.bmj.com/campaign/e-cigarettes

[20] British Medical Association. E-cigarettes: balancing risks and opportunities. https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-health/tobacco/e-cigarettes

cigarettes[21] and the processing of applications to permit some nicotine products to be marketed as so-called Modified Risk Tobacco Products.[22]

However, in the 2014 report by the US Surgeon General; *The Health Consequences of Smoking – 50 Years of Progress*, it was signalled that tobacco use could not be considered as equivalent to smoking. It was pointed out that there were cigarettes and other combustible tobacco products that were the cause of the high number of tobacco-related deaths in the country. In one of the 10 main conclusions of the over 1000-page report it says[23]:

> *The burden of mortality and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden (US Surgeon General s. 4).*

In a joint policy statement from the American Association for Cancer Research and American Society of Clinical Oncology published in 2014, a wait and see position is adopted to the use of Electronic Nicotine Delivery Systems (ENDS) for use in harm reduction measures. This position may have been representative for many American health organisations at that point in time.

> *ENDS may be beneficial if they reduce smoking rates or prevent or reduce the known adverse health effects of smoking. However, ENDS may also be harmful, particularly to youth, if they increase the likelihood that non-smokers or formers smokers will use combustible tobacco products or if they discourage smokers from quitting. The American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (ASCO) recognize the potential ENDS have to alter patterns of tobacco use and affect the public's health; however, definitive data are lacking. AACR and ASCO recommend additional research on these devices, including assessing the health impacts of ENDS, understanding patterns of ENDS use, and determining what role ENDS have in cessation*[24].

The US Surgeon General's report „E-Cigarette Use Among Youth and Young Adults" (2016) does not discuss e-cigarettes from a harm reduction perspective. There is no attempt to weigh the expected benefits against the expected disadvantages. The report focuses solely on the risk e-cigarettes can represent for youth, and refers to the growth in the use of e-cigarettes among young people as a major health concern[25]. In fact, the report rejects the idea of granting e-cigarettes a competitive advantage over cigarettes, and instead explicitly proposes to employ the same preventive measures for both products.

> *We know a great deal about what works to effectively prevent tobacco use among young people (USDHHS 2012). Now we must apply these strategies to e-cigarettes – and continue to apply them to other tobacco products.*

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[21] Guidelines for FDAs premarket tobacco product application for electronic delivery systems process here: https://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/ucm499352.pdf

[22] FDAs Guidelines for Modified Risk Tobacco here: https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm304465.htm

[23] https://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html

[24] http://clincancerres.aacrjournals.org/content/early/2015/01/08/1078-0432.CCR-14-2544#

[25] https://www.surgeongeneral.gov/library/2016ecigarettes/index.html

On August 16th 2017, the Food and Drug Administration (FDA) published the "*Regulatory Plan for Tobacco and Nicotine Regulation*" in the New England Journal of Medicine[26]. The plan must be seen as openly supporting the harm reduction ideology and marked a breach of what had previously been signalled by the United States authorities. Some excerpts from the plan illustrate this change:

> *The agency's new tobacco strategy has two primary parts: reducing the addictiveness of combustible cigarettes while recognizing and clarifying the role that potentially less harmful tobacco products could play in improving public health. ...*
>
> *Nicotine, though not benign, is not directly responsible for the tobacco-caused cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year. The FDA's approach to reducing the devastating toll of tobacco use must be rooted in this foundational understanding: other chemical compounds in tobacco, and in the smoke created by combustion, are primarily to blame for such health harms...*
>
> *With these considerations in mind, and led by the best available evidence, the FDA will pursue a regulatory framework that focuses on nicotine and supports innovation to promote harm reduction.*

In the FDA plan harm reduction is introduced as one half of a total package solution where the other half is to reduce nicotine content in cigarettes until they no longer have the potential to cause addiction amongst users[27].

3.3 WHO

In Article 1 of the World Health Organisation's Framework Convention on Tobacco Control (FCTC) harm reduction is part of the actual definition of Tobacco Control[28]:

> *"Tobacco control" means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke.*

The World Health Organization's connection to e-cigarettes has nevertheless been somewhat reserved. In anticipation of its sixth meeting of the Moscow Framework Convention in October 2014, an ambivalence that was representative of many of the member states was expressed.

> *ENDS are the subject of a public health dispute among bona fide tobacco-control advocates that has become more divisive as their use has increased. Whereas some experts welcome ENDS as a pathway to the reduction of tobacco smoking, others characterize them as products that could undermine efforts to de-normalize tobacco use. ENDS, therefore, represent an evolving frontier filled with promise and threat for tobacco control*[29].

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[26] Regulatory plan for tobacco and nicotine regulation-from FDA Commissioner Scott Gottlieb. http://www.nejm.org/doi/full/10.1056/NEJMp1707409?query=featuredhome

[27] The gradual reduction of nicotine content in cigarettes was originally proposed as a strategy as early as in 1994. Benowitz NL, Henningfield JE. Establishing a nicotine threshold for addiction. The implications for tobacco regulation. N Engl J Med 1994;331:123–5

[28] http://www.who.int/tobacco/framework/final text/en/index3.html

[29] http://apps.who.int/gb/fctc/PDF/cop6/FCTC COP6 10Rev1-en.pdf

> *Governments should consider that if their country has already achieved a very low prevalence of smoking and that prevalence continues to decrease steadily, use of ENDS will not significantly decrease smoking-attributable disease and mortality even if the full theoretical risk reduction potential of ENDS were to be realized.*

Prior to its Seventh Meeting on the Framework Convention in India November 2016 (COP7), the World Health Organization circulated a new note discussing the role of Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS / ENNDS) in tobacco control

> *POTENTIAL ROLE OF ENDS/ENNDS IN TOBACCO CONTROL*
>
> *If the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement. This could only be the case if the recruitment of minors and non-smokers into the nicotine-dependent population is no higher than it is for smoking, and eventually decreases to zero. Whether ENDS can do this job is still a subject of debate between those who want their use to be swiftly encouraged and endorsed on the basis of available evidence, and others who urge caution given the existing scientific uncertainties as well as the performance variability of products and the diversity of user behaviour*[30].

The quote shows that the World Health Organization has provisionally adopted a wait and see and conditional attitude to the use of e-cigarettes as a harm reduction measure.

3.4 Other countries

In 2016, an international working group appointed by the Johns Hopkins Bloomberg School of Public Health in New York – including amongst other bodies the Public Health Institute – published an overview of 68 countries' regulation of e-cigarettes[31] (see Appendix 2). The rules varied from a total ban on the sale and possession of e-cigarettes to the product being granted significant market benefits in relation to tobacco products. To the extent that the legal practice relevant to e-cigarettes in 2016 serves to illustrate the countries' approaches to harm reduction ideology, the report indicates extremely varied perceptions

This is also evident in the various countries' strategy papers. In Finland, for example, the authorities set themselves the goal of eliminating all recreational use of tobacco and tobacco derivatives – including e-cigarettes[32]. In Australia the authorities recently ruled that a sales ban on e-cigarettes is to be upheld[33]:

> *The Department of Health is taking a precautionary approach to e-cigarettes and is continuing to examine the regulatory framework governing e-cigarettes in Australia. The Department's position on e-cigarettes is based on the need to consider the overall impacts that e-cigarettes pose to population health, including on non-smokers and smokers.*

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[30] http://www.who.int/fctc/cop/cop7/FCTC COP 7 11 EN.pdf

[31] Institute for Global Tobacco Control. Country Laws Regulating E-cigarettes: A Policy Scan. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health. http://globaltobaccocontrol.org/node/14052

[32] Senthilingam M. CNN, January 26, 2017. What Finland's plan to be tobacco-free can teach the world. http://edition.cnn.com/2017/01/26/health/finland-tobacco-free-plan/index.html

[33] The Australian Government. Department of Health. E-cigarettes. 19. October, 2017. E-cigarettes. http://www.health.gov.au/internet/main/publishing.nsf/Content/mc16-031907-reduce-the-harm-from-tobacco

Australia is in a far advanced phase in the cigarette epidemic, has a robust infrastructure for tobacco control and a low incidence of smoking. The fact that the country is in a kind of end-game for tobacco smoking as a mass proliferation phenomenon – and for that reason may regard e-cigarettes as redundant – has not been used as a justification for the ban on e-cigarettes. Conversely, one might think that the authorities in countries that are in earlier phases in the cigarette epidemic – like Turkey, Indonesia and Thailand – would use the high volume of smokers as a reason for introducing nicotine-containing alternative products. This has not been the case. In Turkey for example, the original plan to allow the sale of Combustion-free products was recently withdrawn by the authorities[34].

In New Zealand, which, like Australia, is also in an end-game phase, the health authorities have signalled that they will use e-cigarettes and snuff in the process of phasing out smoking[35].

> *In 2011, the Government set a goal for Smokefree 2025. The goal aims to reduce smoking prevalence to minimal levels. The Ministry of Health believes e-cigarettes have the potential to make a contribution to the Smokefree 2025 goal and could disrupt the significant inequities that are present. The potential of e-cigarettes to help improve public health depends on the extent to which they can act as a route out of smoking for New Zealand's 550,000 daily smokers, without providing a route into smoking for children and non-smokers. Recent decisions taken by Government have increased the focus on harm reduction with an aim to support smokers to switch to significantly less harmful products like e-cigarettes.*

In several countries, including Canada, the authorities have not yet reached a conclusion about the question of whether harm reduction should be a complementary element in tobacco policy. Overall, we therefore see that Western countries authorities have adopted very different approaches to regulating e-cigarettes. The approaches vary from the Finnish approach of combating e-cigarettes in line with conventional tobacco products, to the English with active promotion of e-cigarettes as alternatives to cigarettes.

3.5 The Tobacco Products Directive

The EU Tobacco Products Directive 2014/40 was adopted on 3rd April 2014 and came into force from May 2016. Article 20 of the Directive imposes minimum regulations and standards for e-cigarettes in the form of amongst other things quality and safety standards,

Limitations on size, limitations on ingredients, standards for user instructions and labelling and packaging, hereunder product presentation and health warnings on the packaging. E-cigarettes covered by the directive cannot have a nicotine content of more than 20 ml / mg, nicotine e-cigarettes and other products must comply with drug legislation. The same applies if it is claimed that the e-cigarette has an effect on giving up smoking or is marketed with other claims that it has a positive effect on illnesses.

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[34] World Health Organization. Turkey withdraws plans to loosen tobacco control laws. 31. October 2017. http://www.euro.who.int/en/health-topics/disease-prevention/tobacco/news/news/2017/10/turkey-withdraws-plans-to-loosen-tobacco-control-laws

[35] Ministry of Health. Ministry of Health position statement – E-cigarettes. Vaping (e-cigarettes). 11. October 2017 http://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/e-cigarettes

The result of the Tobacco Directive was that for the first time there was a common harmonized regulatory framework for e-cigarettes. Implementation of Article 20 of the Tobacco Directive resulted in several Member States and EEA countries – including Norway – changing their legislation for e-cigarettes. The directive did not prevent countries with a total ban (see Appendix 2) in continuing this, but most countries authorities found it most appropriate to regulate e-cigarettes in accordance with the new EU rules.

For a group of countries such as Sweden and Norway the implementation resulted in a liberalisation of the rules, while for other countries, such as Cyprus and England, the directive meant a tightening of the regulations. However, the Directive left the regulation of the use of e-cigarettes to the individual member states[36]. While the authorities in Norway and most other countries have chosen to have indoor vaping to be regulated in the same way as tobacco smoking, the authorities in England have left the owners and operators of establishments to determine the rules for indoor vaping.

Neither does the Directive interfere in any way with taxation of e-cigarettes in member countries. In Norway taxation is under discussion. In Sweden, the government recently (November 2017) tabled a proposal under which: (a) the taxable item is nicotine-containing liquid (nicotine-free liquid is exempted; b) taxation is calculated according to the volume of liquid; and c) the tax rate is set at Kr 2000.- per litre (Kr 2 / ml). This means that the price of a container of 10 ml of nicotine-containing e-liquid, which today costs Kr 40, will increase to Kr 65[37].

4. Harm reduction in practical politics

Article 19 of the EU Tobacco Products Directive provides Member States with the choice of introducing a registration system or approval system for new nicotine products[38]. In Norway, we will get an approval scheme where manufacturers and importers of new tobacco products must apply for approval from the Norwegian Medicines Agency within six months prior to the product being released on the market. The application must include a detailed description of the product, contain instructions for use and information on ingredients, emissions, toxicity, addiction, etc. If the product is not approved, it will not be released in the market.

Furthermore, Section 34c of the Prevention of the Harmful Effects of Tobacco Act establishes an obligation for manufacturers and importers of e-cigarettes to report on sales volumes, consumer preferences, market research, etc. to the Norwegian Directorate for Health and Social Affairs. In addition, Section 42 of the same act provides the Directorate with the authority to prohibit the import and sale of certain product categories if it is considered necessary for the protection of public health on the basis of particular circumstances[39].

[36] https://www.regjeringen.no/contentassets/3d8aadf5a8874cdab1107a7d6ec55590/horingsnotat---implementering-av-tpd-261015-l945753.pdf
[37] http://www.regeringen.se/4ac4de/contentassets/583e0cf22dcc416ba9c061521374acd8/beskattning-av-elektroniska-cigaretter-och-vissa-andra-nikotinhaltiga-produkter.pdf
[38] https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir 201440 en.pdf (page 25)
[39] **https://lovdata.no/dokument/NL/lov/1973-03-09-14**

4.1 Stage 1: Regulated market access

The first step in a practical harm reduction policy will be to allow potentially less harmful nicotine products access to the market. In Norway, this may be subject to approval by the competent authority. As already mentioned, the Storting has already decided that the ban on nicotine-containing e-cigarettes should be lifted. This will mean that a heterogeneous group of providers will be able to sell a heterogeneous group of products – but in accordance with a more detailed approval scheme. Finally, the authorities will soon have to decide whether other products should be allowed. Initially, it applies to non-combustible cigarettes such as iQOS[40] from Philip Morris and nicotine-containing powder (nicopad) as Zyn[41] from Swedish Match.

It is also likely that in the near future the authorities will receive applications for market access for products from the heterogeneous portfolio of so-called „next generation products" developed by British American Tobacco / Reynolds Tobacco (i.e. 'glo', 'iFUSE' , 'Vype', 'Core' and others). Japan Tobacco also has such products under development (i.e. 'Ploom TECH'). Tobacco free nicopad products such as 'Fresh Free', 'on!', 'Alt.id' and 'Sisu' – where the manufacturers neither belong to the tobacco or pharmaceutical industry – may also be relevant for the Norwegian market.

In short, the nicotine market, traditionally dominated by combustion products (cigarettes, rolling and pipe tobacco, cigars, cigarillos), and where products have for the most part been manufactured by tobacco oligopolies, is becoming differentiated both in terms of product types and sources of supply / suppliers. The new nicotine products come from industry that has traditionally manufactured cigarettes, from industry that has traditionally produced nicotine drugs, from industries that have not previously manufactured cigarettes or drugs, from the tobacco industry participants who have now also started to produce pharmaceuticals and from pharmaceutical industry wholly or partly owned by participants who also produce tobacco.

Common to the so-called 'reduced risk products' (RRPs) is that consumption does not involve the combustion phase of the tobacco where the majority of and the most dangerous toxins are formed. For example, the products may contain Combustion-free, a tobacco-free nicotine vapour (e-cigarette) or tobacco-free nicotine salts designed for oral consumption /nicopads) (see Table 2).

Only a small number of the new nicotine products are marketed for use when giving up smoking. Most are launched as so-called alternative cigarette products. This means that the products have a target group in addition to the minority of smokers who wish to use the products to help them give up smoking cigarettes. In Norway, this group constitutes only 20-25% of smokers. As 'alternative products', these innovations are primarily geared towards the percentage of smokers who have no specific plan to stop smoking, but who may be open to replacing cigarettes with perceived harm-reducing alternatives if the products satisfactory compensatory physiological, sensory, motor and social functions

[40] https://www.pmi.com/smoke-free-products/iqos-our-tobacco-heating-system
[41] https://zyn.com/Account/LogOn?ReturnUrl=%2fFind%2f

Table 2. Nicotine products in use or coming into use in Norway

Product category	***Contains tobacco***	***Product status***
Combustible products		
Cigarettes	Yes	Tobacco product
Rolling/pipe tobacco	Yes	Tobacco product
Cigars/cigarillos	Yes	Tobacco product
Hookah	Yes	Tobacco product
Warm products		
E-cigarettes	No	Tobacco surrogate/medicinal*
Combustion-free**	Yes	Tobacco product
Products for absorption in the mouth/pharynx		
Inhaler	No	Medicinal
Mouth spray	No	Medicinal
Products for oral use		
Snus	Yes	Tobacco product
Chewing tobacco	Yes	Tobacco product
Nicopads***	No	Tobacco surrogate / Medicinal
Chewing gum	No	Medicinal
Lozenges	No	Medicinal
Products for application to the skin		
Patches	No	Medicinal

** status as a medicinal product if the product is marketed with therapeutic claims, or if Nicotine content in e-juice exceeds 20 mg / ml. ** Heat sticks that are inserted into and heated by inhalation from a rechargeable battery-powered device (holder), examples are Iqos and iFuse. *** flavoured nicotine salts extracted from tobacco leaves wrapped in single use packs of cellulose, examples are Zonnic, Zyn and Fresh Free*

There is little reason to believe that the manufacturers of the harm reduction nicotine options will limit their interest in the ever-diminishing customer group of smokers. In countries where it is permitted to advertise e-cigarettes – as is the case in China[42] and the USA[43] – semiotic content analysis of marketing materials shows that the message may be targeted to a wide range of potential customers. It is not concern about public health concerns but earnings that motivate the nicotine industry's focus on RRP.

4.2 Stage 2: Regulation on the basis of potential for causing harm

Following approval and where applicable market access, the next stage of a practical harm reduction policy could be to apply the proportionality principle by regulating the products. This implies that the damage potential of the product is emphasized when writing the regulations. This means in practice that harm-reducing nicotine products will have a competitive advantage contra cigarettes so that the consumption of risk groups (smokers and

[42] Yao T, Jiang N, Grana R, Ling PM, Glantz SA. A content analysis of electronic cigarette manufacturer websites in China. Tob Control. 2016 Mar;25(2):188-94. .https://www.ncbi.nlm.nih.gov/pubmed/25335902

[43] Grana RA, Ling PM. „Smoking revolution": a content analysis of electronic cigarette retail websites. Am J Prev Med. 2014 Apr;46(4):395-403. https://www.ncbi.nlm.nih.gov/pubmed/24650842

potential smokers) is channelled to the least dangerous products. Specifically, this may, for example, mean lower taxation, exemption from a ban, exemption from standardized packaging, granting certain types of communication to consumers i.e. advertising restrictions rather than a total ban on advertising), exemption from indoor use prohibitions (i.e. by permitting lessees and owners of premises determine rules for indoor use themselves), exemption from regulations that limit the attractiveness of the products (i.e. flavour and design) mm.

4.3 Stage 3: Information on the relative risk of harm

In addition to the fact that taxation and regulatory means emphasize the degree of risk of harm, a harm reduction policy can also mean that health authorities are informed about the risk differences of nicotine products in such a way that misconceptions held by the population at large are corrected. A number of Norwegian studies show that the general population and smokers in particular have perceptions about the relative risk of nicotine and nicotine products that do not concur with medical consensus[44],[45],[46],[47],[48]. Such misconceptions concerning the relative degree of risk and harm in the various nicotine products have been observed in a number of other countries, such as amongst others the USA[49],[50] and has been the subject of a debate about ethics in healthcare authorities' communications about risk[51],[52],[53].

5. Harm reduction – a wolf in sheep's clothing propaganda from the tobacco industry?

5.1 The commercialisation of harm reduction

Harm reduction has long been an accepted strategy for many other types of risk associated behavioural conduct such as sexual conduct in vulnerable groups (free condom distribution to gay men), opiate use (substitution treatment, syringe dispensing, safe or supervised injection

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[44] Øverland S1, Hetland J, Aarø LE. Relative harm of snus and cigarettes: what do Norwegian adolescents say? Tob Control. 2008 Dec;17(6):422-5. https://www.ncbi.nlm.nih.gov/pubmed/18849315

[45] Lund I, Scheffels J. Perceptions of the Relative Harmfulness of Snus Among Norwegian General Practitioners and Their Effect on the Tendency to Recommend Snus in Smoking Cessation, Nicotine & Tobacco Research, Volume 14, Issue 2, 1 February 2012, Pages 169–175. https://academic.oup.com/ntr/article/14/2/169/1041163

[46] Lund KE. Association Between Willingness to Use Snus to Quit Smoking and Perception of Relative Risk Between Snus and Cigarettes, Nicotine & Tobacco Research, Volume 14, Issue 10, 1 October 2012, Pages 1221–1228. https://academic.oup.com/ntr/article/14/10/1221/1749452

[47] Norwegian response, Habits and attitudes to snus usage. Nationwide Omnibus. Report , 2005, Oslo

[48] Lund I, Scheffels J. Perceptions of relative risk of disease and addiction from cigarettes and snus. Psychol Addict Behav. 2014 Jun;28(2):367-75. https://www.ncbi.nlm.nih.gov/pubmed/23647153

[49] Kiviniemi, MT, Kozlowski LT. Deficiencies in public understanding about tobacco harm reduction: Results from a United States national survey. Harm Reduction Journal. 2015; 12: 21

[50] National Cancer Institute. Health Information National Trends Survey. https://hints.cancer.gov/view-questions-topics/question-details.aspx?red=1&qid=864&PK Cycle=8

[51] Kozlowski LT, Sweanor D. Withholding differential risk information on legal consumer nicotine/tobacco products: The public health ethics of health information quarantines. Int J Drug Policy. June 2016Volume 32, Pages 17–23. http://www.ijdp.org/article/S0955-3959(16)30092-5/fulltext

[52] Kozlowski, L.T. Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options. Nicotine & Tobacco Research. 2002; 4: S55–S60

[53] Kozlowski LT, Edwards BQ. "Not safe" is not enough: Smokers have a right to know more than there is no safe tobacco product. Tobacco Control. 2005; 14: ii3–ii7

facilities), conduct in traffic (cycle helmets and crash helmets, seat belts), alcohol consumption (alcohol limits when in control of road vehicles and other means of transport, advice on moderation), and so forth. The framework conditions for harm reduction measures may however vary in the various areas.

Substitution treatment for opiates addicts is accomplished through prescription drugs and includes individual medical follow-up. The free distribution of clean syringes and the distribution of condoms to prevent the spread of HIV is organised with no profit motive for the distributor. At the safe or supervised injection facilities, the intervention consists of creating a safe area for the injection of narcotics by the user. Crash and bicycle helmets and seat belts result in improved road safety. Harm reduction in tobacco use is dominated by substitution mechanisms, which are increasingly controlled by a commercial market.

5.2 Harm reduction as a hidden agenda

Cigarettes were a contributory cause of approximately 100 million deaths worldwide in the 20th century. The tobacco industry has a long history of counteracting smoking prevention measures and has been accused of manipulation, conspiracy and lying. That the tobacco industry is capable of playing a part in the development of products that can be used for harm reduction purposes is difficult to accept. In the international debate on harm reduction it has been argued that the tobacco industry uses the concept as an appropriate strategy to maintain earnings in a market where cigarette sales are falling, to engage with the authorities and to falsely represents itself as an industry that practises corporate social responsibility.

> *Transnational tobacco companies' harm reduction discourse should be seen as opportunistic tactical adaptation to policy change rather than a genuine commitment to harm reduction. Harm reduction offered the tobacco industry two main benefits: an opportunity to (re-) establish dialogue with and access to policy makers, scientists and public health groups and to secure reputational benefits via an emerging corporate social responsibility agenda. (Peeters & Gilmore, 2015)*[54]

5.3 Bad experiences

The tobacco industry's pursuit of „the harmless cigarette" has been ongoing since the late 1950s when the first epidemiological research proved that cigarette smoking caused significant health risks. In the 1960s, the tobacco industry launched cigarettes with a 'protective' filter. In Norway, these were marketed with information about a *„double filter that adds extra softness", „the cigarette that draws in air when you inhale „, „a snow-white fibre filter with thousands of tiny cells and a special carbon filter with active absorbent carbon", „an alternative – active double filter that provides cleaner smoking pleasure" and a „ high-efficiency multifilter resulting from research"*[55].

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[54] Peeters S, Giolmore AB. Understanding the emergence of the tobacco industry's use of the term tobacco harm reduction in order to inform public health policy. Tobacco Control 2015; 24:182-189. http://tobaccocontrol.bmj.com/content/early/2014/01/22/tobaccocontrol-2013-051502.full

[55] Lund KE. What did the Norwegian tobacco industry communicate to consumers via advertising? The journal of the Norwegian Medical Association 2002 (3) 122:310-6. http://tidsskriftet.no/2002/01/tema-royking/hva-kommuniserte-norsk-tobakksindustri-til-forbrukerne-i-reklamen

Two decades later, cigarettes with lower contents of tar, carbon fumes and nicotine labelled *'light', 'ultra light', 'mild', 'extra mild'* and so forth were marketed. Such texts imply a message of harm reduction. Epidemiological research then proved that neither filter cigarettes nor cigarettes with lower levels of toxins resulted in reduced health risks for the user. Some of the scepticism against harm reduction expressed in today's debate must be interpreted in light of these historical experiences.

Figure 1. Filter cigarettes marketed as a harm reduction product.

Figure 2. Cigarettes med reduced and nicotine content marketed as harm-reducing products.

5.4 The Philip Morris case

The management of one of the world's largest tobacco producers – Philip Morris – has repeatedly claimed that their future lies in smoke-free tobacco products. They have also developed new so-called 'platforms' for their future product portfolio. The motto for the tobacco giant is now „Designing a smoke-free future"[56] and on its websites, the company's new course is emphasised as follows:

> *We've built the world's most successful cigarette company, with the world's most popular and iconic brands. Now we've made a dramatic decision. We will be far more than a leading cigarette company. We're building PMI's future on smoke-free products that are a much better choice than cigarette smoking. Indeed, our vision – for all of us at PMI – is that these products will one day replace cigarettes.*

It also says on the web pages that cigarettes are the company's core product[57]. In an effort to increase the credibility of this rhetoric, Philip Morris refers to that since 2008 they have invested over $ 3 billion and employ over 400 scientists to develop new smoke-free platforms. The company has also established the Foundation for a Smoke-Free World[58] with Derek Yach as leader. Yach led the work of establishing the WHO Framework Convention on Tobacco Control while Gro H. Brundtland was Secretary General.

Despite the above, Philip Morris continues to sell the cigarettes they claim to be life-threatening and the company continues to file litigation against authorities in different countries – including Norway – for the right to market cigarettes. The WHO has urged member states not to enter into partnership with the Foundation for a Smoke-Free World[59].

[56] https://www.pmi.com/
[57] http://www.altria.com/our-companies/philipmorrisusa/making-our-cigarettes/Pages/default.aspx
[58] http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2817%2932602-8/fulltext#.WeA4JEXOpRg.facebook
[59] WHO Statement on Philip Morris funded Foundation for a Smoke-Free World. 28 September 2017 http://www.who.int/mediacentre/news/statements/2017/philip-morris-foundation/en/

Part II. The prevalence of harm-reducing nicotine products, the products' consumer groups and their roles in quitting smoking

In the international discussion about harm reduction with regards to tobacco, the use of four product types are generally referred to. Those are nicotine-containing medications, nicotine-containing snus with or without tobacco, nicotine-containing e-cigarettes and combustion-free cigarettes, which are classed as Combustion-free (HnB).

A shared feature of these is that the nicotine intake happens without tobacco undergoing the combustion process, which results in less exposure to known harmful compounds. The health hazard linked to the use of the different harm-reducing alternatives (the absolute risk), and the difference in harm in comparison to cigarette smoking (relative risk) for the various tobacco-related illnesses, is not the subject of this document.

Nicotine-containing medications and snus containing tobacco have been on the market for a long time, and both have been subject to studies regarding the health hazards, the dependency potential, therapeutic effect, appeal (likeability), use patterns, etc. A lot of knowledge has been obtained that is relevant to discussing the products' benefits and disadvantages in relation to harm reduction. Such knowledge is missing for the other products. Below we will shortly summarise the research literature on the different harm-reducing nicotine products prevalence, who uses them and their role in starting and quitting smoking. In order to identify differences between the different harm reduction products, we also include medications and snus, even though those aren't counted among the innovation products on the nicotine market.

6. Nicotine-containing medications

6.1 History

Nicotine-containing medications – nicotine gum, nicotine plasters and nicotine inhalers – have been purchasable in Norway since 1986. At the time, nicotine gum had already been available in Switzerland since 1978, in Sweden since 1982 and the USA since 1984. Until 2003, nicotine medications were only available on prescription, but were subsequently released for over-the-counter sale in shops. As therapeutic products, nicotine medications were originally designed solely to be marketed towards use in quitting smoking. Each year the presented products have grown somewhat „fresher". Gradually, mouth-sprays, lozenges and oral powders in portion bags, the so-called nicopads (nicotine salts packed in cellulose pads) have been added to the range of nicotine-containing medications – all in a variety of flavours. The nicotine in the medications is extracted from tobacco leaves. Most of the products come from the pharmaceutical industry (e.g. Nicorette) or from pharmaceutical companies owned by the cigarette industry (e.g. Zonnic) (see chapter 10). A common characteristic is that they are marketed with therapeutic claims regarding quitting smoking and that they have been subject to tests regarding tolerance and side effects. The products' status as prescription free has given rise to the producers advertising to the public within the limitations set by the Norwegian Medicines Act [legemiddelloven] and Medicines Regulations [legemiddelforskriften].

6.2 User composition

The users of nicotine gum, nicotine plaster and nicotine inhalers – the classic nicotine medications – are for all intents and purposes solely used by smokers or former smokers. Use among non-smokers hasn't been subject to research or been a concern for the tobacco control community for the 30+ years that the nicotine-containing medications have been available.

Among smokers the medications have three functions, i) a way to stop smoking cigarettes, ii) a way to limit nicotine withdrawal when spending time in smoke-free environments and iii) among former smokers, a way to prevent relapsing back to cigarettes. The first two functions might involve shorter or longer periods with concurrent use of nicotine medications and cigarettes. Nevertheless, concurrent use hasn't been used as a significant objection to the nicotine medications. In the latter function, the medications present a risk of extended nicotine use. This too has not caused any significant concern within the tobacco control movement. In 2010 the U.K. Medicines and Healthcare Products Regulatory Agency declared that long-term use of nicotine medications was acceptable as a harm-reducing alternative for smokers that didn't intend to quit smoking[60]

No user surveys have been carried out for newer nicotine medications on the Norwegian market, such as oral powder in portion bags (nicopads e.g. Zonnic). However, the Norwegian Directorate for Health and Social Affairs has cracked down on a string of adverts for Zonnic, which they feel was likely to appeal to target audiences beyond smokers.

6.3 Effect on quitting smoking

At the population level the effectiveness of a product for quitting smoking is determined by a combination of three factors. Firstly, the effect – that the use actually increases the likelihood of successfully quitting. Secondly, how many people use the product to quit smoking, including whether the product appeals to smokers who don't want to use the recommended methods for quitting smoking. Thirdly, whether the product has the ability to produce „accidental quitters". These are smokers who are experimenting with an alternative nicotine product for other reasons than quitting smoking, but who, as a result of this experimenting, stop smoking anyway.

Nicotine medications have been subject to comprehensive testing in randomised controlled studies over several decades. In these the outcomes of quitting smoking after 6 or 12 months in groups that were given nicotine medications were compared to groups that were given placebos or no medication. Systematic summaries of the research literature showed that about 16% of smokers managed to stay smoke-free after one year with the use of nicotine medications[61]. This means that approximately 84% relapsed into smoking over the course of

[60] Medicines and Healthcare products Regulatory Agency (February 2010). Extension of the indication for nicotine replacement therapy (NRT) to include harm reduction. https://www.gov.uk/drug-safety-update/nicotine-replacement-therapy-and-harm-reduction

[61] http://www.cochrane.org/CD000146/TOBACCO_can-nicotine-replacement-therapy-nrt-help-people-quit-smoking
https://www.ncbi.nlm.nih.gov/pubmed/23152200

the observation period – most of them after a short time. For every smoker that is „cured" there are thus between 5 and 6 that aren't. The quitting rate is better than the results in the control groups, where the relapse rate was 90% in the placebo group and 92% in the group without medicine. In adverts for the nicotine medications it is said that the usage doubles the odds of successfully quitting.

6.2.1 Effects in studies and in the „real world"

The 16% estimated quitting rate is, in the research world, seen as an optimistic result. Several[62],[63],[64],[65],[66],[67],[68],[69] – but not all[70] – studies have shown that a lot of the effect vanishes when the medications are used outside the study context – that is, in the smokers' natural context. This may to some extent be due to the smokers not following the usage recommendations when they have to administer it themselves, and that they thus don't obtain the full potential effect.

Another reason might be that the experimental studies were carried out in conditions that produced overly positive results. Firstly, research shows that the strict requirements for the acceptance of smokers into the experimental tests leads to the studied people being quite different from the remaining group of smokers in society. In a nationally representative American study on about 5000 smokers, they found that a total of 66% of them had one or more of the characteristics that the pharmaceutical industry use to exclude certain patient groups from participating in the testing of their nicotine medications – including people with cardiovascular diseases, high blood pressure, depression, eating disorders, high alcohol consumption, use certain medication types and 20 other conditions[71]. Simultaneously another American study showed that more than half the volume of tobacco was consumed by people who reported that they'd had an episode of mental illness of some type within the last month.

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[62] Alpert HR, Connolly GN, Biener L. A prospective cohort study challenging the effectiveness of population-based medical intervention for smoking cessation. Tobacco Control 2013;22:32-37. http://tobaccocontrol.bmj.com/content/22/1/32

[63] Alberg AJ, Patnaik JL, May JW, et al. Nicotine replacement therapy use among a cohort of smokers. J Addict Dis 2005;24:101–13.

[64] Buck D, Morgan A. Smoking and quitting with the aid of nicotine replacement therapies in the English adult population. Results from the Health Education Monitoring Survey 1995. Eur J Public Health 2001;11:211–17

[65] Walsh RA. Over-the-counter nicotine replacement therapy: a methodological review of the evidence supporting its effectiveness. Drug Alcohol Rev 2008;27:529–47.

[66] Pierce JP, Gilpin EA. Impact of over-the-counter sales on effectiveness of pharmaceutical aids for smoking cessation. JAMA 2002;288:1260–4.

[67] Cummings KM, Hyland A. Impact of nicotine replacement therapy on smoking behavior. Annu Rev Public Health 2005;26:583–99

[68] Thorndike AN, Biener L, Rigotti NA. Effect on smoking cessation of switching nicotine replacement therapy to over-the-counter status. Am J Public Health 2002;92:437–42

[69] Kotz D, Brown J, West R.'Real-world' effectiveness of smoking cessation treatments: a population study. Addiction. 2014 Mar;109(3):491-9.

[70] West R, Zhou X. Is nicotine replacement therapy for smoking cessation effective in the "real world"? Findings from a prospective multinational cohort study. Thorax 2007;62:998-1002. http://thorax.bmj.com/content/62/11/998.info

[71] Le Strat Y, Rehm J, Le Foll B. How generalisable to community samples are clinical trial results for treatment of nicotine dependence: a comparison of common eligibility criteria with respondents of a large representative general population survey. Tobacco Control 2011;20:338-343. http://tobaccocontrol.bmj.com/content/20/5/338

The group of smokers invited to participate in the experimental studies are more resourceful and more able to master things than other smokers in society, and this might reduce the scope for generalising the result to all smokers.

Secondly, research shows that the pharmaceutical industry pays for 55% of the experimental studies itself. The results of these studies are, on average, better than in the remaining 45% of the studies that aren't paid for by the pharmaceutical industry[72]. The cause for this might be that the industry to a greater extent fails to publish studies that don't show an effect, as it doesn't serve their economic interest. This is in addition to the general tendency for studies that cannot show any effect from an intervention – regardless of financing and subject – to remain unpublished more often than studies that can document an effect. The portfolio of studies that are included in the systematic summaries on the nicotine medications can thus be somewhat selective and display overly positive results.

Thirdly, those who participate in the experimental studies have to report results to the health staff managing the study. The smokers' recognition that they are being observed and monitored activates the so-called Hawthorne effect, which increases effort and performance, both in those who are given active medication and in those who are given a placebo[73]. This artificial condition is not present for „real world"-situations.

Fourthly, research shows that about 30% of those that manage to remain smoke-free through nicotine medications for the duration of the experiment start smoking again once the observation period has finished[74].

In addition to the problem of lack of effect comes the problem of lack of use. At a population level, even a weak effect from a nicotine medication may be significant if enough people choose to use the products. However, nicotine medications were designed to be unattractive and they provide smokers with small, potentially unsatisfactory, nicotine doses. They are used in a treatment context where the smoker is a patient and withdrawal from cigarettes is medicated. Most smokers, however, do not regard smoking as an illness that needs to be treated. Among the 25% of smokers that try to quit each year, roughly 15% report that nicotine medications were among the methods they used.

Even though nicotine medications have helped a lot of smokers cut out cigarettes, the moderate effect on quitting smoking, combined with the low prevalence, means that the decrease in smoking in Norway – and other countries in the later stages of the cigarette epidemic – must be primarily due to other factors[75].

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[72] Etter, JF, Burri M, Stapleton J. (2007). The impact of pharmaceutical company funding on results of randomized trials of nicotine replacement therapy for smoking cessation: a meta-analysis. Addiction, 102: 815–822. https://www.ncbi.nlm.nih.gov/pubmed/?term=Etter%2C+Burri%2C+Stapleton

[73] Chen, L., Vander Weg, M., Hofmann, D., & Reisinger, H. (2015). The Hawthorne Effect in Infection Prevention and Epidemiology. Infection Control & Hospital Epidemiology, 36(12), 1444-1450. https://www.ncbi.nlm.nih.gov/pubmed/26383964

[74] Etter J, Stapleton JA. Nicotine replacement therapy for long-term smoking cessation: a meta-analysis. Tobacco Control 2006;15:280-285. https://www.ncbi.nlm.nih.gov/pubmed/?term=Etter+%26+Stapleton+2006

[75] Cummings KM, Hyland A. Impact of nicotine replacement therapy on smoking behavior. Annu Rev Public Health. 2005;26:583-99. https://www.ncbi.nlm.nih.gov/pubmed/15760302

7. Snus containing tobacco

7.1 History

The use of Scandinavian types of snus is not prevalent outside of Norway and Sweden but, as a potential harm-reducing product, snus has still gained international attention. Already in the 1980s, some scientific articles claimed that snus could be a harm-reducing alternative to cigarettes[76],[77]. It was only in 2001 that snus was categorised as a „potentially reduced exposure product" by the Institute of Medicine in the USA, in the book „Clearing the Smoke: The Science Base for Tobacco Harm Reduction"[78]. In 2006 an international scientific panel tried to say something about the potential rewards to public health in letting snus compete with cigarettes on the American nicotine market[79]. In 2007 snus was included in the portfolio of harm-reducing products by the Royal College of Physicians (RCP) in the report „Harm reduction in nicotine addiction: helping people who can't quit". In addition to communicating the difference in harm between snus and cigarettes, snus was also judged by RCP *as being part of a possible solution to smoking as a public health issue.* They referred, among other things, to the extraordinarily low occurrence of tobacco-related deaths among Swedish men, who had consumed just as much tobacco as the European average, but where the most of the tobacco had been consumed as snus[80],[81]. Swedish men have for a long time had the lowest proportion of smokers in Europe by far[82].

In 2014, the snus producer Swedish Match applied to the FDA to get snus categorised as a „modified risk tobacco product (MRTP)", and that increased international awareness of snus as a harm reduction product. With MRTP status, the producer would have been able to change the health warning on snus from „This product is not a safe alternative to smoking" to „No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes.". In December 2016, however, the FDA decided that not to be given MRTP status, while recommending that Swedish Match send in a revised application[83].

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[76] Russell MAH, Jarvis MJ, Feyerabend C. A new age for snuff? Lancet 1980; 1: 474–475.

[77] Kirkland LR. The nonsmoking uses of tobacco. New Engl J Med 1980; 303: 165

[78] Clearing the Smoke. Assessing the Science Base for Tobacco Harm Reduction. Institute of Medicine (US) Committee to Assess the Science Base for Tobacco Harm Reduction; Editors: Kathleen Stratton, Padma Shetty, Robert Wallace, and Stuart Bondurant. Washington (DC): National Academies Press (US); 2001. https://www.ncbi.nlm.nih.gov/books/NBK222375/

[79] Levy DT, Mumford EA, Cummings KM, Gilpin EA, Giovino GA, Hyland A, Sweanor D, Warner KE, Compton C. The potential impact of a low-nitrosamine smokeless tobacco product on cigarette smoking in the United States: estimates of a panel of experts. Addict Behav. 2006 Jul;31(7):1190-200. https://www.ncbi.nlm.nih.gov/pubmed/16256276

[80] Ramström L, Wikmans T. Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report. Tobacco Induced Diseases. 2014;12(1):14. https://www.ncbi.nlm.nih.gov/pubmed/25191176

[81] Rodu B, Cole P. Lung cancer mortality: Comparing Sweden with other countries in the European Union. Scandinavian Journal of Public Health Vol 37, Issue 5, pp. 481 – 486. https://www.ncbi.nlm.nih.gov/pubmed/19535408

[82] Share of individuals who currently smoke cigarettes, cigars, cigarillos or a pipe in selected European countries in 2017. https://www.statista.com/statistics/433390/individuals-who-currently-smoke-cigarettes-in-european-countries/

[83] https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm533454.htm

Ireland banned snus in 1988, followed by England and Belgium in 1990. The cause of this was an aggressive marketing campaign by an American snus-like product „Skoal Bandits" from the US Smokeless Tobacco Company (USSTC)[84]. The EU introduced its ban on snus in 1992. The reason for the ban was to prevent the spread of a new potentially carcinogenic tobacco product in countries that previously didn't have any history of snus consumption. As a result, Sweden was granted an exemption from the ban when it joined the EU in 1995. The EU decided to renew the snus ban in its tobacco products directives of both 2001 and 2014. Following complaints from Swedish Match, the European Court of Justice will reassess the legality of the snus ban over the course of 2018.

In contrast with the nicotine-containing medications and e-cigarettes, snus is a tobacco product, and as a result the snus producers are counted as a branch of the general tobacco industry – even if they don't produce cigarettes themselves. This industry has incurred a justified reputation issue. The snus industry thus starts out from a position of low trustworthiness when sending messages about snus in a harm reduction policy.

7.1.1 Snus and harm reduction in Norway

In Norway, the harm reduction perspective is only superficially discussed in the Norwegian Knowledge Centre for the Health Services' report „The effects of snus use" of 2005[85]. It is accepted that the absence of a harm reduction perspective should be seen as a limitation of the report, and that this omission is due to the subject being deemed quite complicated, and thus burdened with normative judgements outside the mandate. The report does still present some interesting questions – but without providing any answers:

1. *Is harm-reducing use of snus morally acceptable?*
2. *Does this change the status of snus: Should snus thus be seen as a medication?*
3. *How should one handle the negative (side) effects of the use of snus?*
4. *How should the negative effects be weighed against the benefit (the benefit principle)?*
5. *How should one (in official contexts) recommend means that one knows are harmful and addictive (the principle of do no harm)?*

In 2007 The Norwegian Dental Associations' Journal published two articles, in which the authors debated whether snus could be considered a recommended harm-reducing alternative for those who fail to quit smoking[86],[87]. In 2009, the harm reduction potential of snus was discussed in a separate report from SIRUS[88]. The matter was subsequently subject to a year-long debate in print and broadcast media. Similarly to the 2005 report from the Norwegian Knowledge Centre for the Health Services, the 2014 report from the Norwegian Institute of

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[84] Raw M, White P, McNeill A. Case Study 9: Skoal Bandits, in "Clearing the Air: A guide for action on tobacco", 1990, British Medical Association, on behalf of the World Health Organization, Regional Office for Europe, London, p. 100-112.

[85] Virkninger av snusbruk. (The effects of the use of snus) Dybing E, Gilljam H, Lind P, Lund K, Mørland J, Stegmayr B, Hofmann B, Elvsaas I. Virkninger av snusbruk. Report from the Norwegian Knowledge Centre for the Health Services no. 06 – 2005. http://www.kunnskapssenteret.no/publikasjoner/virkninger-av-snusbruk

[86] Lund KE. „Snus bør kunne brukes i røykeavvenning av mislykkede 'sluttere'." (Snus should be usable to help failed 'quitters' stop smoking) http://www.tannlegetidende.no/i/2007/6/dntt-241065.

[87] Huseby K. & Klepp KI. «Anbefaler ikke snus som røykavvenningsmiddel». (Do not recommend snus as a means to quit smoking) http://www.tannlegetidende.no/i/2007/7/dntt-245400

[88] Lund KE. „Tobakksfritt samfunn eller skadereduksjon?", Norwegian Institute for Alcohol and Drug Research (SIRUS). Rapport 2/2009. https://www.fhi.no/publ/eldre/tobakksfritt-samfunn-eller-skadereduksjon/

Public Health „Helserisiko ved snus" (Health risks from snus) did not discuss the harm reduction potential of snus[89]. As the title suggests, the subject of the report was solely the potential for harm from the use of snus.

7.1.2 The suggestion to ban the sale of snus

A publicly appointed expert committee, under the leadership of professor Grethe S. Tell at the University of Bergen/The Norwegian Institute of Public Health suggested in February 2013 that, among other things, snus should be banned in Norway before 2017[90]. The committee had been tasked by the Norwegian Directorate for Health and Social Affairs to assess measures that might reduce the occurrence of non-contagious chronic diseases such as cancer, cardiovascular diseases and COPD. While snus was to be banned, the stance of the Tell-committee was that cigarettes could continue to be sold with nothing more than an increase of the age limit from 18 to 20 years. The suggestion from the Tell-committee may serve as an illustrative example of policymaking that is quite far from a harm reduction ideology. The same can be said for previous years' adjustments to the government budget regarding the taxation of tobacco products. Here the increase in the taxation of snus has been greater than the increase for cigarettes.

The then health and care minister Jonas Gahr Støre immediately replied that a ban on snus wasn't appropriate[91], a decision that his successor Bent Høie would later stick to[92]. The health ministers' decision not to take up the suggestion of the Tell-committee could be interpreted as being in line with step 1 (market access) in a harm reduction policy (see chapter 4.1). Even though the yearly tax increases have been higher for snus than for cigarettes, the tax level on snus is still considerably lower than for cigarettes and other combustion products. This difference in tax level could be said to be in line with step 2 (the proportionality principle) of a damage reduction policy (see chapter 4.2).

7.2 User composition

In 2017 an article in Addiction accounted for changes in the distribution of snus-users in Norway[93]. By analysing data from annual questionnaires of the population, the researchers studied the development of the number of smokers, former smokers, never-smokers among men (15-74 years) that stated that they were users or former users of snus. During the 12-year observation period, 2003-2015, the number of smokers within the population had decreased markedly, and the problem posed was thus to investigate whether the section of never-smokers among snus users had increased at the cost of current and past smokers.

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[89] Helserisiko ved bruk av snus (Health risks from snus), Norwegian Institute of Public Health. Rapport November 2014. https://www.fhi.no/publ/2014/helserisiko-ved-bruk-av-snus/

[90] Anderssen, S; Graff-Iversen, S; Grimsrud, TK; Hjelmesæth, J; Devold, KK; Krokstad, S; Kumar, BN; Løchen, ML; Rugtvedt, L; Tell, GS; Øzerk, O. Reduksjon i ikke-smittsomme sykdommer – nasjonal oppfølging av WHOs mål (Reduction in non-contageous diseases – national follow-up of the targets of the WHO). Oslo: The Norwegian Directorate for Health and Social Affairs 2013 77

[91] https://www.aftenposten.no/norge/i/3J9K9/Helseeksperter-vil-forby-snus-og-pappvin

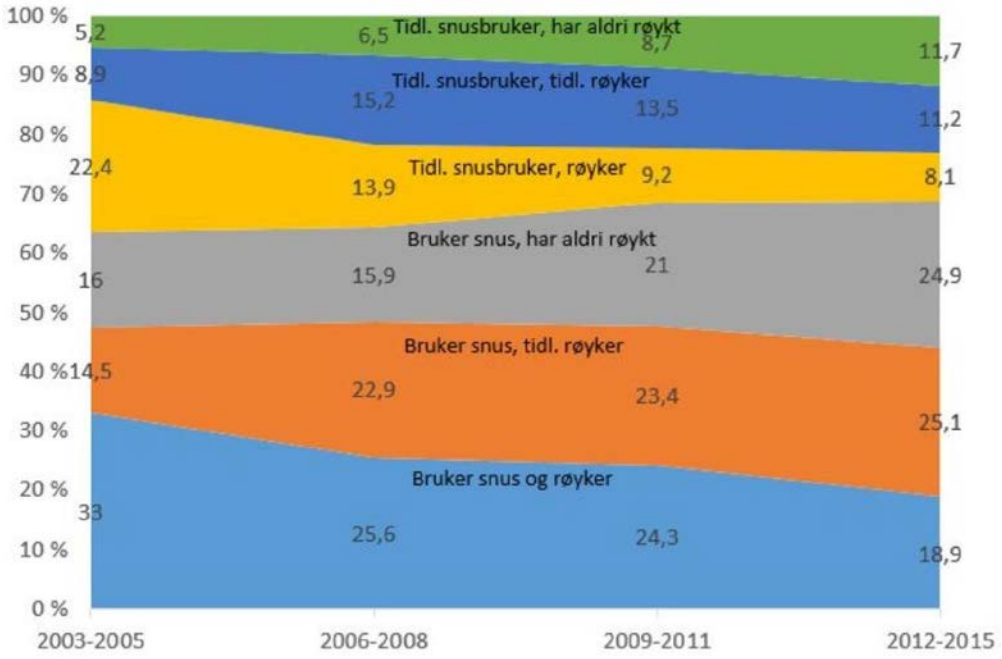
[92] https://www.nrk.no/norge/-synd-at-hoie-avviser-snus-forbod-1.12052387

[93] Lund, K. E., Vedøy, T. F., and Bauld, L. (2017) Do never smokers make up an increasing share of snus users as cigarette smoking declines? Changes in smoking status among male snus users in Norway 2003–15. Addiction, 112: 340–348. https://www.ncbi.nlm.nih.gov/pubmed/?term=Lund%2C+Ved%C3%B8y+%26+Bauld+2017

The Norwegian Institute of Public Health summarised the results of the study on its website as follows:

> **Most men who use snus or who have used snus are smokers or former smokers**
>
> *In spite of the proportion of smokers decreasing, most snus users come from the smoking section of the population. Among men that, in the period 2011-15, reported that they used snus or had previously used snus, a total of 63% were either former (36%) or current smokers (27%). In 2003, however, the proportion of people without previous experience of smoking had increased from 21 to 37 percent within the same group. This is shown in a new study from The Norwegian Institute of Public Health*[94].

Figure 3. Norwegian men (15-74 years old) that use or have used snus, divided into six groups according to their smoking status. The period 2003-2015.



> *Group 1: Concurrent users of snus and cigarettes (light blue). The relative size of this group among snus users was reduced from 33 percent to 19 percent during the study period. All of 70 percent had started with cigarettes before they started snus. 75 percent had used snus in an attempt to stop smoking. When the researchers compared them to people who only smoked cigarettes, concurrent users reported a 37 percent lower cigarette consumption, twice as many had cut back from smoking daily to smoking occasionally, significantly more thought they would be smoke-free in 5 years' time.*
>
> *Group 2: Former smokers that use snus (orange). The relative size of this group had increased from 15 percent to 25 percent. 83 percent reported that they had used snus when they stopped smoking. 68 percent had started smoking before they started snus. 86 percent thought they would also be smoke-free in 5 years' time.*
>
> *Group 3: Current snus users that have never smoked (grey). The group comprised 16 percent at the start of the period and 24 percent at the end. 95 percent also saw themselves being smoke-free in 5 years' time.*

[94] De fleste menn som snuser eller har brukt snus er røykere eller tidligere røykere. Folkehelseinstituttet 22 desember 2016. https://www.fhi.no/nyheter/2016/de-fleste-menn-som-snuser-eller-har-brukt-snus-er-roykere-eller-tidligere-r/

Group 4: Former snus users, current smokers (yellow). The relative share was reduced from 22 percent to 8 percent over the period. 77 percent had started with cigarettes as their first product. The cigarette consumption within the group was just as high as the one in the group of smokers that had never used snus, and thus much higher than with the concurrent users (group 1).

Group 5: Former snus users, former smokers (dark blue). The proportion remained more or less stable at 10-15 percent across the period. 77 percent had started with cigarettes. 90 percent saw themselves being smoke-free in 5 years' time. 48 percent reported that they had used snus when they stopped smoking.

Group 6: Former snus users that have never smoked (green). The proportion had increased from 5 percent to 12 percent. 96 percent thought they would be smoke-free in 5 years' time

7.2.1 Future user composition

When the most important reservoir of potential snus users – the smokers – is shrinking, this would be expected to result in fewer snus users in the future. It is hard to believe that the prevalence of snus use will reach the same epidemic proportions as cigarette smoking had among men in the start of the 1960s. In the group of males born 1925-35, the share of smokers at that time almost reached 80%[95].

Another consequence of the decrease in smoking is that it will also end up shifting the ratio of smokers and non-smokers among snus users. We must expect the proportion of people with previous smoking experience to continue to decrease among new snus users.

7.3 What segment do the new snus users come from?

In 1985, 5% of the tobacco in Norway was consumed as snus, while 95% was consumed as cigarettes. In 2017, this has risen to 40% snus and 60% cigarettes. Within the same period, the total tobacco consumption had been reduced by approx. 35%. The growth in snus consumption accelerated from the start of the 1990s, and was particularly fast for a period after the turn of the century. The number of daily snus users among adult men (16-74 years old) increased from 5% in 1985 to 15% in 2016. In this period the proportion that reported using snus occasionally was stable at about 5%. For women, the proportion of daily snus users increased from 0% in 1985 to 5% in 2016. The proportion that used snus occasionally increased from 0% to 3%.

The growth in snus usage happened in parallel with a reduction in the cigarette consumption, and this inverse relationship was particularly apparent among youths. Among men in the age range of 16-24 years, daily use of snus increased from 5% in 1985 to a peak of 25% in 2011, to then drop to 20% in 2015. Occasional use increased from 8% to 16% in 2005, but is now back at 8%. The same flattening has not yet been observed among women within the same age range. Amongst young women, the proportion of daily users has increased from 1% to 17%, while the proportion of occasional users has increased from 3% to 8%.

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[95] Lund I, Lund KE. Lifetime smoking habits among Norwegian men and women born between 1890 and 1994: a cohort analysis using cross-sectional data. BMJ Open 2014;4:e005539. http://bmjopen.bmj.com/content/4/10/e005539

The increase in snus usage amongst youths occurs i) partially because young smokers also use snus to quit or cut down on cigarettes, ii) partially because potential smokers choose snus instead of cigarettes and iii) partially because youths that never would have started smoking start using snus. The increase in snus usage thus occurs as a result of an increasing inflow of people from *all* these three segments. The empirical challenge is to separate these.

7.3.1 'Primary smokers, secondary snus users'

Approximately 25% of young male snus users in 2015 had started with cigarettes as their first product, to then switch to snus (primary smokers, secondary snus users). In 2003 the relative share of this group was all of 60%. The fact that even fewer young snus users have previous experience of smoking is a consequence of the decimation of the number of young men that smoke.

7.3.2 'Primary snus users'

Thus in 2015, it was 75% of the young male snus users that hadn't previously smoked cigarettes (primary snus users). This group must again be divided in two. This group firstly consists of youths that would have been free of tobacco in the hypothetical absence of the availability of snus. In a harm reduction context, these are regarded as 'unnecessary snus users', as their snus usage doesn't have a harm-reducing function in relation to smoking. We don't know how large this segment is, but we must assume that their relative proportion of the group 'primary snus users' will increase as smoking is denormalised.

7.3.3 Is there a predestined group of smokers?

Secondly, the group of 'primary snus users' consists of potential smokers that have chosen snus over cigarettes. These are youths that might have characteristics that have been shown to predict taking up smoking – that is, psychological, environmental, demographic and possibly even genetic characteristics that increase the probability of smoking – but they then chose snus instead of cigarettes. It is impossible to estimate the size of this segment. But as smoking is denormalised in society, smoking will start to appear as a less appropriate choice of action for youths. This is both due to changes in the environmental conditions surrounding the decision to take up smoking, and changes to the preference structure regarding relevant counter-normative choices of action.

The narrowing of the social settings wherein smoking can take place, fewer smokers in one's social environment and a more negative symbolism in both behaviour (smoking) and in the product itself (the cigarettes and packs) will end up reducing the smoking-inducing effects from such *environmental* influencing factors.

The number of youths with *personality* (and possibly genetic) traits that predispose them to counter-normative and/or risky choices of action (e.g. smoking), however, must be assumed to be quite stable. But in a situation where the cigarette is denormalised, smoking will likely be given a lower priority in the repertoire of counter-normative choices of action for those youths where that might be relevant. Sensation-seeking youths might, instead of smoking, end up choosing e.g. base hopping or metro-surfing to distinguish themselves. It thus doesn't make

much sense to speak of a certain segment of youths as being statutorily predestined to be smokers. Even in the group of youths with characteristics that predispose them towards problematic behaviour, smoking will appear as a possible individual choice of action in competition with other behavioural choices that might symbolise a lot of the same as smoking to the surroundings[96].

On the other hand, the denormalisation of smoking might also enhance the cigarette's function as a mark of distinction in a youth segment that precisely wishes to highlight its separation from normality and mainstream culture[97],[98]. For them it is the marginalisation itself and the social 'outing' of smoking that makes the behaviour attractive. We do not know how large this segment is. Nor do we know whether snus is used by youths to replace the cigarette's symbolic function as a mark of being different. A Norwegian study of tobacco user's perceptions of themselves and their product in part showed large differences between smokers and snus users[99], something that might suggest that snus has different symbolic functions than cigarettes.

There is no perception, in the concept of 'potential smokers', of a clearly defined youth segment that surely would have chosen cigarettes in the hypothetical absence of snus or e-cigarettes. Still, we must assume that some 'primary snus users' would have chosen cigarettes, had snus not been available. The opposite would be very surprising – that the entire population of young 'primary snus users' (and 'primary vapers' with regards to e-cigarettes) would have been nicotine-free in the hypothetical absence of these products.

7.3.4 When does the increase in snus use among youths become a problem?

The growth in snus use would constitute a problem were the increase primarily caused by an inflow of youths that, in the absence of snus, would have remained tobacco free. If that growth has instead arisen as a result of youths having chosen snus over cigarettes, either as part of quitting smoking or as their initiation into the use of tobacco, the increase in snus use would not equate to something negative – quite the contrary.

There has been a lot of attention surrounding the increased use of snus among youths, and the growth has been regarded as being very worrisome throughout. A more nuanced picture emerges if the increase in the use of snus is also considered in the light of the parallel reduction in smoking, and by establishing a perspective where one tries to identify and weigh the negative against the positive health outcomes in the three segments that have caused the growth in snus use among youths. This is a task for future research.

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[96] Jessor R. Problem-behavior theory, psychosocial development, and adolescent problem drinking, British Journal of Addiction, 1987, Vol. 82, pp. 331-342.

[97] Bilgrei O. Forsvar og motstand. En sosiologisk studie av røyking og stigma. Masteroppgave. 2011, UiO. https://www.duo.uio.no/handle/10852/15359

[98] Pampel FC. Socioeconomic Distinction, Cultural Tastes, and Cigarette Smoking. Soc Sci Q. 2006 Mar; 87(1): 19–35. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3160811/

[99] Lund M, Lund KE, Halkjelsvik T. Contrasting smokers' and snus users' perceptions of personal tobacco behavior in Norway. Nicotine Tob Res. 2014 Dec;16(12):1577-85. https://www.ncbi.nlm.nih.gov/pubmed/24991039

7.4 Effect on quitting smoking

Snus containing tobacco is not presented to consumers with therapeutic claims regarding quitting smoking, and it is thus not appropriate for the producer to fund expensive and time-consuming experimental studies in the way that is done for nicotine-containing medications. Among the few experimental studies that have been carried out the results vary between having found the same effect as nicotine medications[100],[101], a favourable effect on the biomarkers for smoking[102], reduced cigarette consumption and increased motivation to quit smoking[103], reduced alcohol-related smoking[104], superior effects to NRT (financed by Swedish Match)[105] and a reduced urge to smoke[106]. A lot of the criticism that was directed towards the experimental studies regarding the effect of nicotine medications on quitting smoking (chapter 6.3.1) can also be directed at these studies.

In spite of snus not being considered a product for quitting smoking, snus has still become the most commonly used method – after unassisted attempts at quitting – of quitting in Norway (see figure 7). The fact that snus seems to play a role in quitting smoking is supported by results from survey studies that show that quitting smoking is a widespread motivation for the additional use of snus among Norwegian smokers[107]. Added to this is the fact that intentions of becoming smoke free in five years' time are more prevalent among concurrent users than among smokers that don't use snus[108]. Several observational studies have documented that the quitting rate for smoking among users of snus is higher than the quitting rate for smoking among people who don't use snus[109],[110],[111],[112],[113],[114],[115],[116],[117],[118],[119],[120]. Three observational

[100] Hatsukami DK, Severson H, Anderson A, et al. Randomised clinical trial of snus versus medicinal nicotine among smokers interested in product switching. Tobacco Control 2016;25:267-274. https://www.ncbi.nlm.nih.gov/pubmed/25991608

[101] Kotlyar M, Hertsgaard LA, Lindgren BR, et al. Effect of oral snus and medicinal nicotine in smokers on toxicant exposure and withdrawal symptoms: a feasibility study. Cancer Epidemiol Biomarkers Prev. 2011 Jan;20(1):91-100 https://www.ncbi.nlm.nih.gov/pubmed/21068204

[102] Hatsukami DK, Severson H, Anderson A, et al. Randomised clinical trial of snus versus medicinal nicotine among smokers interested in product switching. Tobacco Control 2016;25:267-274. https://www.ncbi.nlm.nih.gov/pubmed/25991608

[103] Burris JL, Carpenter MJ, Wahlquist AE et al. Brief, Instructional Smokeless Tobacco Use Among Cigarette Smokers Who Do Not Intend to Quit: A Pilot Randomized Clinical Trial, Nicotine & Tobacco Research, Volume 16, Issue 4, 1 April 2014, Pages 397–405 https://www.ncbi.nlm.nih.gov/pubmed/24130144

[104] Peloquin MP, Hecimovic K, Sardinha J et al. The effect of snus on alcohol-related cigarette administration in dependent and non-dependent smokers. Pharmacol Biochem Behav. 2013 Dec;114-115:97-102. https://www.ncbi.nlm.nih.gov/pubmed/24012648

[105] Fagerstrom K, Rutqvist LE, Hughes JR. Snus as a Smoking Cessation Aid: A Randomized Placebo-Controlled Trial, Nicotine & Tobacco Research, Volume 14, Issue 3, 1 March 2012, Pages 306–312 https://www.ncbi.nlm.nih.gov/pubmed/21994343

[106] Barrett SP, Campbell ML, Temporale K, Good KB. The acute effect of Swedish-style snus on cigarette craving and self-administration in male and female smokers. Hum Psychopharmacol. 2011 Jan;26(1):58-62. https://www.ncbi.nlm.nih.gov/pubmed/21305611

[107] Lund KE, McNeill A. Patterns of Dual Use of Snus and Cigarettes in a Mature Snus Market, Nicotine & Tobacco Research, Volume 15, Issue 3, 1 March 2013, Pages 678–684. https://academic.oup.com/ntr/article/15/3/678/1088963

[108] Lund, K. E., Vedøy, T. F., and Bauld, L. (2017) Do never smokers make up an increasing share of snus users as cigarette smoking declines? Changes in smoking status among male snus users in Norway 2003–15. Addiction, 112: 340–348. https://www.ncbi.nlm.nih.gov/pubmed/?term=Lund%2C+Ved%C3%B8y+%26+Bauld+2017

[109] Lund KE, Scheffels J, McNeill A. The association between use of snus and quit rates for smoking: results from seven Norwegian cross-sectional studies. Addiction. 2011 Jan;106(1):162-7. https://www.ncbi.nlm.nih.gov/pubmed/20883459

studies found that smokers that had used snus as a way of quitting were more often smoke-free than smokers that had used nicotine-containing medications[121], [122], [123].

7.4.1 Accidental quitters

When researchers have to identify effects from a quitting product, three approaches have to be used. At the individual level, we attempt to trace the effect through the use of randomised controlled experiments (RCT). In these the result of the treatment with the actual product (e.g. snus) for quitting smoking is compared with the result in so-called control groups that have either been given a placebo, been subject to an already approved treatment form (e.g. NRT) or not been offered any treatment. RCT primarily provides information on a products *effect potential* – i.e. what can be achieved within the conditions that apply in a clinical setting. As previously mentioned (see chapter 6.3.1), results from RCT cannot be simply transferred to real world situations.

When we need to find out the effect of a method for quitting smoking at a population level we thus need to consider the loss of effect between the product being used in the clinical setting to the product being used in a natural setting and – more importantly – how willing smokers would be to use the product. How many smokers with intentions of quitting actually use the product?

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[110] Ramström LM, Foulds J. Role of snus in initiation and cessation of tobacco smoking in Sweden. Tobacco Control 2006;15:210-214. http://tobaccocontrol.bmj.com/content/15/3/210

[111] Gilljam H1, Galanti MR. Role of snus (oral moist snuff) in smoking cessation and smoking reduction in Sweden. Addiction. 2003 Sep;98(9):1183-9. https://www.ncbi.nlm.nih.gov/pubmed/12930201

[112] Lund I, Lund KE. How has the availability of snus influenced cigarette smoking in Norway? Int J Environ Res Public Health. 2014 Nov 13;11(11):11705-17. https://www.ncbi.nlm.nih.gov/pubmed/25402565

[113] Stegmayr B, Eliasson M, Rodu B. The decline of smoking in northern Sweden. Scand J Public Health. 2005;33(4):321-4. https://www.ncbi.nlm.nih.gov/pubmed/16087495

[114] Rodu B, Stegmayr B, Nasic S, Asplund K. Impact of smokeless tobacco use on smoking in northern Sweden. J Intern Med. 2002 Nov;252(5):398-404. https://www.ncbi.nlm.nih.gov/pubmed/12528757

[115] Rodu B, Stegmayr B, Nasic S, Cole P, Asplund K. Evolving patterns of tobacco use in northern Sweden. J Intern Med. 2003 Jun;253(6):660-5. https://www.ncbi.nlm.nih.gov/pubmed/12755962

[116] Lindström M1, Isacsson SO; Malmö Shoulder-Neck Study Group. Smoking cessation among daily smokers, aged 45-69 years: a longitudinal study in Malmö, Sweden. Addiction. 2002 Feb;97(2):205-15. https://www.ncbi.nlm.nih.gov/pubmed/11860392

[117] Furberg H, Lichtenstein P, Pedersen NL, Bulik CM, Lerman C, Sullivan PF. Snus use and other correlates of smoking cessation in the Swedish Twin Registry. Psychol Med. 2008 Sep;38(9):1299-308. https://www.ncbi.nlm.nih.gov/pubmed/18680625

[118] Furberg H, Bulik CM, Lerman C, Lichtenstein P, Pedersen NL, Sullivan PF. Is Swedish snus associated with smoking initiation or smoking cessation? Tob Control. 2005 Dec;14(6):422-4. https://www.ncbi.nlm.nih.gov/pubmed/16319367

[119] Stenbeck M, Hagquist C, Rosén M. The association of snus and smoking behaviour: a cohort analysis of Swedish males in the 1990s. Addiction. 2009 Sep;104(9):1579-85. https://www.ncbi.nlm.nih.gov/pubmed/19686528

[120] Lund KE, Tefre EM, Amundsen A, Nordlund S. Cigarette smoking, use of snuff and other risk behaviour among students. Tidsskr Nor Laegeforen. 2008 Aug 28;128(16):1808-11. https://www.ncbi.nlm.nih.gov/pubmed/?term=lund+KE+%26+Nordlund+S

[121] Scheffels J, Lund KE, McNeill A. Contrasting snus and NRT as methods to quit smoking. an observational study. Harm Reduct J. 2012 Feb 29;9:10. https://www.ncbi.nlm.nih.gov/pubmed/22376006

[122] Rutqvist LE. Population-based survey of cessation aids used by Swedish smokers. Harm Reduct J. 2012 Dec 4;9:38. https://www.ncbi.nlm.nih.gov/pubmed/23206988

[123] Lund KE, McNeill A, Scheffels J. The use of snus for quitting smoking compared with medicinal products. Nicotine Tob Res. 2010 Aug;12(8):817-22. https://www.ncbi.nlm.nih.gov/pubmed/20622023

In addition to the above-mentioned approaches at the individual and population level, the number of smokers *that don't intend to quit* that the product appeals to will also be of importance. Including whether the product appeals to smokes that – for various reasons – don't want to use the recommended methods to quit smoking. While the use of one conventional quitting method (nicotine gum, plasters and inhalers, Zyban, Champix, health service assistance, self-help material) increases the likelihood of using other recommended methods, the use of snus seems to negatively correlate with the use of the aforementioned conventional methods[124]. This is an indication that snus attracts people who are quitting smoking who, for various reasons, don't want to make use of the recommended methods.

In contrast to the nicotine medications, we also see that snus appeals to smokers that don't intend to quit[125]. The segment of smokers that don't have implementation intensions for quitting comprise about 75% of smokers[126]. Snus – and perhaps to a greater extent e-cigarettes – have a greater potential than nicotine medication for producing what literature defines as „accidental quitters". These are smokers who are experimenting with an alternative nicotine product for other reasons than quitting smoking, but who, as a result of this experimenting, stop smoking anyway. However, we do not have any safe indications of how many people quit smoking after casual experimentation with snus or e-cigarettes. This is a challenge for future research.

8. E-cigarettes

8.1 History

It was the emergence of the e-cigarettes that seriously activated an interest in damage reduction in the area of tobacco. When Michael Russell wrote his famous 1991-article in Addiction on the need for competitive damage reducing nicotine alternatives to the cigarettes (cf. 2.1), he expected these to primarily come from the pharmaceutical industry. This was not the case.

E-cigarettes were patented in 2003, and have been on sale internationally since 2007. Several countries, including Norway, has practiced a ban on sale of e-cigarettes containing nicotine. Norwegian vapers have still been able to buy the vaping-unit domestically. Nicotine juice – in a pure or watered form – for up to 3 months of private consumption, the vapers have been able to import from abroad. A survey conducted by the Institute of Public Health among approx 800 vapers for the period February 2015 – October 2016, showed that only 22% have bought their last dosage of e-liquid in Norway (either through a retail outlet or in an online store), while 42% answered that the last used vaper-unit had been purchased here[127]. Evaporators and e-juice are most often bought from internet retailers or from retail outlets

[124] Lund KE, McNeill A & Scheffels J. The use of snus for quitting smoking compared with medicinal products. Nicotine Tob Res. 2010 Aug; 12(8): 817–822. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2910876/

[125] Lund KE, Scheffels j, McNeill A. The association between use of snus and quit rates for smoking: results from seven Norwegian cross-sectional studies. Addiction. 2011 Jan;106(1):162-7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3021722/

[126] Implementation intensions for quitting smoking consist of the percentage among smokers that plan to quit within the following 3 months.

[127] Vedøy TF, Lund KE. Self-reported sources of supply for cigarettes, snuff and e-cigarettes. Tidsskr Nor Laegeforen. 2017 Aug 15;137 (16). http://tidsskriftet.no/article/16-0994

during visits to Sweden or Denmark. The upcoming repeal of the ban on domestic sales of product containing nicotine (during 2018), will most likely contribute to shift the supply towards Norwegian retail outlets.

E-cigarettes are a heterogeneous product group, and further new generations consistently arrive on the market. The innovation pace has been very high. Looks vary a lot. Some products can mimic ordinary cigarettes (cig-a-likes). These can be for one-time use (disposables) or re-chargeable (rechargeable). Other e-cigarettes fall under the term tank-systems, and are refillable. Some tank-systems are modifiable where the user can vary i.e. the level of power and coil (personal vaporizers). Some products also have digital displays for different types of information about e.g. liquid volume, voltage, temperature, etc. In 2014 there were approximately 7,700 different varieties of taste on the market. The same year, 466 brand names were registered.

The product development of e-cigarettes has happened outside of the control, approval and blessing of the health services. Most of the product portfolio was originally produced by consumer-run smaller companies without a connection to the tobacco industry and the target group for these products was smokers only. The quote below illustrates a user's view on the product development:

> *„- It was vapers who took the original e-cigarette, pulled it apart and turned it into something that works. Thorough thousands of informal channels such as forums and YouTube reviews we pushed industry to improve designs and options and we still do so today"*[128]

The tobacco industry launched their products from 2012 only, and currently owns a significant part of the market for cig-a-likes. Most vapers, on the other hand, prefer tank-systems, and modifiable varieties. A survey conducted by the Institute of Public Health among 1,091 vapers in the period 2015-2017, showed that 58% of the vapers preferred e-cigarettes that in size and shape did not look like ordinary cigarettes. It was only among vapers over the age of 55, that cig-a-likes were the most preferred product (these data are so far not published).

8.2 User configuration

Approximately 250 articles (as of November 1st, 2017) which in one way or another describe the user pattern for e-cigarettes in different countries have been published. In Norway, the Institute of Public Health has taken over the monitoring of the use of e-cigarettes started by SIRUS in 2013. On an assignment from FHI, Statistics Norway has included questions about vaping in their annual surveys on usage of nicotine. In addition, information about vaping is also gathered through a time series of omnibus surveys on sources of supply for tobacco, conducted by IPSOS on an assignment from FHI.

Because vaping so far has been a low-prevalent phenomenon in Norway (see Table 3), the data basis has, until recently, not been robust enough for surveys of user configuration. Only lately have we gathered a sufficient amount of uses to be able to conduct meaningful analyses. Most robust is the data basis in the surveys from IPSOS.

[128] Sara Jakes, New Nicotine Alliance, Keynote speech at the E-cig Summit 18. November 2017, London.

Table 3. Usage of e-cigarettes among persons over the age of 15. Data collected for the period February 2015 – October 2017. IPSOS.

	Women	Men	All
Using e-cigarettes daily	0.9	1.3	1.1
Using e-cigarettes occasionally	2.2	2.5	2.4
Stopped using e-cigarettes	3.9	4.8	4.4
Have never used e-cigarettes	93.0	91.4	92.1
Sum	100	100	100
N	16,012	15,948	31,960

From the IPSOS-survey it can be calculated that ca. 50,000 persons (1.1%) use e-cigarettes daily, and that a further 120,000 persons (2.4%) use e-cigarettes occasionally. The occurrence in Norway in 2017, is approximately the same as what was found in the US in a survey from 2014[129].

Table 4 shows that only 3.6% of present users and 4.7% of former users of e-cigarettes did not have a past as smokers. The vapers mainly consist of persons who either smoke daily or occasionally, or persons who have stopped smoking. This is also a result that is consistent in systematic summaries[130].

[129] Schoenborn CA, Gindi RM. Electronic Cigarette Use Among Adults: United States, 2014. Hyattsville, MD: *National Center for Health Statistics;* 2015. *NCHS Data Brief No. 217.*

[130] http://onlinelibrary.wiley.com/doi/10.3322/caac.21413/full
http://www.sciencedirect.com/science/article/pii/S0749379716305736?via%3Dihub

Table 4. Smoking status among current vapers (N=1,091) and former** vapers (N=1392). IPSOS 2015-2017*

	Current vapers	Former vapers
Smokes daily	43.3	42.2
Have gone from daily to occasional smoking	15.4	12.5
Have always smoked occasionally	8.2	4.3
Stopped smoking	29.6	36.3
Have never been smoking	3.6	4.7
Sum	100	100
N	1,091	1,392

** daily + occasionally ** used daily or occasionally in the past*

In the survey from IPSOS, 85% of the vapers (current or former) reported that cigarettes were the first nicotine product they started using. 11% reported snuff as their first product, while 2% reported that medical nicotine products started their usage of nicotine. Only 1% reported e-cigarettes as their first nicotine product (N=2,095)

The average ages of current and former vapers were 42 and 41 years respectively. This was approximately the same as with the smokers, while the snuff-users were, on average, ca. 7 years younger. Slightly below 15% of the vapers belonged to the age group below 25 (Table 5).

Table 5. Current and former vapers by age. IPSOS 2015-2017

	Current vapers	Former vapers
15-24 yrs	14.1	14.7
25-34 yrs	19.7	24.5
35-44 yrs	24.7	21.5
45-54 yrs	20.3	19.5
55 yrs+	21.2	19.8
Sum	100	100
N	1,091	1,392

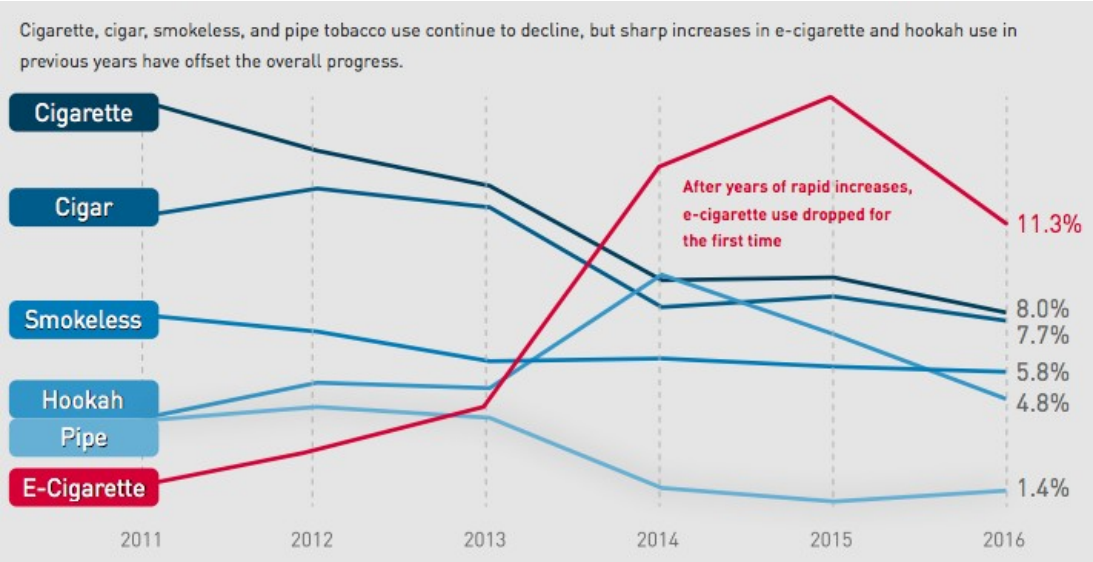
8.2.1 Usage among youth

There is an existing worry that youth whom would otherwise not use nicotine at all, will start using e-cigarettes. Schneider & Diehl (201&) have tried to identify which mechanism could be in effective in these cases[131]. They state that youth will be more inclined to try e-cigarettes than tobacco cigarettes because the first mentioned i) are offered with more variety of taste, ii) are considered less damaging, iii) are cheaper, iv) have a more positive symbol content, v) are easier to hide from the surroundings and vi) appears as more socially acceptable. There is therefore a large interest attached to the user-pattern for e-cigarettes among youth, and several good data sets have lately emerged – especially in the US and England.

[131] *Schneider S, Diehl K. Vaping as a catalyst for smoking? An initial model on the initiation of electronic cigarette use and the transition to tobacco smoking among adolescents. Nicotine Tob Res. 2016;18:647-653*

The longest time series in the US is the NYTS-study (National Youth Tobacco Survey). NYTS shows that the number of 12-18 year olds who reported using e-cigarettes the last month had increased from 1.5% in 2011 to 16% in 2015, and was then reduced to 11.3% in 2016[132](see figure 2). Daily usage of e-cigarettes in this age group was only 1.1% in 2016.

Figure 4. Usage of nicotine products during the last month among 12-18 tear olds in the US. Source: National Youth Tobacco Survey, 2017.



PATH-study from the FDA showed that 88.2% of American youth that had ever tried e-cigarettes, had not been using the product during the last month. Only 0.2% of those who had tried e-cigarettes reported that they used the product every day. This illustrates that the majority of experimentation with e-cigarettes among youth does not result in regular usage, and it underlines the necessity of separating between experimentation and regular usage when scientists should report occurrence. In the longitudinal PATH-study, 2.2% of the non-smokers in the age group 12-17 years at baseline, reported that they had used e-cigarettes during the last month, when measured one year later[133].

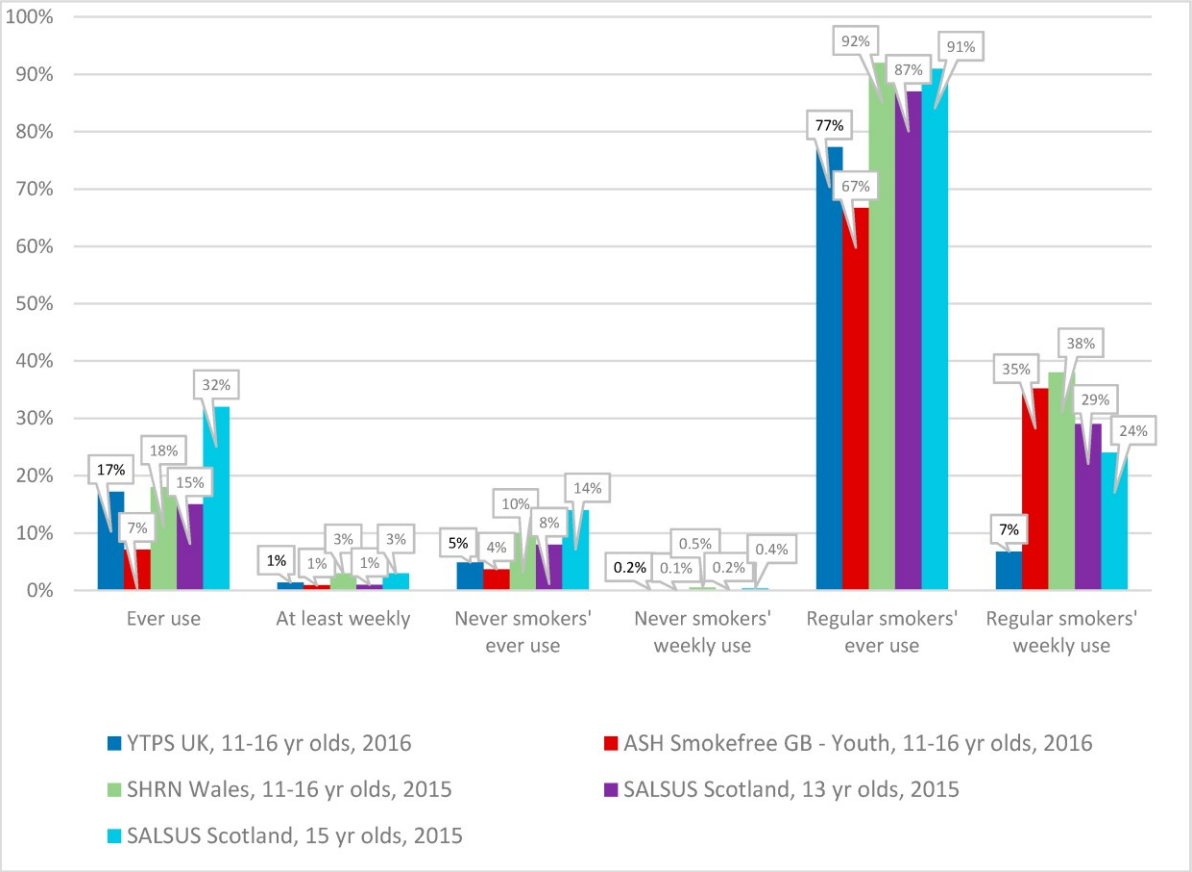
In the study Monitoring the Future (MTF), American youth were asked which product they vaped. Here 2/3 reported that they used e-cigarettes without nicotine, while 1 out of 5 used variations containing nicotine.[134]. For youth, it looks as though the taste is more important than the supply of nicotine when choosing product. The result further illustrates that the usage of e-cigarettes cannot be treated as synonymous with usage of nicotine.

[132] https://www.fda.gov/downloads/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/UCM569880.pdf

[133] Ambrose B. E-Cigarette Use Transitions: A Case Study from Waves 1 & 2 of the PATH Study. 2017. Presented at: Society for Research on Nicotine and Tobacco (SNRT) Pre-Conference Workshop: FDA's Population Health Standard: Balancing the Risks and Benefits in Regulatory Decision-Making; March 8, 2017; Florence, Italy. c.ymcdn.com/sites/www.srnt.org/resource/resmgr/conferences/2017_annual_meeting/FDA_PreCon_Slides/SRNT_2017_Pre-Conf_Workshop_.pdf. Accessed August 28, 2017.

[134] Miech R, Patrick ME, O'Malley PM, Johnston LD. What are kids vaping? Results from a national survey of US adolescents. Tob Control. 2017;26:386-391

Figure e5. Prevalence for usage of e-cigarettes among English teens 2015/2016. Sources: Youth Tobacco Policy Survey (YTPS), United Kingdom, n = 1213 (2016); Action on Smoking and Health Smokefree Great Britain-Youth Survey n = 1205 (2016); Schools Health Research Network (SHRN), Wales, n = 32,479 (11 to 16 year olds in 2015); and, Scottish Schools Adolescent Lifestyle and Substance Use Survey (SALSUS), n = 13,607 (13 year olds in 2015), n = 11,697 (15 year olds in 2015). Base for regular smokers in YTPS and ASH Smokefree GB is less than 50[135]



In England, the number of vapers has increased from ca. 700,000 in 2012 to 2.9 million in 2017[136]. A collected presentation of five surveys done in England, shows that the usage of e-cigarettes among non-smoking youth, was very small (figure 3). Admittedly, between 4% and 14% of non-smoking youth had tried e-cigarettes, but only between 0.1% and 0.5% used e-cigarettes on a weekly basis or more often.

[135]Bauld L, MacKintosh AM, Eastwood B et al Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015–2017. J. Environ. Res. Public Health 2017, 14(9), 973.
[136]Action on Smoking and Health,, Use of electronic cigarettes (vapourisers) among adults in Great Britain, 16 May 2017. http://ash.org.uk/information-and-resources/fact-sheets/use-of-e-cigarettes-among-adults-in-great-britain-2017/

8.3 The gateway-theory[137]

A common find within literature on youth and risk behaviour, is that involvement in one type of risk behaviour increases the likelihood of following start-up of another type of risk behaviour. In line with this, a number of surveys show that non-smoking youth who experiment with e-cigarettes – and to for that matter snuff[138] – have an increased inclination to start smoking, compared to youth abstaining from the usage of e-cigarettes[139]. It is, however, very difficult, if not to say impossible, to decide how much of this association that potentially can be ascribed to the product as such.

The gateway-theory is often used to legitimize a restrictive policy towards „softer" drugs. Most often actors from what KE Warner called the activist camp in the „tobacco control community" (see chapter 2.4) are those using this reasoning. From these, the gateway-theory is put forward more as a worry than as a claim. But also in the Institute of Public Health's reports on damage effects from snuff and e-cigarettes, the theory on a possible gateway between these product and smoking, is supported.

From the scientific community, the idea was discussed within the area of narcotics from the mid 1970s. The main worry was that cannabis could lead to the usage of „hard" or illegal substances, such as cocaine and heroin[140]. Especially important was an article by the French born professor Denise Kandel (1933–) in Science in 1975. She argued that *«… legal drugs are necessary intermediates between non-use and marihuana»* and that *«Marihuana, in turn, is a crucial step on the way to other illicit drugs»*[141].

In the same way as with cannabis and alcohol, the usage of cigarettes was considered a possible gateway to „harder" substances, if somewhat less important than cannabis.

However, the interest for the idea of tobacco as a gateway grew in tune with the increasing use of snuff and chewing tobacco in the US towards the end of the 1980s[142] and later with the introduction of the e-cigarettes from the mid 2000s.

8.3.1 Sequencing, association & causation

Even if the abovementioned quotes from Denise Kandel strongly implies that there is a causal connection between the usage of different substances, this, and other articles from the same

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[137] This paragraph is based on an article by Tord Finne Vedøy «From snuff to intoxication – prejudice or fact?» Tidsskr Nor Legeforen 2016 (6); 136:544-6. http://tidsskriftet.no/2016/04/kronikk/fra-snus-til-rus-fordom-eller-fakta

[138] Grøtvedt L, Forsén L, Stavem K, Graff-Iversen S. Patterns of snus and cigarette use: a study of Norwegian men followed from age 16 to 19. Tob Control. 2013 Nov;22(6):382-8. https://www.ncbi.nlm.nih.gov/pubmed/22634571

[139] US Department of Health and Human Services, Office of the Surgeon General. E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General. Rockville, MD*: Office of the Surgeon General, Public Health Service, US Department of Health and Human Services;* 2016. e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf

[140] Hamburg BA, Kraemer HC, Jahnke W. A hierarchy of drug use in adolescene: behavioral and attitudinal correlates of substantial drug use. Am J Psychiatry 1975; 132: 1155 – 63

[141] Kandel D. Stages in adolescent involvement in drug use. Science 1975; 190: 912 – 4.

[142] Connolly GN, Winn DM, Hecht SS et al. The reemergence of smokeless tobacco. N Engl J Med 1986; 314: 1020 – 7.

period underlines[143],[144] that such a connection must be understood as associative. In later publications, however, the idea of a causal connection explicitly formulated[145],[146]. For example, Denise Kandel writes in 2003 that the „gateway"-hypotheses presumes that the usage of a given substance normally takes place before the usage of another („sequencing"), that usage of the first substance increases the likelihood of usage of the second („association") and that usage of the first substance actually is the reason for usage of the second substance („causation").

No matter whether one wishes to examine gateways between different narcotics or between different nicotine- and tobacco products, one will meet a basic problem with confirming that usage of a narcotic or substance is the reason for later use of another. This problem arises with the use of both cross section- and panel data.

The most common solution is to attempt to conduct control of all relevant background variables, something that is obviously difficult. Results from studies that have gone far in addressing this, give little support to the gateway-idea, both for nicotine and tobacco products[147],[148],[149] for narcotics in general[150],[151].

Another solution to conduct control of social and biological background variables is to use twin-studies. In a Finnish twin-study it was for instance found that starting to smoke was positively connected to starting to use cannabis[152]. A contiguous objection, however, is that differences in smoking behaviour between twins indicate that they are not similar with respect to relevant background factors and that this instead mirrors social or psychological differences between the two[153]. In addition it is usual to use tobacco when you smoke cannabis, something that proves difficult to control.

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[143]Kandel D, Faust R. Sequence and stages in patterns of adolescent drug use. Arch Gen Psychiatry 1975; 32: 923 – 32.

[144]Kandel DB, Kessler RC, Margulies RZ. Antecedents of adolescent initiation into stages of drug use: a developmental analysis. J Youth Adolesc 1978; 7: 13 – 40.

[145]Kandel DB, Yamaguchi K, Chen K. Stages of progression in drug involvement from adolescence to adulthood: further evidence for the gateway theory. J Stud Alcohol 1992; 53: 447 – 57

[146]Kandel DB, Yamaguchi K, Klein LC. Testing the gateway hypothesis. Addiction 2006; 101: 470 – 2, discussion 474 – 6

[147] Timberlake DS, Huh J, Lakon CM. Use of propensity score matching in evaluating smokeless tobacco as a gateway to smoking. Nicotine Tob Res 2009; 11: 455 – 62.

[148]Tomar SL. Smokeless tobacco use is a significant predictor of smoking when appropriately modeled. Nicotine Tob Res 2003; 5: 571 – 3

[149] O'Connor RJ, Flaherty BP, Quinio Edwards B et al. Regular smokeless tobacco use is not a reliable predictor of smoking onset when psychosocial predictors are included in the model. Nicotine Tob Res 2003; 5: 535 – 43.

[150]Fergusson DM, Horwood LJ. Does cannabis use encourage other forms of illicit drug use? Addiction 2000; 95: 505 – 20

[151]Morral AR, McCaffrey DF, Paddock SM. Reassessing the marijuana gateway effect. Addiction 2002; 97: 1493 – 504.

[152] Huizink AC, Levälahti E, Korhonen T et al. Tobacco, cannabis, and other illicit drug use among Finnish adolescent twins: causal relationship or correlated liabilities? J Stud Alcohol Drugs 2010; 71: 5 – 14

[153]Anthony JC. Steppingstone and gateway ideas: a discussion of origins, research challenges, and promising lines of research for the future. Drug Alcohol Depend 2012; 123 (suppl 1): S99 – S104

8.3.2 Mechanisms of explanation

A third, less technical and more theoretic solution is to fine possible mechanisms of explanation that can substantiate a causal connection. For example, it is possible that the usage of e-cigarettes teaches the body motor and sensory patterns that make it easier to start smoking traditional cigarettes. With respect to gateways between different narcotics, some have argued that the usage of illegal substances gives an entry to environments where other illegal substances are available or that experimentation with cannabis can lead to other narcotics appearing less risky.[154]. In a Norwegian prospective study, the scientists examined whether experimentation with and usage of snuff among non-smokers would change their cognitions in a smoking-strengthening direction. The results did not support such a mechanism existed.[155].

8.3.3 Changes in the brain

In later years, Kandel and associates have, however, published several articles where they on the background on studies on mice argue that certain narcotics, among others nicotine, can influence the brain in advance for addiction to other narcotics, such as cocaine. A necessary condition is, however, that the intake of nicotine has to take place quite some time ahead, and continue at the same time as the intake of cocaine.[156].

Even with both good data and robust models, the idea of a gateway is however burdened with a series of theoretical problems. If one examines possible gateways between narcotics, a first objection would be that there is no consensus about the definition of „soft" and „hard" substances. Many will, for example, disagree in categorizing cannabis as „harder" than alcohol[157]. Similarly it is unclear what is the first gateway, something that leads to infinite recourse. If both alcohol and tobacco smoking are gateways, why not sugar?

A connected limitation is that persons do not necessarily start with „soft" substances before „hard", but that this rather mirrors local patterns of usage and the local market situation[158]. In addition, if a „gateway"-effect of any significance exists, one should find a positive correlation between the usage of different substances over time. This is often not the case. For example, it is found that the usage of cocaine among youth increased relatively substantially towards the end of the 1990s, at the same time as the prevalence for smoking decreased[159]. This does not support the idea of influencing in advance.

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[154]Yamaguchi K, Kandel DB. Patterns of drug use from adolescence to young adulthood: III. Predictors of progression. Am J Public Health 1984; 74: 673 – 81

[155]Larsen E, Rise J, Lund KE. The relationship between snus use and smoking cognitions. Addict Res Theory. 2012 Dec;20(6):447-455. https://www.ncbi.nlm.nih.gov/pubmed/23204990

[156]Kandel ER, Kandel DB. Shattuck Lecture. A molecular basis for nicotine as a gateway drug. N Engl J Med 2014; 371: 932 – 43.

[157]Nutt DJ, King LA, Phillips LD. Drug harms in the UK: a multicriteria decision analysis. Lancet 2010; 376: 1558 – 65.

[158] Degenhardt L, Dierker L, Chiu WT et al. Evaluating the drug use «gateway» theory using cross-national data: consistency and associations of the order of initiation of drug use among participants in the WHO World Mental Health Surveys. Drug Alcohol Depend 2010; 108: 84 – 97.

[159]Vedøy TF, Skretting A. Youth and narcotics: results from questionnaire surveys 1968 – 2008. Oslo: Statens institutt for rusmiddelforskning, 2009.

In addition, the arrow can point in the opposite direction. Over the last decades, the increased usage of snuff in Norway is, for instance, accompanied by a substantial decrease in tobacco smoking. If there is a connection between the two, it seems more likely that snuff displace tobacco smoking, rather than snuff leading to more tobacco smokers.

With respect to the idea of bio-chemical advanced influencing, this can, in theory, explain why some get addicted to a new addictive substance, but cannot explain why some decided to try this substance in the first place. This is naturally not a problem in the studies of mice.

Advanced influencing can also not explain a potential transfer between different nicotine and tobacco products, when the narcotic in all instances is nicotine. To the extent that nicotine increases the tolerance for and the need for more nicotine, users of snuff or e-cigarettes/nicotine vaporizers could simply increase their nicotine intake with snuff or e-cigarettes/nicotine vaporizers, without resorting to tobacco smoking. A possible causal connection must in that case completely or partly be due to other circumstances.

8.3.4 Selection

Possibly the most serious objection is that in those studies where one examines the usage of „hard" substances, the observed connection is a natural cause of the results stemming from a selected group, that is persons who have used „hard" substances. If one instead examine the part that has used „hard" substances among those who at some point have used „soft" substances, the connection will, naturally, be insignificant[160](26). In a similar way, this will be a problem if one examines the effect of the usage of snuff or e-cigarettes/nicotine vaporizers on smoking.

8.3.5 Status of the gateway-theory

Does this mean that there cannot be any possible causal connections between different narcotics and nicotine and tobacco products? Of course not. It means that in the absence of unambiguous empirical observations, there must be a good explanation for such connections. This is also necessary for good statistical modelling of causal connections. No good explanations for a causal connection between the usage of snuff and e-cigarettes and smoking exist. As such, the „gateway"-concept is superfluous.

After explaining the methodical challenges in identifying a causal effect from e-cigarettes on smoking, Public Health England wrote in their 2015-report: "*we strongly suggest that use of the gateway terminology be abandoned until it is clear how the theory can be tested in this field."*[161] A fresh systematic summary of the research literature also concluded that due to methodological challenges, it was not possible to decide whether e-cigarettes could be a causal cause of subsequent smoking among youth[162]. The topic however continues to be an object for a heated international debate.

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[160]Earleywine M. Understanding marijuana: a new look at the scientific evidence. New York, NY: Oxford University Press, 2002.

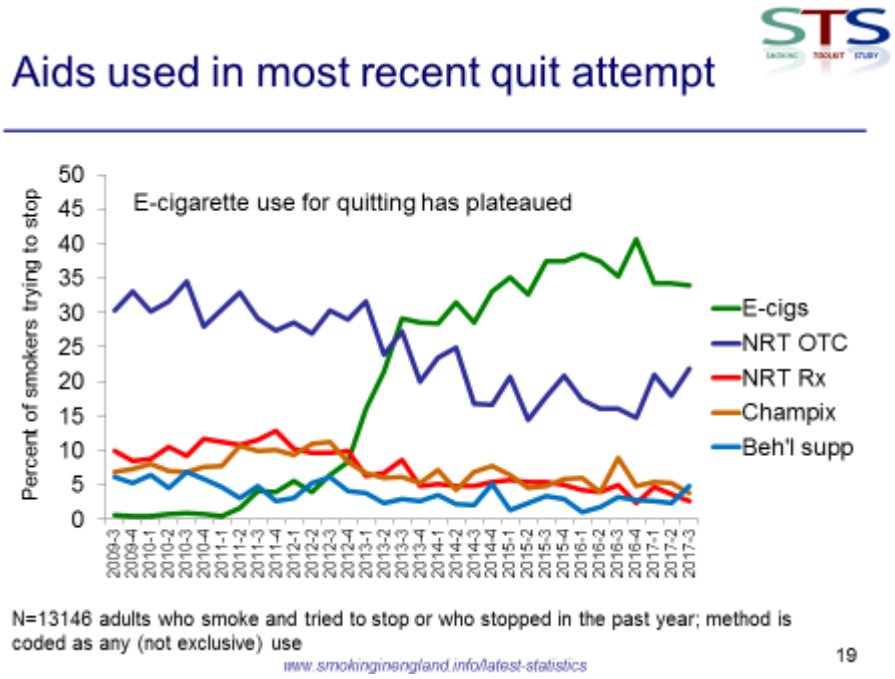
[161] McNeill A, Brose LS, Calder R, Hitchman SC, Hajek P, McRobbie H. E-Cigarettes: An Evidence Update. London, UK*: Public Health England;* 2015. gov.uk/government/publications/e-cigarettes-an-evidence-update.

[162]http://onlinelibrary.wiley.com/doi/10.3322/caac.21413/full

8.4 Quitting smoking

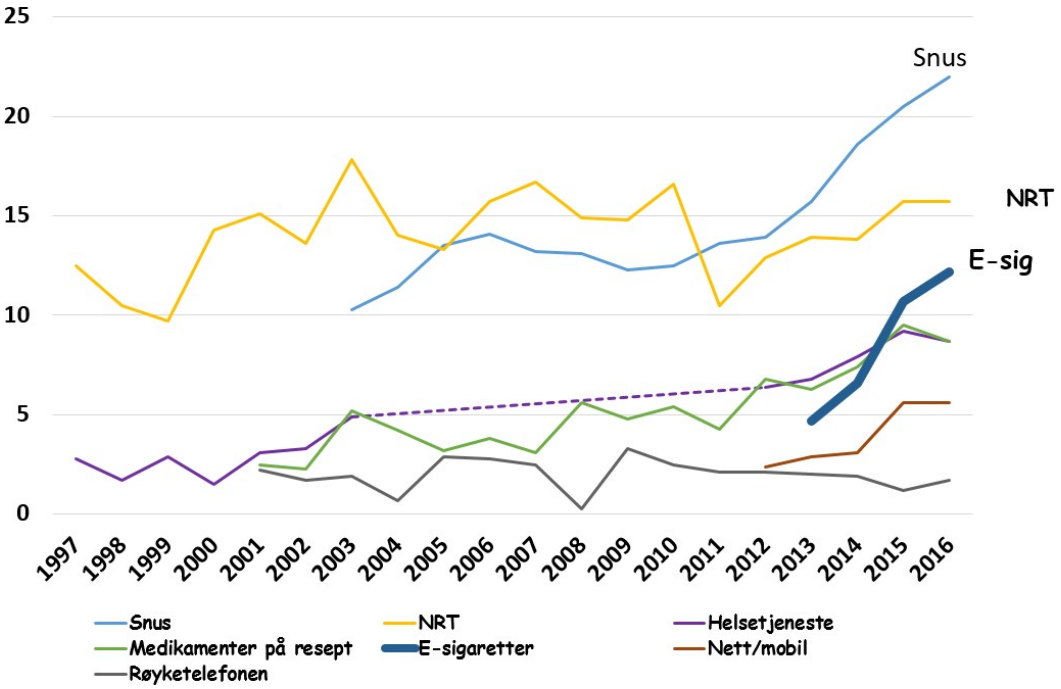
Most people, who successfully or unsuccessfully attempt to quit smoking, use no assistance. Approximately 70% of the approximate 700 000 living former smokers in Norway, quit on their own. Of those using aids, e-cigarettes come up as a frequently used alternative. In England, e-cigarettes became the most preferred method to quit smoking already in 2013. The last few years, this growth has, however, flattened, and tendencies towards a decrease has occurred (figure 6). Also in Norway, an increase in the usage of e-cigarettes as a method to quitting smoking has occurred, but snuff is still the most used method, followed by nicotine pharmaceuticals (figure 7).

Figure 6. Method used during the last attempt to quit smoking among English smokers 2009-2017. Source: Smoking toolkit survey (STS)[163].



[163] http://www.smokinginengland.info/latest-statistics/

Figure 7. Method at the last attempt to quit smoking (present and former smokers) in Norway 1997- 2016. Source: Statistics Norway's surveys on smoking habits conducted on an assignment for FHI.



How successful a replacement product will be in the weaning from smoking cigarettes depends i.e. on its ability to supply nicotine to the blood path. There is a tendency for vapers to start with a relatively high nicotine concentration in the liquid, and then decrease this[164]. Studies of supply of nicotine from first generation e-cigarettes showed a minimal and slow absorption of nicotine[165],[166], while new generations have showed more effective supply of nicotine[167],[168] without this being the case for all products[169].

8.4.1 Experimental studies

How big an effect e-cigarettes have on quitting smoking is a heavily debated topic. There is a lot of anecdotic evidence from where vapers report that e-cigarettes soften abstinence symptoms, that they function satisfactory as a replacement for conventional cigarettes and that

[164] Farsalinos KE Romagna G Tsiapras D Kyrzopoulos S Voudris V . Evaluating nicotine levels selection and patterns of electronic cigarette use in a group of "vapers" who had achieved complete substitution of smoking. Subst Abuse . 2013;7:139–146.
[165] Farsalinos KE Spyrou A Tsimopoulou K Stefopoulos C Romagna G Voudris V . Nicotine absorption from electronic cigarette use: comparison between first and new-generation devices. Sci Rep . 2014;4:4133.
[166] Nides MA Leischow SJ Bhatter M Simmons M . Nicotine blood levels and short-term smoking reduction with an electronic nicotine delivery system. Am J Health Behav . 2014;38(2):265–274.
[167]Dawkins LE Kimber CF Doig M Feyerabend C Corcoran O . Self-titration by experienced e-cigarette users: blood nicotine delivery and subjective effects. Psychopharmacology (Berl) . 2016;233(15–16):2933–2941.
[168] Spindle TR Breland AB Karaoghlanian NV Shihadeh AL Eissenberg T . Preliminary results of an examination of electronic cigarette user puff topography: the effect of a mouthpiece-based topography measurement device on plasma nicotine and subjective effects. Nicotine Tob Res .2015;17(2):142–149.
[169] Hajek P Przulj D Phillips A Anderson R McRobbie H . Nicotine delivery to users from cigarettes and from different types of e-cigarettes. Psychopharmacology (Berl) . 2017;234(5):773–779.

they function well in attempts to quit smoking[170],[171],[172]. Such data are low-ranking in the evidence hierarchy for effect on quitting smoking, where investigations with experimental designs are at the top.

However, very few randomized controlled trials have been conducted[173], but, at this point; five RCTs on e-cigarette usage for weaning smoking are ongoing.

The results of these can be expected during 2018 and 2019. In a summary article from 2017, the results from the trials already conducted are summarized as such[174]:

> *Four RCTs show that ENDS are effective in helping some adult smokers to quit or to reduce their cigarette consumption. In the studies that assessed smoking cessation, rates of cessation in the ENDS study groups were similar to or higher than rates of cessation seen in previous clinical trials of nicotine-replacement therapy (NRT).*

The scientists' conclusions were in line with a summary in Cochrane from 2016[175]:

> *Combined results from two studies, involving 662 people, showed that using an EC containing nicotine increased the chances of stopping smoking in the long term compared to using an EC without nicotine. We could not determine if EC was better than a nicotine patch in helping people stop smoking, because the number of participants in the study was low.*

There are several reasons for there being so few RCTs about e-cigarettes in quitting smoking. Primarily this is due to the fact that the producers of e-cigarettes do not have the same evidence burden to document the effect in weaning of smoking as the producers of nicotine pharmaceuticals – where approximately 55% of the study-portfolio is financed by the medical industry itself. It will appear as a disadvantage for the e-cigarette producers to use messages of effect in weaning smoking in their marketing. This is because the product then after its presentation will be categorized as a drug, and therefore be subject to an obligation for

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[170]Farsalinos KE, Poulas K, Voudris V, Le Houezec J. Prevalence and correlates of current daily use of electronic cigarettes in the European Union: analysis of the 2014 Eurobarometer survey. Intern Emerg Med. 2017 Mar 4. https://www.ncbi.nlm.nih.gov/pubmed/28260221

[171]Berg. H. Den store Norske Dampundersøkelsen. Rapport 2017. https://www.minervanett.no/wp-content/uploads/2017/11/Helene-Berg-2017-Den-store-norske-dampeundersøkelsen.pdf

[172] Dawkins L, Turner J, Hasna S, Soar K. The electronic-cigarette: effects on desire to smoke, withdrawal symptoms and cognition. Addict Behav. 2012 Aug;37(8):970-3. https://www.ncbi.nlm.nih.gov/pubmed/22503574

[173]P. Caponnetto, D. Campagna, F. Cibella, et al. Efficiency and Safety of an electronic cigarette (ECLAT) as tobacco cigarettes substitute: a prospective 12-month randomized control design study
K. Adriaens, D. Van Gucht, P. Declerck, F. Baeyens. Effectiveness of the electronic cigarette: an eight-week Flemish study with six-month follow-up on smoking reduction, craving and experienced benefits and complaints. Int J Environ Res Public Health, 11 (11) (2014), pp. 11220-11248
C. Bullen, C. Howe, M. Laugesen, et al. Electronic cigarettes for smoking cessation: a randomised controlled trial Lancet, 382 (9905) (2013), pp. 1629-1637
T.Y. Tseng, J.S. Ostroff, A. Campo, et al. A randomized trial comparing the effect of nicotine versus placebo electronic cigarettes on smoking reduction among young adult smokers Nicotine Tob Res, 18 (10) (2016), pp. 1937-1943

[174] Glasser AM, Collins L, Pearson JL et al. Overview of Electronic Nicotine Delivery Systems: A Systematic Review. Am J Prev Med. 2017 Feb;52(2):e33-e66 http://www.sciencedirect.com/science/article/pii/S0749379716305736?via%3Dihub

[175]Hartmann-Boyce J, McRobbie H, Bullen C, Begh R, Stead LF, Hajek P. Can electronic cigarettes help people stop smoking, and are they safe to use for this purpose? Cochrane Database of Systematic Reviews 2016, Issue 9. Art. No.: CD010216http://www.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-and-are-they-safe-use-purpose

documentation and limited marketing. E-cigarettes are therefore most often presented from the producers as an *alternative* to the tobacco cigarettes, and not as a product to quit smoking.

The rapid product development of e-cigarettes also deprives the producers of a motive to conduct effect-studies. On average, approximately 10 new products are launched each month, from a number of producers[176]. The differences between the different generations are big. Conducting experimental studies takes time. The type of e-cigarette examined will most likely not still be on the market when the results are ready.

A third circumstance is that most producers are small and without an ability to manage expensive and extended testing — which they neither need to get market access, nor will be able to use in their marketing.

8.4.2 prospective studies

There are, however, more than 100 articles (as of Nov. 1st 2017) based on studies with longitudinal data or cross section investigations. Several of these have deficits that makes it difficult to conclude certainties on the strength of the effect. A group of scientists, who recently examined this portfolio, concluded that those of the best quality concurred with the results from the experimental studies[177]:

> *Twenty-four papers did not examine the outcomes of interest. Forty did not assess the specific reason for e-cigarette use as an exposure of interest. Twenty papers did not employ prospective study designs with appropriate comparison groups. The few observational studies meeting some of the criteria (duration, type, use for cessation) triangulated with findings from three randomized trials to suggest that e-cigarettes can help adult smokers quit or reduce cigarette smoking. Only a small proportion of studies seeking to address the effect of e-cigarettes on smoking cessation or reduction meet a set of proposed quality standards. Those that do are consistent with randomized controlled trial evidence in suggesting that e-cigarettes can help with smoking cessation or reduction*

These conclusions also concurred with the results in an earlier systematic examination based on 63 studies[178]:

> *This is the most comprehensive systematic evidence review to examine the relationship between e-cigarette use and smoking cessation among smokers. This review offers balanced and rigorous qualitative and quantitative analyses of published evidence on the effectiveness of e-cigarette use for smoking abstinence and reduction as well as important outcomes such as withdrawal symptoms and craving to smoke. While inconclusive due to low quality, overall the existing literature suggests e-cigarettes may be helpful for some smokers for quitting or reducing smoking.*

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[176] Zhu SH, Sun JY, Bonnevie E et al (2014). Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. Tobacco Control, 23 (suppl 3), iii3-iii9. doi: http://dx.doi.org/10.1136/tobaccocontrol-2014-051670

[177] Villanti AC, Feirman SP, Niaura RS et al. How do we determine the impact of e-cigarettes on cigarette smoking cessation or reduction? Review and recommendations for answering the research question with scientific rigor. Addiction. 2017 Oct 3. https://www.ncbi.nlm.nih.gov/pubmed/28975720

[178] Malas M, van der Tempel J, Schwartz R et al. Electronic Cigarettes for Smoking Cessation: A Systematic Review. Nicotine Tob Res. 2016 Oct;18(10):1926-1936. https://www.ncbi.nlm.nih.gov/pubmed/27113014

A recent WHO-financed systematic summary underlined the deficits in the portfolio of observational studies[179]:

> *There is very limited evidence regarding the impact of ENDS or ENNDS on tobacco smoking cessation, reduction or adverse effects: data from RCTs are of low certainty and observational studies of very low certainty. The limitations of the cohort studies led us to a rating of very low-certainty evidence from which no credible inferences can be drawn. Lack of usefulness with regard to address the question of e-cigarettes' efficacy on smoking reduction and cessation was largely due to poor reporting.*

8.4.3 Accidental quitters

Similar to snuff (see chap. 7.4.1), e-cigarettes will attract quitting smokers whom for different reasons do not wish to use the recommended methods. To the extent e-cigarettes also attracts users without implementation intentions for quitting smoking, the product – similar to snuff – has the potential to produce „accidental quitters". These are smokers who are experimenting with an alternative nicotine product for other reasons than to quit smoking, but who as a result of this experimentation ends up with quitting smoking after all. As with snuff, we have no certain indications for how many ends up quitting smoking after casual experimentation with e-cigarettes.

This quote may illustrate how the users themselves considers e-cigarettes and quitting smoking:

> *" – One of the biggest challenges for consumers is in getting regulators, and those who advise them, to understand that for a great many people vaping is not a medicine, or simply a smoking cessation intervention, it works precisely because it isn't those things. It works because they enjoy it. They love the personalization that's made possible by the diversity of the market in devices, and the thousands of flavours available. They enjoy the identity of being a vaper and the sense of community that that entails. They love that vaping is similar to smoking, but at the same time a million miles away from it"*[180]

8.4.4 Ethnographic studies

Several scientists think that ethnographic studies are more suitable than experimental designs to explain how e-cigarettes work when related to quitting smoking. Scientists who have followed vapers in their natural environments reports that most of them take a long time, and tries several varieties of vaporizers, nicotine strength and tastes before they find a combination that can replace tobacco. When the smokers in experimental studies are supplied with a standardized e-cigarette without modification possibilities, the effect on quitting smoking is only applicable to this type of product combination (vaporizer, nicotine strength, battery, coil, aroma, etc). A more correct result for the effect of e-cigarettes in quitting smoking will be achieved it the test persons themselves will have the opportunity to find their

[179] El Dib R, Suzumura EA, Akl A, et al (2017). Electronic nicotine delivery systems and/or electronic non-nicotine delivery systems for tobacco smoking cessation or reduction: a systematic review and meta-analysis. BMJ Open 2017;7:e012680http://bmjopen.bmj.com/content/bmjopen/7/2/e012680.full.pdf

[180] Sara Jakes, New Nicotine Alliance, Keynote speech at the E-cig Summit 2017, London.

own substitute product (naturalistic design)[181],[182],[183],[184],[185],[186],[187],[188]. The usage of newer types of e-cigarettes (tank-systems) for instance, seem to have a better effect on quitting smoking than cig-a-likes[189],[190],[191],[192].

8.4.5 cross section studies

As mentioned (see chap. 6.3.1 and chap. 7.4.1), randomized controlled experiments are well suited to identify the effect potential from a product in the weaning of smoking on an individual level, but insufficient to be able to make statements on the effect on a population level. Investigations with naturalistic designs could be a valuable addition to randomized controlled experiments – whether these are prospective (see chap. 8.4.2) or building on observations gathered at a certain time. The strength is that the result builds on observations of the usage of products to quit smoking in the real world. The weakness is that the groups using different methods to quit smoking are self-selected, and could be unevenly composed with a reduced possibility of identifying the reason for possible result variations between the groups. During the analyses one can keep control of confounders – other factors that will influence the result – but this is normally limited. In the literature summing up the research on e-cigarettes and quitting smoking, there are, however, two naturalistic country-representative studies that are mentioned as especially good.

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[181]Megan W. Moving beyond vaping as a cessation-only practice. Addiction 4. December 2017 http://onlinelibrary.wiley.com/doi/10.1111/add.14095/full

[182]Fraser D., Weier M., Keane H., Gartner C. Vapers' perspectives on electronic cigarette regulation in Australia. Int J Drug Policy 2015; 26: 589–594.

[183]Keane H., Weier M., Fraser D., Gartner C. Anytime, anywhere': vaping as social practice. Crit Public Health 2017; 27: 465–476.

[184] Pokhrel P., Herzog T. A., Muranaka N., Regmi S., Fagan P. Contexts of cigarette and e-cigarette use among dual users: a qualitative study. BMC Public Health 2015; 15: 859.

[185]Russell C., Dickson T., McKeganey N. Advice from former-smoking e-cigarette users to current smokers on how to use e-cigarettes as part of an attempt to quit smoking. Nicotine Tob Res 2017; https://doi.org/10.1093/ntr/ntx176

[186] Barbeau A. M., Burda J., Siegel M. Perceived efficacy of e-cigarettes versus nicotine replacement therapy among successful e-cigarette users: a qualitative approach. Addict Sci Clin Pract 2013; 8: 5.

[187] Smiley SL, DeAtley T, Rubin LF et al. Early Subjective Sensory Experiences with „cigalike" E-cigarettes Among African American Menthol Smokers: A Qualitative Study. Nicotine Tob Res. 2017 May 26. https://www.ncbi.nlm.nih.gov/pubmed/28549156

[188] Carpenter MJ, Heckman BW, Wahlquist AE, et al. A Naturalistic, Randomized Pilot Trial of E-Cigarettes: Uptake, Exposure, and Behavioral Effects. Cancer Epidemiol Biomarkers Prev. 2017 Dec;26 (12): 1795-1803. https://www.ncbi.nlm.nih.gov/pubmed/?term=A+Naturalistic%2C+Randomized+Pilot+Trial+of+E-Cigarettes%3A+Uptake%2C+Exposure%2C+and

[189]Hitchman SC, Brose LS, Brown J, Robson D, McNeill A. Associations between e-cigarette type, frequency of use, and quitting smoking: findings from a longitudinal online panel survey in Great Britain. Nicotine Tob Res2015;358:1187-94.

[190]Chen C, Zhuang Y-L, Zhu S-H. E-cigarette design preference and smoking cessation: a U.S. population study. Am J Prev Med2016;358:356-63.

[191]Malas M, van der Tempel J, Schwartz R, et al. Electronic Cigarettes for Smoking Cessation: A Systematic Review. Nicotine Tob Res2016;358:1926-36.

[192]Dawkins L, Kimber C, Puwanesarasa Y, Soar K. First- versus second-generation electronic cigarettes: predictors of choice and effects on urge to smoke and withdrawal symptoms. Addiction. 2015 Apr;110(4):669-77.https://www.ncbi.nlm.nih.gov/pubmed/25407505

In England, Brown et al (2014) examined 5,836 smokers who had made an attempt to quit during the last year either with e-cigarettes (*n* = 464), NRT (*n* = 1922) or without assistance (*n* = 3477). The scientists concluded as follows[193]:

> *E-cigarette users were more likely to report abstinence than either those who used NRT bought over-the-counter [odds ratio (OR) = 2.23, 95% confidence interval (CI) = 1.70–2.93, 20.0 versus 10.1%] or no aid (OR = 1.38, 95% CI = 1.08–1.76, 20.0 versus 15.4%). The adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.17–2.27) times higher compared with users of NRT bought over-the-counter and 1.61 (95% CI = 1.19–2.18) times higher compared with those using no aid. This difference persists after adjusting for a range of smoker characteristics such as nicotine dependence.*

In the US, Zhu et al examined (2017)[194] whether the quitting ratio for smoking had changed after the introduction of e-cigarettes to the market, and whether the outcome of quitting smoking with the help of e-cigarettes provided different results than attempts to quit using other methods. The article, published in BMJ, concluded as follows:

> *This study, based on the largest representative sample of e-cigarette users to date, provides a strong case that e-cigarette use was associated with an increase in smoking cessation at the population level. We found that e-cigarette use was associated with an increased smoking cessation rate at the level of subgroup analysis and at the overall population level. It is remarkable, considering that this is the kind of data pattern that has been predicted but not observed at the population level for cessation medication, such as nicotine replacement therapy and varenicline. This is the first statistically significant increase observed in population smoking cessation among US adults in nearly a quarter of a century. These findings need to be weighed carefully in regulatory policy making and in the planning of tobacco control interventions.*

8.4.6 Conversion ratio

The conversion ratio is an indication of the potential a nicotine product has to convert smokers from cigarettes to a constant use of an alternative. In the case of e-cigarettes, the conversion ratio will express the percentage of smokers who have become constant vapers, calculated from the number of smokers who have at some point tested an e-cigarette. Data from England shows that the number of smokers who have tried e-cigarettes is four times higher than the number who uses e-cigarettes on a regular basis[195]. Data from Norway similarly indicates that the conversion ratio for e-cigarettes is fairly low. In table 3, it is shown that 42% of former users of e-cigarettes still smoke tobacco cigarettes on a daily basis (see chap. 8.2). Future research will have a purpose of standardizing, identifying and comparing the conversion ratio between the different nicotine alternatives.

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[193]Brown J, Beard E, Kotz D, Michie S, West R. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. Addict. 2014;109:1531-1540

[194] Zhu Shu-Hong, Zhuang Yue-Lin, Wong Shiushing, Cummins Sharon E, Tedeschi Gary J. E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys BMJ 2017; 358 :j3262 http://www.bmj.com/content/358/bmj.j3262

[195]ONS, Adult smoking habits in the UK: 2016, 15 June 2017, para 28. https://www.ons.gov.uk/releases/adultsmokinghabitsingreatbritain2016

9. Combustion-free

While the Scandinavian snuff brands comes from tobacco producers who no longer produce cigarettes, the non-burning cigarettes – Combustion-free – are developed by businesses who mainly produces cigarettes or by producers who cooperate with this businesses (i.e. PAX Labs). Philip Morris has already launched iQOS[196] on the nicotine market in several countries, and will shortly launch TEEPS[197]. British American Tobacco/Reynolds Tobacco is about to develop their so-called «next generation products»[198] – glow, iFUSE, Vype, Core – and has warned that they wish to market test these shortly. Japan Tobacco makes Ploom TECH[199]and PAX Labs who cooperate with Japan Tobacco – has Pax2[200]. A business that already produces the cig-a-like-type of e-cigarettes, V2, has launched the V2 Pro-series [201]of HnB-products. Another– Vapor Tobacco Manufacturing – has launched T3 on the market[202]. The mechanisms for heating the tobacco varies from product to product and the temperature can vary as well.

As of November 2017, the HnB-products have been tested on nicotine markets in i.e. Japan, South-Korea, Switzerland, Italy, Canada and Russia. WHO[203] however informs that the industry is planning to apply for market access for non-burning cigarettes in i.e. Australia, Austria, Belgium, Colombia, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Israel, Kazakhstan, Lithuania, Luxembourg, Monaco, The Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Serbia, South-Africa, Spain, Sweden, Ukraine, Great Britain and the US. According to an industry-analyst, the market share for HnB can be expected to take up 30% of the American nicotine market in 2025[204]. Philip Morris has applied to the FDA to market iQOS in the US as a 'Modified Risk Tobacco Product' (the application can be read here[205]).

9.1 History

The tobacco industry made attempts already in the end of the 1980s to develop products where the tobacco would only be heated, but without going through the burn phase where most and the most dangerous toxins occurred. Such a product – Premier from RJ Reynolds – had the ability to deposit nicotine, but only with extremely intensive usage. This gave the product low usability, and in addition the smokers reported that Premier had an unpleasant taste[206],[207]. Premier was quickly removed from the market, but was re-introduced later as a re-

[196] https://www.pmi.com/smoke-free-products/iqos-our-tobacco-heating-system
[197] https://www.pmi.com/smoke-free-products/teeps-carbon-heated-tobacco-product
[198] http://www.bat.com/group/sites/uk 9d9kcy.nsf/vwPagesWebLive/DOA89DQ4
[199] https://www.jt.com/media/news/2016/0126_01.html
[200] https://www.paxvapor.com/pax-2/
[201] https://www.buyv2cigs.co.uk/v2-pro-vaporizers/
[202] https://www.3torganic.com/home
[203] http://www.who.int/tobacco/publications/prod_regulation/combustion-free-products-information-sheet/en/
[204] Caputi TL. Industry watch: combustion-free tobacco products are about to reach their boiling point. Tob Control 2016; 26:609–10.
[205] https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm546281.htm#6
[206] Sutherland G Russell MA Stapleton JA Feyerabend C . Glycerol particle cigarettes: a less harmful option for chronic smokers. Thorax . 1993;48(4):385–387.

designed product with the name Eclipse. Eclipse delivered larger doses of nicotine, but also produced more carbon monoxide[208]. Eclipse did not get appeal with the smokers either, but stayed on the market up until 2014. During this period, Eclipse changed its name to Revo and had gone through another re-launching, but in 2015, Reynolds decided to stop the production[209].

Philip Morris International (PMI) launched Accord in 1998 and Heatbar in 2007, without either of these non-burning cigarettes receiving a good reception.

Today's non-burning cigarettes consists of finely-cut tobacco wrapped in a paper sleeve with a filter (looks like a min-cigarette) – often called Heets or HeatSticks – which is inserted in a rechargeable battery-run unit which when sucking heats the tobacco to approximately 350 degrees. This produces an inhalable aerosol. Different from the e-cigarettes, the HnB-products contain tobacco, and taste more like regular cigarettes.

Some chemical, toxicological and clinical research on the levels of damaging connections in the non-burning cigarettes is done. Most of this research is done by the tobacco industry, which – opposed to many of the e-cigarette producers – have advanced laboratories and more than enough resources for research purposes. The results from some none-industry-financed studies indicate that HnB can supply the same concentration of nicotine as when smoking conventional cigarettes, at the same time as the concentration of nitrosamine (TSNA), formaldehyde, carbon monoxide and a number of other toxins, is much lower[210],[211],[212],[213],.

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[207] Stapleton JA Russell MA Sutherland G Feyerabend C . Nicotine availability from Eclipse tobacco-heating cigarette. Psychopharmacology (Berl) . 1998;139(3):288–290.

[208] Slade J Connolly GN Lymperis D . Eclipse: does it live up to its health claims? Tob Control . 2002;11(suppl 2):ii64–ii70

[209]Reynolds' decision to stop marketing of heated cigarette Revo illustrates challenges in selling adult smokers on new products. Richard Craver/Winston-Salem JournalAug 2, 2015.
http://www.journalnow.com/business/business_news/local/reynolds-decision-to-stop-marketing-of-heated-cigarette-revo-illustrates/article_afc1a516-29dc-55a5-8a54-75bd32cddd60.html

[210]Bekki K, Inaba Y, Uchiyama S, Kunugita N. Comparison of Chemicals in Mainstream Smoke in Combustion-free Tobacco and Combustion Cigarettes. Journal of UOEH Vol. 39 (2017) No. 3 pp 201-207.
https://www.jstage.jst.go.jp/article/juoeh/39/3/39_201/_article

[211] Farsalinos KE, Yannovits N, Sarri T, Voudris V, Poulas K. Nicotine delivery to the aerosol of a combustion-free tobacco product: comparison with a tobacco cigarette and e-cigarettes.
Nicotine Tob Res. 2017 Jun 16. https://academic.oup.com/ntr/advance-article/doi/10.1093/ntr/ntx138/3868870

[212]Auer R, Concha-Lozano N, Jacot-Sadowski I. et al. Combustion-free Tobacco Cigarettes: Smoke by Any Other Name. JAMA Intern Med. 2017 Jul 1;177(7):1050-1052https://cdn.doctorsonly.co.il/2017/06/jamainternal_Auer_2017_ld_170021.pdf

[213]COMMITTEES ON TOXICITY, CARCINOGENICITY AND MUTAGENICITY OF CHEMICALS IN FOOD, CONSUMERPRODUCTS AND THE ENVIRONMENT. Toxicological evaluation of novel combustion-free tobacco products – non- technical summary.
https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_summary.pdf

Figure 8. Packaging and product. iQOS from Philip Morris.

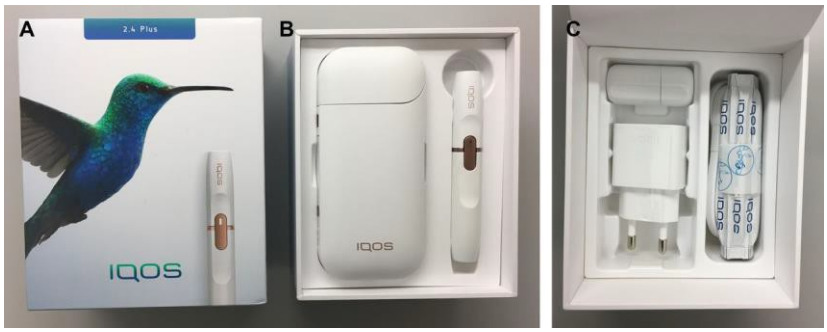
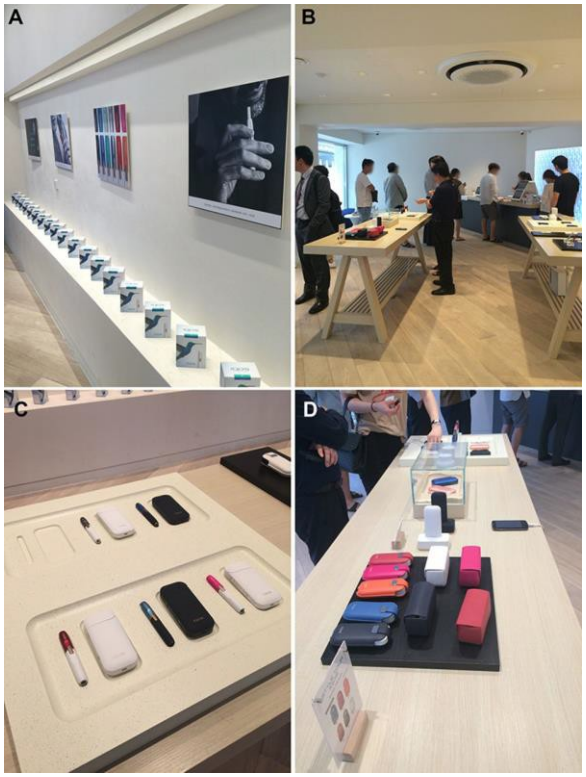


Figure 9. Retail outlet for iQOS.



The retail outlets for iQOS looks a lot like Apple-Stores or other stores selling high-tech consumer equipment (figure 9). The packaging has the same character as a smart-phone (figure 8).

9.2 User configuration

At this point there are too few studies to give a powerful statement. From Japan, a large interest in iQOS is reported. Observations show that Google-searches for HnB-products in Japan have increased dramatically[214]. iQOS was introduced in Japan towards the end of 2914,

[214] Theodore L. Caputi, Eric Leas, Mark Dredze, Joanna E. Cohen, John W. Ayers. They're heating up: Internet search query trends reveal significant public interest in combustion-free tobacco products. PLOS ONE, 2017; 12 (10): e0185735

and in the fall of 2017, Philip Morris informed that the product had occupied 12.7 % of the national marked for tobacco products. E-cigarettes and snuff are illegal in Japan.

Preliminary analyses indicate that the conversion ratio (see chap. 8.5.6) for iQOS seems to be significantly higher than the conversion ratio for e-cigarettes[215]. This can be an indication that the HnB-products, with their tobacco flavour and –smell, are closer to the smokers' preferences than the e-cigarettes. It can also, however, be an indication that the vapers – in the multitude of product combinations – spends more time in finding a replacement product.

9.3 Quitting smoking

At this point there are too few studies to give a powerful statement.

10. Tobacco free snuff

10.1 History

Sweden, Zyn – a type of snuff free of tobacco but containing nicotine – was launched for sale in a selected number of stores from December 2016. From 2014, the product has been tested in certain states in the US. Swedish Match has also warned that they wish to sell Zyn in Norway.

Similar to e-cigarettes, Zyn has no plant-material from tobacco. The product consists of a white, dry powder wrapped in small pillows, in the same way as snuff portions containing tobacco. The producer[216] informs that the powder contains nicotine salts washed from tobacco leaves, with added aroma (lemon/mint), acid regulating substances, sweetener, stabilizers and a filler (E 965, E 460, E 414).

While Zyn comes from the snuff industry, an almost identical product – Zonnic from the pharmaceutical industry – was launched in 2008, and released on the Norwegian market a few years later.

Zonnic is a Swedish brand that was founded in 2000, by the scientist and expert on weaning of smoking Karl Olov Fagerström. In addition to the snuff-variety of Zonnic, the product also comes as a lozenge and a mouth spray. Zonnic is sold over the counter and can be bought in both pharmacies and in kiosks and grocery stores[217]. With a status as a pharmaceutical – with a mention in Felleskatalogen [218] – the producer can advertise the product.

Before what Ken Warner called «the tobacco control community (see chap. 2.4), the launch of Zonnic disturbed the established views on which actors could be considered acceptable and allied in the work against tobacco[219],[220]. The company that produces the pharmaceutical –

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[215] iQOS in Pictures A Visual Overview of the Global Opportunity Through 2025. Bonnie Herzog, Senior Analyst. Wells Fargo. June 5 2017

[216] https://www.swedishmatch.com/sv/Media/Pressmeddelanden-och-nyheter/Nyheter/swedish-match-lanserar-en-helt-ny-produkt-zyn/

[217] http://www.zonnic.no/

[218] https://www.felleskatalogen.no/medisin/pasienter/pil-zonnic-niconovum-591986

[219] Kostygina G, England L, Ling P. New Product Marketing Blurs the Line Between Nicotine Replacement Therapy and Smokeless Tobacco Products. Am J Public Health. 2016 Jul;106(7):1219-22. https://www.ncbi.nlm.nih.gov/pubmed/27077338

Niconovum AB – is owned by Reynolds Tobacco Inc[221]. A third product within the category of snuff containing nicotine but without tobacco relevant on the Norwegian market is Fresh-free, where the produces do not belong to either the pharmaceutical or the snuff industry. In Germany, a similar nicotine product called 'On', has recently gained market access.

The Nicipads-products – Zyn, Zonnic, Fresh-free, On et al. –illustrates how challenging it has become to divide the nicotine market by the uses of the products (therapy vs. recreation) and producers (pharmaceutical industry, snuff industry, other industry). Very similar products risk being regulated by different regulations (pharmaceutical regulations vs. tobacco regulations).

10.2 User configuration

No scientific articles informing of user configurations have been identified.

10.3 Quitting smoking

There are some experimental studies on Zonnic in weaning of smoking. These show that the product has a higher score on 'likability' than nicotine gum, is more effective against 'craving', and can give as good or better results than pharmaceuticals containing nicotine[222],[223],[224].

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[220]Gong M, Dunbar MS, Setodji C, Shadel WG. Zonnic®: a new player in an old field. Subst Abuse Treat Prev Policy. 2017 Sep 6;12(1):40. https://www.ncbi.nlm.nih.gov/pubmed/28877727

[221]Tommy J. Payne. Smoking Harm Reduction. Am J Public Health. 2016 December; 106(12): e2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5105003/

[222]McRobbie H, Thornley S, Bullen C et al. A randomized trial of the effects of two novel nicotine replacement therapies on tobacco withdrawal symptoms and user satisfaction. Addiction. 2010 Jul;105(7):1290-8. https://www.ncbi.nlm.nih.gov/pubmed/20491724

[223]Caldwell B1, Burgess C, Crane J. Randomized crossover trial of the acceptability of snus, nicotine gum, and Zonnic therapy for smoking reduction in heavy smokers. Nicotine Tob Res. 2010 Feb;12(2):179-83. https://www.ncbi.nlm.nih.gov/pubmed/20064899

[224]Thornley S, McRobbie H, Lin RB et al. A single-blind, randomized, crossover trial of the effects of a nicotine pouch on the relief of tobacco withdrawal symptoms and user satisfaction. Nicotine Tob Res. 2009 Jun;11(6):715-21. https://www.ncbi.nlm.nih.gov/pubmed/19454549

Part III. What is the potential impact of various policy instruments on current and future generations' addiction to tobacco and nicotine products?

In Part I, we addressed the various perspectives of harm reduction as the principle is reflected in the international debate on tobacco. We endeavoured to show what implications adoption of the harm reduction principle might have on the tobacco strategy's objective and how such a policy might lead to different treatment of products according to their degree of harm.

A potential dilemma may arise if market access, competitive advantages and information about reduced harm were to create a temptation pressure in population groups that in the absence of such a harm reduction policy would *not* be exposed to temptation. Examples of such groups include young people who do not perceive smoking as an alternative course of action, or ex-smokers who could easily have given up all nicotine products, but who instead perpetuate their use with one or several of the new nicotine products. Comprehensive research has shown that tobacco advertising, changes in prices, the visibility of smoking and information affect recruitment to and withdrawal from the smoking population. We must assume that these results relating to influence factors for smoking also have a transfer value with regard to use of other nicotine products for recreational purposes.

The WHO (2014) has described the dilemma as follows:

> *Although ENDS present a range of potential benefits to smokers, there is an extensive and often heated debate about whether ENDS will prove to have a positive or negative impact on population health and particularly tobacco control. Areas of legitimate concern include avoiding nicotine initiation among non-smokers and particularly youth while maximizing potential benefits for smokers. Such concerns are referred to as the gateway and renormalization effects.*
>
> *The gateway effect refers to two potential circumstances: (i) the possibility that children (and generally non-smokers) will initiate nicotine use with ENDS at a rate greater than expected if ENDS did not exist; and (ii) the possibility that once addicted to nicotine through ENDS children will switch to cigarette smoking*
>
> *The renormalization effect refers to the possibility that everything that makes ENDS attractive to smokers may enhance the attractiveness of smoking itself and perpetuate the smoking epidemic. ENDS mimic the personal experience and public performance of smoking and their market growth requires marketing that is challenging commercial communication barriers erected to prevent the promotion of tobacco products*[225].

11. Weighing the pros and cons

A harm reduction policy that facilitates a choice of less harmful nicotine products for established and potential smokers (hereinafter referred to as the *high-risk group*), may also at the same time reduce barriers to use for a group that in the absence of a harm reduction policy would have remained nicotine free (hereinafter referred to as the *low-risk group*). This means

[225] Electronic nicotine delivery systems. Report by WHO. FCTC/COP/6/10 Rev.1 1 September 2014 http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf (side 6-7)

that policy makers should weigh the presumed pros in the high-risk group against the presumed cons in the low-risk group. Will the positive results achieved for the harm reduction policy target group (the high-risk group) be offset by unintentional negative consequences for those not in the target group (the low-risk group)?

The weighing comprises two components: *the number of people* who are affected by the harm reduction policy (the so-called group transition) and *the health effect* for those people who are influenced in one direction or the other.

To be precise, this means that decision makers must have a fairly clear understanding of how many people in the high-risk group are affected by the harm reduction policy in a way that is positive for their health, and how many people in the low-risk group are influenced in a negative direction. Moreover, decision makers must be aware of the extent of the health benefits to smokers and potential smokers who choose a harm-reducing product instead of cigarettes. Correspondingly, they must be aware of the health deterioration that will affect people from the low-risk group who instead of choosing to be nicotine-free, are tempted into using a harm-reducing product containing nicotine.

By applying estimates for the various group transitions and the health results for the people who change user status, it is possible to model the future net effect of a harm reduction policy at public health level.

To what extent the new nicotine products gain ground, as well as their user configuration, will to a large degree be determined by regulations imposed on product content, product presentation, taxation and area of use. In Appendix 1, we present calculations comparing the results from liberal regulation of e-cigarettes with the result of restrictive regulations as regards burden of disease and welfare gain (cf. Appendix 1).

Several attempts have already been made to construct models for calculating the impact on public health when people have access to e-cigarettes[226],[227],[228]. The most recent model concluded that[229]:

> *Compared with the Status Quo, replacement of cigarette by e-cigarette use over a 10-year period yields 6.6 million fewer premature deaths with 86.7 million fewer life years lost in the Optimistic Scenario. Under the Pessimistic Scenario, 1.6 million premature deaths are averted with 20.8 million fewer life years lost. The largest gains are among younger cohorts, with a 0.5 gain in average life expectancy projected for the age 15 years cohort in 2016.*

In Table 6, we present the ratio of use for a harm reduction product where the health gains among smokers who quit smoking (high-risk-group) will be offset by health deterioration among nicotine-free people who start using a nicotine product (low-risk group). In research

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[226] Levy DT, Borland R, Villanti AC, et al. The Application of a Decision-Theoretic Model to Estimate the Public Health Impact of Vaporized Nicotine Product Initiation in the United States. Nicotine Tob Res 2017;19:149–59

[227] Levy DT, Cummings KM, Villanti AC, et al. A framework for evaluating the public health impact of e-cigarettes and other vaporized nicotine products. Addiction 2017;112:8–17

[228] Cobb CO, Villanti AC, Graham AL et al . Markov modeling to estimate the population impact of emerging tobacco products: A proof-of-concept study. Tob Reg Sci . 2015;1(2):129–141.

[229] David T Levy, Ron Borland, Eric N Lindblom, Maciej L Goniewicz, et al. Potential deaths averted in USA by replacing cigarettes with e-cigarettes. Tobacco Control 2017. http://tobaccocontrol.bmj.com/content/early/2017/08/30/tobaccocontrol-2017-053759.long

literature this is referred to as the „risk – use equilibrium"[230]. So the question that we are asking – given the different harm levels for a harm reduction product compared with cigarettes, is how many nicotine-free people must start using this product to offset the health gains for each smoker or potential smoker who chooses the harm reduction product instead of cigarettes (high-risk group)?

Table 6. Ratio of use between the high-risk and low-risk group that will result in a harm reduction product having as many negative as positive consequences, given various levels of harm compared to cigarettes.

A. Degree of harm compared to cigarettes (per cent)	B. Number of smokers who start using a product	C. Number of nicotine-free persons who start using a product	Net result at aggregated level (public health effect)
1	1	100	0
2	1	50	0
5	1	20	0
10	1	10	0
15	1	6.7	0
20	1	5	0
25	1	4	0

11.1 How is the degree of harm calculated?

The size of the risk reduction when switching from cigarettes to a harm-reducing nicotine product will of course vary for various diseases. For instance, in the case of *snus* (moist snuff), it can vary from a 100% reduction for respiratory disorders (which cause almost half of all tobacco-related deaths in Norway), to significantly lower risk reduction for other diseases such as diabetes (which causes relatively few tobacco-related deaths). The difference in risk between cigarette smoking and other nicotine use might be even less in connection with, for instance, pregnancy complications.

Recently, several epidemiological studies have become available which will make it easier for decision makers to determine the degree of hazard compared to cigarettes for individual diseases. This is more difficult for new nicotine products such as e-cigarettes, Combustion-free and tobacco-free snus. In the absence of observations of potential harm to people after extensive use, estimations are made on the basis of toxicological studies, animal testing and acute physiological reactions in humans. The British public health institute, Public Health England, has estimated that the degree of harm for e-cigarettes is 5% compared to cigarettes containing tobacco. Consequently, the figure emerges as a `global' result of risk differences between vaping and smoking that presumably exist for a number of individual diseases, combined with the weight of each of these diseases for the total harm panorama for tobacco

[230] Kozlowski L, Strasser AA. et al. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. Tobacco Control 2001;10:201–203
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1747574/pdf/v010p00201.pdf

use. This estimate has been disputed. Some people believe it is too low[231],[232]and some believe that it is probably much lower[233], whereas others believe that such estimations are of little use as long as we lack exact knowledge about long-term effects.

A more fundamental objection to indicating the degree of harm is that harm caused by smoking is used as a comparative basis. Some Norwegian public documents argue against this practice, suggesting that the degree of harm when using a harm-reducing nicotine product should only be contrasted with non-use. This objection is relevant to the extent that the harm-reducing product in question is not primarily a substitution product for cigarettes, but exists in the market as an independent benefit (i.e. a product which does not affect the consumption of cigarettes).

11.2 The equilibrium – a numerical example

In brief, it is the user configuration and relative degree of harm that will determine the effect of a harm reduction product on public health. We can illustrate this reasoning in a simple numerical example. Say that five adolescents start using e-cigarettes over a one month's period. They all have in common that they have chosen to smoke e-cigarettes instead of tobacco cigarettes, either because they have used e-cigarettes in a successful attempt to quit smoking, and then continued to use e-cigarettes, or that they chose e-cigarettes at initiation instead of tobacco cigarettes (for whatever reason). In the hypothetical absence of e-cigarettes these five people would have smoked tobacco cigarettes (high-risk group). Given that the cigarettes have a 5 per cent degree of harm, these five people would therefore have gained a major health benefit as permanent vapers, compared to what they would have risked as permanent smokers of tobacco.

However, during the same month, some adolescents start using e-cigarettes who in the hypothetical absence of e-cigarettes would have remained nicotine-free (low-risk group). As long-term vapers, these young people would risk health damage that they would not have suffered as permanent abstainers from nicotine, but with just 5 per cent of the degree of harm that would befall the group of smokers.

From a public health perspective, we would like to know how many nicotine-free adolescents would have to take up vaping to offset the health gains for the five who managed to quit smoking by using the new nicotine product. The answer is 100 adolescents. A ratio of 5/100 would result in equilibrium between the advantages and disadvantages. To put it differently; to make up for the health gains for each adolescent who prefers e-cigarettes to tobacco cigarettes, 20 adolescents – who would otherwise have been nicotine free – would have to start using e-cigarettes (5 x 20 = 100) (cf. Table 6).

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[231] McKee M, Capewell S. Evidence about electronic cigarettes: a foundation built on rock or sand? BMJ 2015;351:h4863 http://www.bmj.com/content/351/bmj.h4863

[232] E-cigarettes: Public Health England's evidence-based confusion. The Lancet , Volume 386 , Issue 9996 , 829 http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)00042-2/fulltext?rss=yes

[233] Philips CV. Saying e-cigarettes are “95% less harmful” is a very bad idea. https://antithrlies.com/2016/05/25/saying-e-cigarettes-are-95-less-harmful-is-a-very-bad-idea-part-143-of-10000/

Thus, a relevant question that decision makers should ask is how many nicotine users can be accepted from the low-risk group for each person who, due to the harm reduction policy, chooses a harm reduction product instead of cigarettes.

In its 2016 report, the Royal College of Physicians discuss this equilibrium logic:

> *A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, e.g. exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.*
>
> *However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (page 187).*

12. Decisions under uncertainty

In Part II, we described the four product groups that are currently considered harm reducing compared to cigarettes, we described the typical users of such products and what role the products play in smoking cessation. These were nicotine pharmaceuticals, snus, e-cigarettes and Combustion-free products. However, new nicotine products are under development.

Faced with a heterogeneous portfolio of new nicotine products, it will be challenging for the authorities to decide what products should potentially be included – and what products should be excluded – from the arsenal of products that are considered acceptable for harm-reduction purposes. In this context, decision makers might ask a number of questions, not all of which can be answered empirically. This is because the existing observational basis will be insufficient or because the questions also call for assessments where emotions, values, ethics and ideology will play a part.

12.1 Questions that can be answered empirically

Some questions, such as those mainly relating to harm, different degrees of harm and user groups, can be answered empirically given that the observational basis is sufficient:

> *a) What are the health risks of long-term use of the product compared with abstaining from use (absolute risk)?*
>
> *b) Can the product be considered a substitution product for cigarettes or is it an independent beneficial product?*
>
> *c) If it is a substitution product – how harmful is it compared to cigarettes?*
>
> *d) Will use of the product lead to complete or partial substitution of cigarettes?*
>
> *e) For partial substitution – will double-use lead to so much less use of the most harmful products (the cigarettes) that the risk of tobacco-related disease is also reduced?*
>
> *f) Will use of the harm reduction product defer or accelerate smoking cessation?*
>
> *g) Does the product appeal to those groups that would have the presumed highest health benefit – established and potential smokers (high-risk groups)?*
>
> *h) Does the product also appeal to young non-smokers who would otherwise refrain from using a nicotine product (low-risk group)?*

i) If the product appeals to both the high and low-risk groups – what is the ratio of use between these groups?

j) Should use in the low-risk group be considered experimental (temporary) or permanent?

12.2 Questions that are difficult to answer empirically

However, questions can also be raised that are more difficult to address empirically, even with advanced research design. This could be because researchers come across operationalisation problems (e.g. how to measure renormalisation[234]), or because causal explanations in some areas (e.g. when testing the gateway hypothesis) cannot be offered because the required study design would be unethical (randomised-controlled experience).

k) Could use in the low-risk group be a direct or contributing cause of subsequent experimentation and/or long-term use of tobacco cigarettes (hereinafter referred to as the gateway hypothesis)?

l) Will the visibility of the product (e.g. display of goods, advertising) and the visibility of its use (e.g. vaping of e-cigarettes) re-normalise cigarettes and tobacco smoking (hereinafter referred to as the renormalisation hypothesis)?

m) Or will such visibility contribute to normalising substitution products for cigarette smoking (e.g. e-cigarettes) in a way that reinforces de-normalisation of cigarettes and smoking?

12.3 Questions with emotionally conditioned answers

In the debate on what harm reduction products might be acceptable, emphasis has also been placed on more emotionally conditioned factors. Various assessments relating to the public opinion of the various branches of the nicotine industry and connotations related to tobacco and tobacco derivatives, may be a reason why questions of this type are significant:

n) What industry does the product come from (the tobacco industry or others)?

o) Does the product contain tobacco (as in combustion-free) or only nicotine (as in e-cigarettes)?

p) Is the nicotine in tobacco-free products (such as Zyn and Zonnic) extracted from the tobacco plant or produced synthetically (as in some e-cigarettes)?

12.4 Questions relating to additional value

Moreover, it is of interest to us whether the new nicotine products considered for use in a harm reduction policy have qualities or functions that have additional benefits beyond those that can be obtained from harm reduction products already on the nicotine market (cf. Part II).

q) What marginal benefits for harm reduction do new nicotine products have if assessed against the existing ones?

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[234] Sæbø G, Scheffels J. Assessing notions of denormalization and renormalization of smoking in light of e-cigarette regulation. International Journal of Drug Policy. http://www.sciencedirect.com/science/article/pii/S0955395917302402

12.5 Questions related to the diffusion phase

As we know, there has been a gradual reduction in the number of smokers over many years – from the 1970s for men and the 1990s for women. This reduction has been achieved without a government-intended harm reduction policy (despite the fact that snus can be said to have functioned as a harm reduction product for many smokers during that period).

> *r) Is it strictly speaking necessary to allow market access and competitive advantages for nicotine products during the entire period that the reduction in smoking is likely to continue?*

In a situation where smoking is reduced to a minimum, the harm reduction function of an alternative nicotine product is reduced in the form of smoke cessation. When the prevalence of smokers is low, the harm reduction function will to a larger degree have to be obtained in the initiation phase – i.e. by functioning as an alternative product for young people who may be vulnerable to take up cigarette smoking. In his 1991 Article, Michael Russell claims that the smoking cessation effect from alternative nicotine products would be highest during the cigarette epidemic's middle diffusion phase when the prevalence of smokers peaks. Russell points out that it would be as an alternative to cigarettes for new nicotine users that the alternative products could be expected to have greatest impact in a future phase-out of smoking.

> *s) How much is the potential for harm reduction reduced by an alternative nicotine product, when the number of people who will try to quit smoking is reduced?*

When the prevalence of smokers in society is reduced, the reservoir of potential users of a substitution product for cigarettes will shrink. Furthermore, this will entail a change in the ratio of smokers and non-smokers using nicotine substitution products. Such user configuration changes have already been observed for snus. Among male snus users the proportion of non-smokers increased from 16% during the 2003-2005 period to 35% during the 2011-2015 period (Lund, Vedøy, Bauld 2017).

> *t) What proportion of non-smokers can we accept among users of an alternative harm-reducing nicotine product?*

12.6 The precautionary principle

At present, research will not be able to supply the authorities with certain and consistent answers to all the questions above. This uncertainty can be used, and is being used, as an argument for postponing the authorities' decision to include harm reduction as a supplement in the disease prevention work for tobacco.[235]. Below follows an illustrative example from an interview in the medical journal *Dagens Medisin* with a representative for the respiratory group Lunger i Praksis, Dr. Anders Østrem:

> *„The main problem with e-cigarettes is that we still don't know enough. After all, it did take us 40-50 year before we could document the health hazard of conventional cigarettes. From a public health principle point of view, we will not recommend anything before we are certain*

[235] Bush AM, Holsinger JW Jr, Prybil LD. Employing the Precautionary Principle to Evaluate the Use of E-Cigarettes. Front Public Health. 2016 Feb 4;4:5 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4740382/

> *that it doesn't cause any harm. And when we don't know, we must be cautious making recommendations, Østrem says to Dagens Medisin*[236].

Whilst awaiting more answers, and more consistent and certain answers, it may be legitimate for decision-makers to apply the precautionary principle as a normative rule. When politicians must assess the consequences of their own choices of action made on behalf of society, caution is warranted. However, is it certain that the most health-beneficial option is to exclude alternative nicotine products whilst waiting for epidemiological long-term studies to document with certainty that e-cigarettes, snus or HnB products pose less health risk than cigarette smoking?

Decision theorists emphasise that the required caution should not be rooted in moralism, emotions, political direction or prevalent moods in society, but that the precautionary principle could potentially be applied after having weighed the presumed advantages against the presumed disadvantages[237], [238], [239], [240], [241]. The precautionary principle can be misused and become a substitute motive for resistance to harm reduction which in fact is more ideologically founded[242].

In his overview article „Føre-var-prinsippet som rasjonelt beslutningskriterium" (*The precautionary principle as a rational decision criterion*) Professor of Political Science Jon Hovi (2001) pointed to general conditions that decision theorists assert must be prevalent for the precautionary principle to be applied:

> *i) there must be a large degree of uncertainty, and the larger uncertainty, the more legitimate the use of the precautionary principle*
>
> *ii) scenarios or models must be available based on scientific reasoning showing major potential or likely harmful effects*
>
> *iii) the probable harm must have a high degree of irreversibility – i.e. be irreparable or serious for current and future generations, or in other ways be morally unacceptable*
>
> *iv) effective countermeasures will be significantly more difficult or more costly at a later stage*

This means that in order to invoke the precautionary principle, it is insufficient to express vague insecurity or concern. Scenarios or models must be established based on scientific reasoning that can substantiate that the harmful effects from a harm reduction policy within the field of tobacco will be extensive, irreversible and irreparable.

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[236] Nilsen L. Researchers believe the use of e-cigarettes is not risk-free. Dagens Medisin. 9 September 2017

[237] Aven T. On Different Types of Uncertainties in the Context of the Precautionary Principle. Risk Anal. 2011 Oct;31(10):1515-25. http://onlinelibrary.wiley.com/doi/10.1111/j.1539-6924.2011.01612.x/abstract;jsessionid=8967F477C25977DAE9BD0F7F6D6EA26E.f04t04

[238] Tubiana M. The precautionary principle: advantages and risks. J Chir (Paris). 2001 Apr;138(2):68-80. https://www.ncbi.nlm.nih.gov/pubmed/11319454

[239] Saltelli A, Funtowicz S. The Precautionary Principle: implications for risk management strategies. Int J Occup Med Environ Health. 2004;17(1):47-57. https://www.ncbi.nlm.nih.gov/pubmed/15212206

[240] Hovi J. The precautionary principle as a rational decision criterion. CICERO Working Paper 2001:13. https://www.duo.uio.no/bitstream/handle/10852/32763/1627.pdf?sequence=1

[241] Aslaken L, Brekke KA. The precautionary principle. Samfunnsøkonomen, Årg. 126, nr. 6 (2012), S. 42-47

[242] Farsalinos KE, Le Houezec J. Regulation in the face of uncertainty: the evidence on electronic nicotine delivery systems (e-cigarettes). Risk Manag Healthc Policy. 2015 Sep 29;8:157-67 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4598199/

12.6.1 Costs associated with the precautionary principle

Hovi also pointed out that this precautionary rule may incur costs. When applied to tobacco, the cost of not applying a harm reduction policy may be that smokers and potential smokers (high-risk groups) are denied access to harm-reducing forms of nicotine intake. Paradoxically, the precautionary principle may strengthen the position of the most harmful product of all – cigarettes – and protect the cigarette industry against competition in the nicotine market.

It can be claimed that low-risk substitutes for tobacco smoking satisfy the criteria from Hovi. There is substantial uncertainty related to the impact on the future spread of nicotine addiction. Such addiction is highly undesirable, and the effect can be difficult and/or costly to reverse, should it occur.

However, Hovi's criteria must be understood as *necessary* conditions for adhering to the precautionary idea. They are not *sufficient* conditions for concluding that 'it pays to be cautious'. Such a conclusion cannot be drawn until the costs have been assessed, i.e. it should be clarified what is being sacrificed by applying such caution. In principle, it is possible to sacrifice too much on the altar of precaution.

12.6.2 Weighing advantages against costs

Costs related to low-risk substitutes for tobacco smoking can be significant. This can be illustrated by an example. Say we are going to decide whether e-cigarettes should be given advantages compared to conventional cigarettes, e.g. in the form of lower taxes and more lenient restrictions against vaping than smoking. There is a risk that this will result in more people becoming part of one of the groups with adverse outcomes, cf. our discussion of potential unintentional effects above. How big the risk is, is uncertain. However, one often wants to safeguard against such potential outcomes by being restrictive, i.e. by being cautious.

Furthermore, let us assume that a restrictive policy entails a strong likelihood that fewer smokers will switch to vaping, and that many lives that could have been saved (actually: extended to normal length), would be lost. The greater the loss under a restrictive policy, the more difficult it is to justify adopting a precautionary approach. At a certain point it will no longer be reasonable to claim that precaution 'pays off'.

In this decision situation, the precautionary idea per se may be reversed. How many lost lives a restrictive policy may lead to, is uncertain. The loss of life constitutes major harm, and such harm is irreversible. However, one wants to safeguard against such potential loss. One wants to exercise caution. However, this entails not being restrictive.

It emerges that the core of the precautionary idea – i.e. maintaining an attitude of reserve towards alternative courses of action that entail a risk of serious negative consequences (without it being possible to quantify such risk exactly) – can be used as an argument for being restrictive as well as for not being restrictive. Consequently, the precautionary principle per se provides little guidance.

As exercising precaution often costs something, choosing a precautionary alternative is not correct per se, i.e. not 'correct in principle' or something that automatically overrides other considerations. A precautionary action is intended to prevent a theoretically possible loss. This must be weighed against the known costs of the action. This is also the case with, e.g.,

decisions relating to new medicine. The fact that it cannot be ruled out that the medicine has certain negative consequences in the long term is disregarded if a large number of people would be affected by not using them.

It is problematic to use the precautionary idea as an independent, general norm when choosing which policy to adopt for substitutes for tobacco smoking. The question that needs to be raised is whether what we want to safeguard against by being restrictive, will justify the expected losses caused by a restrictive policy. Consequently, what is required in a broad sense is a specific cost-benefit analysis.

The EU Commission has issued some general guidelines on how to apply a precautionary principle. In its memorandum, the EU Commission also emphasises the need for a prior cost-benefit analysis:

> *Where action is deemed necessary, measures based on the precautionary principle should be based on an examination of the potential benefits and costs of action or lack of action (p 3)…. A comparison must be made between the most likely positive or negative consequences of the envisaged action and those of inaction in terms of the overall cost to the Community (EU), both in the long- and short-term. The measures envisaged must produce an overall advantage as regards reducing risks to an acceptable level (p 18)*[243].

[243] COMMISSION OF THE EUROPEAN COMMUNITIES. Brussels, 2.2.2000 COM(2000) 1 final COMMUNICATION FROM THE COMMISSION on the precautionary principlehttps://publications.europa.eu/en/publication-detail/-/publication/21676661-a79f-4153-b984-aeb28f07c80a/language-en

13. Conclusive remark

The intention of this memorandum has not been to provide a certain recommendation on whether harm reduction should be adopted as a supplement in the strategy to reduce disease and death caused by tobacco smoking. The memorandum aims to provide the Ministry of Health and Care Services with a background and framework that can be used in their assessment of whether harm reduction should be part of a tobacco prevention strategy.

Our approach has been to identify presumed pros and cons by applying the harm reduction concept, and then present a method for weighing these against each other. This weighing comprises two main ingredients. Firstly, we need estimates for the *degree of harm* caused by new nicotine products – both in an absolute sense (compared to not using the products), and in a relative sense (compared to tobacco smoking). Then we need predictions for who is going to use the new nicotine products – what we refer to as *user configuration*. Identification of users, the purpose of their use, their user careers and their transitions between various nicotine products, require much more extensive collection of data than is currently taking place at the Norwegian Institute of Public Health.

The method of weighing pros and cons represents a new approach to the conventional logic that has formed the basis for the authorities' regulation of nicotine products.

Traditionally, provisions have been based on three principles within medical ethics, and they have legitimised e.g. the existing ban on introduction of new nicotine products to the market:

> *1) The do no harm principle – which advises against the use of products that cause obvious consequential harm due to their toxic content.*
>
> *2) The precautionary principle – which warns against the use of products when it cannot be precluded that unidentified consequential harm may arise in the future, and that it may be irreversible.*
>
> *3) The loss of autonomy principle – which warns against the use of products that may cause addiction.*

In our approach, we apply a comparative perspective which entails that the harmful effects of cigarette smoking are used as a comparative basis for harmful effects from other nicotine products. This assumes that a so-called substitution relationship exists between conventional tobacco-containing cigarettes and other nicotine products, where user functions and user groups overlap to a great extent.

Even though a transition from tobacco-containing cigarettes to combustion-free nicotine products is highly likely to reduce harm for the individual smoker, the harm reducing effect at society level will depend on to what extent the alternative nicotine products may recruit non-smokers, defer smoking cessation, lead to persistent double-use and function as a gateway to smoking. These potential disadvantages must be weighed against the potential advantages, and this memorandum argues that such a weighing procedure – and to a lesser extent the three medical ethics principles above – should form the basis for the authorities' decision to adopt harm reduction as a supplementary element in their efforts to reduce smoking-related health damage.

If the authorities were to adopt a decision to include harm reduction in their anti-tobacco strategy, it would be advantageous to include the users in the formulation of such a policy. A

user perspective has – as opposed to what has been the case in policies on narcotic drugs – only to a limited extent been applied to tobacco.

14. Literature search

Syntax used in PubMed

(Nicotine[Title]) OR (Electronic cigarette[Title/Abstract]) OR (E-cigarette[Title/Abstract]) OR (Electronic cigarettes[Title/Abstract]) OR (E-cigarettes[Title/Abstract]) OR (Electronic Nicotine Delivery System[Title/Abstract]) OR (Electronic Nicotine Delivery Systems[Title/Abstract]) OR (Alternative Nicotine Delivery System[Title/Abstract]) OR (Alternative Nicotine Delivery Systems[Title/Abstract]) OR (personal vaporizer[Title/Abstract]) OR (Vaping[Title/Abstract]) OR (vapers[Title/Abstract]) OR (heated tobacco[Title/Abstract]) OR (combustion-free tobacco[Title/Abstract]) OR (reduced risk tobacco product[Title/Abstract]) OR (modified risk tobacco product[Title/Abstract]) OR (reduced risk tobacco products[Title/Abstract]) OR (modified risk tobacco products[Title/Abstract]) OR (snus[Title]) OR (smokeless tobacco[Title]) OR (toombak[Title]) OR (spit tobacco[Title])

Appendix 1
Effects on health from a liberal vs. a restrictive policy on e-cigarettes—a calculation

Erik Nord, 2017-05-12

Introduction

Several articles have been published internationally calculating the effects on health in the population at various degrees of transitioning from tobacco smoking to vaping.[244] The most recent study from the United States estimates that in the period from 2016 to 2100, 1.6–6.6 million lives could be saved, depending on the degree of transition.[245] Studies of this kind are called scenario analyses. They do not outline how to achieve the transitions they describe. This appendix calculates the effects of two alternative e-cigarette policies—one liberal and one restrictive.

Uncertainties

E-cigarettes are much less harmful than tobacco cigarettes, but the ratio cannot be reliably calculated and is subject to discussion among researchers. We have calculated a primary alternative, as well as a high alternative, which together cover a plausible scope of possibility. In the primary alternative, we have presumed that the degree of harm of e-cigarettes is 5 percent of that of tobacco cigarettes. In the high alternative, we have estimated the degree of harm to be 20 percent.

One major uncertainty in this calculation is how increased use of e-cigarettes as a result of a liberal policy is distributed in terms of acting as a *replacement* to smoking or as a *supplement to* smoking. The idea of e-cigarettes as measure for harm reduction presupposes that the increased use represents a transition from tobacco to e-cigarettes, i.e. a replacement. However, vaping will be used as a supplement to smoking, insofar as smokers will use it as an alternative in certain situations where smoking is now allowed, thus waiting longer to stop smoking, and insofar as smokers choose to switch to vaping instead of cutting out nicotine completely.

As for the distribution between replacement and supplement, the research is inconclusive. However, the best designed studies in this area suggest that the availability of e-cigarettes has a certain positive effect on quitting tobacco (see chapter 8.4). At the same time, these studies may not be a solid basis on which to estimate the effects of future policy. (The effect of e-cigarettes on quitting tobacco would presumably correlate to how e-cigarettes are presented by authorities.) So far, authorities have been reluctant to recommend them, due to concerns of detrimental effects among young people. There are also some reservations in terms of how much less harmful e-cigarettes are, compared to tobacco cigarettes. However, if authorities do decide to use e-cigarettes as an element in a focused strategy of harm reduction, one would expect authorities to issue positive statements concerning e-cigarettes and to design a wide range of measures that would motivate smokers to transition to vaping without reducing the incentive to quit smoking, and without encouraging young people to take up vaping.

[244] Bachand and Sulsky, Regulatory Toxicology and Pharmacology, 2013; Kalkhoran and Glantz, JAMA Int Med, 2015; Weitkunat et al., Regul Toxicol Pharmacol, 2015; Vugrin et al., PLOS ONE, 2015; Levy et al., NTR, 2016; Cherng et al., Epid, 2016; Hill and Camacho, Reg. Tox. Pharm., 2017; Poland and Teischinger, NTR, 2017; Bachand et al., Risk Analysis, 2017; Levy et al., Tob. Control, 2017

[245] Levy DT, Borland R, Lindblom EN, et al., Potential deaths averted in USA by replacing cigarettes with e-cigarettes, Tobacco Control, Published Online First: 02 October 2017.

Existing research results on the effects of e-cigarettes on quitting tobacco are not necessarily transferable to such aggressive policies and measures. We have specified a possible range of measures below.

We emphasize, however, that we cannot conclusively calculate the degree to which any range of measures will lead to a reduction in smoking. The calculations below must therefore be interpreted as an account of how aggregate numbers for a liberal policy B would look if one were successful in effecting a transition from smoking to vaping to the degree applied in the calculation. This could be used as a basis on which to consider whether it would be worth exploring policy B, with the intention of conducting an evaluation after a short initial period.

The measure

We have compared current policy (called A) with a hypothetical policy (called B), which, compared to A, (1) imposes lower taxes and charges; (2) systematically informs the public of relative degrees of harm, which may motivate smokers to transition; (3) imposes fewer restrictions on indoor use (no ban, local regulations); and (4) raises the purchase age for tobacco products and e-cigarettes.

We have estimated the effects of policy B compared to policy A in the medium term, i.e. 10 years from today.

The effects are largely seen in two main groups of people. One is established smokers, and the other is young people who neither smoke nor vape.

Effects among established smokers

We estimate that policy B could make it more difficult or less important for some smokers to quit, as they will be able to satisfy their nicotine needs by vaping in certain situations where smoking is not allowed. However, based on a comprehensive assessment of existing research in this field, we assume that policy B will have a positive effect on quitting for all smokers overall, cf. evidence presented in chapter 8.4 of this report.

Based on Norwegian and English data, we assume that smokers who take up vaping are distributed relatively equally between mixed users and ‘vaping only’, with the former group being slightly larger, cf. evidence presented in chapter 8.2. We furthermore assume that under policy B, the number of people who abstain completely will be slightly lower, as some of these will end up as vapers instead.

We imagine 100,000 smokers, who either want to reduce their smoking or quit completely. Given the above conditions, we estimate the distribution of these 100,000 people after 10 years under policy A and policy B, respectively:

Table 1: Status of 100,000 smokers in 10 years under two alternative policies. Illustrative estimate.

	Policy A	Policy B
Smokes just as much, does not vape	80,000.	60,000.
Replaced half of smoking with vaping	6,000.	20,000.
Transitioned to vaping	4,000.	15,000.
Quit completely	10,000.	5,000.
Total	100,000.	100,000

We have assumed a 15-percent risk of future smoking-related death in the group of smokers (Vollset et al., 2006). These deaths are clustered around age 65–70, and in this context they are labelled 'premature deaths' or 'lives lost'. Given a degree of harm at 5 percent for e-cigarettes (the primary alternative), the risk of death for vapers is 0.75 percent, which we have rounded up to 1 percent. In the mixed-use group, we have estimated the risk of death to be between the two, i.e. 8 percent.

Therefore, the figures for smoking- and vaping-related deaths are as follows:

Table 2: Risk and estimated number of smoking- and vaping-related deaths under two alternative policies.

	Risk (%)	Policy A	Policy B
Smokes just as much, does not vape	15	12,000	9,000
Replaced half of smoking with vaping	8	480	1,600
Transitioned to vaping	1	40	150
Quit completely	0	0	0
Total:		12,520.	10,750

Now, we can calculate three different figures for policy B:

Figure 1: Table 2 shows that, under the chosen conditions, 1,770 premature deaths in a population of 100,000 current smokers can be avoided by implementing policy B over policy A.

Figure 2a: Table 1 also shows that under policy B, 6,000 additional people would be completely smoke-free, and therefore unaffected by smoking-related health concerns (15,000 + 5,000 – 4,000 – 10,000).

Figure 2b: Table 1 furthermore shows that under policy B, 14,000 additional people would experience a reduction in smoking-related health concerns as a result of replacing some of their smoking with vaping (20,000 – 6,000).

Figure 3: On the other hand, after 10 years, 5,000 fewer people will be completely nicotine-free, i.e. the number of nicotine-dependent people is higher by 5,000 under policy B compared to under policy A.

Effects among nicotine-free young people

In addition to the figures above, one should take into consideration the effect of policy B on behaviours among young people who previously neither smoked nor vaped.

According to Norwegian, English and American data, approx. 95 percent of vapers are former smokers, whereas approx. 5 percent are former non-smoking young people, cf. evidence cited in chapter 8.2. In the latter group, approx 60 percent use exclusively nicotine-free e-cigarettes, whereas 40 percent use e-cigarettes containing nicotine. 40 percent of 5 percent is 2 percent. We assume that this approximate distribution is transferable to the increased number of vapers under policy B compared to policy A. According to table 1, this increase amounts to 25,000 people (20,000 + 15,000 – 6,000 – 4,000). Two percent (40 % of 5 %) of 25,000 is 500. We therefore estimate than in a calculation for a group of 100,000 smokers who want to quit, the health benefits of policy B after ten years will have an offsetting factor as follows:

Figure 4: 500 young people will likely have become nicotine vapers as a result of policy B. Some of these will likely have been using *snus* before becoming vapers. We therefore estimate that 400 out of this group of 500 will have become dependent on nicotine without any prior use.

In addition to these 400, some users will also have transitioned from vaping to smoking. Data collected so far indicates that this number will be very low, cf. evidence presented in chapter 8.2. We therefore estimate the following:

Figure 5: 50 young people will have become smokers as a result of policy B. On the other side of this calculation we have the following:

Figure 6: Policy B will cause some young people to become vapers instead of smokers. Existing data is insufficient to reliably estimate this number. There is no reason to believe figure 5 to be higher than figure 6, and these figures will therefore cancel each other out. For that reason, they are not included below.

Overall assessment of policy B on a cohort of 100,000 smokers who want to quit

After a period of 10 years, policy B will yield the following status compared to policy A:

Pros

Figure 1: 1,770 fewer lives lost

Figure 2a: 6,000 fewer people with smoking-related health concerns

Figure 2b: 14,000 people experience reduced health concerns

Cons

Figure 3: 5,000 additional former smokers who are still dependent on nicotine

Figure 4: 400 additional young people who are dependent on nicotine

One possible interpretation of these figures is that figures 2a and 2b largely balance out figures 3 and 4. If so, policy B shows a net benefit of 1,770 lives saved.

Alternative conditions

Let us first assume that the number of people transitioning from smoking to vaping is smaller. We replace the numbers in the right column of table 1 as follows: 70,000; 12,000; 10,000; and 8,000. We then get the following:

Figure 1: 960 fewer lives lost

Figure 2a: 4,000 fewer people with smoking-related health concerns

Figure 2b: 6,000 people experience reduced health concerns

Figure 3: 2,000 additional former smokers who are still dependent on nicotine

Figure 4: 200 additional young people who are dependent on nicotine

Still, one possible interpretation of these figures remains that figures 2a and 2b largely balance out figures 3 and 4. If so, policy B shows a net benefit of 960 lives saved.

Let us assume, then, *in addition*, that the degree of harm of e-cigarettes is 20 percent that of tobacco smoking. The outcome would then be 780 lives saved under policy B, whereas the other figures remain unchanged (i.e. identical to the initial calculation).

Conclusion

Hopefully, the above calculation can be of use for authorities in deciding whether pursuing e-cigarettes as a harm-reducing strategy to replace cigarette smoking could be worth exploring.

Appendix 2.
Country Laws Regulating E-cigarettes[246]

Policy Domains

E-cigarette policies reviewed included the following regulatory domains: minimum age for purchase, sale, advertising, promotion and sponsorship, packaging (child safety packaging, health warning labelling, trademark), product regulation (nicotine volume/concentration, safety/hygiene, ingredients/flavours), reporting/notification, vape-free and tax. The most common policy domains are discussed in greater detail below.

Minimum age

In twenty-eight countries, the minimum age for e-cigarette purchase mirrors those of traditional cigarettes in the country. The minimum age of purchase is 18 years in Bulgaria, Costa Rica, Croatia, Cyprus, Denmark, Ecuador, Estonia, Fiji, Finland, France, Germany, Italy, Lithuania, Malaysia, Netherlands, New Zealand, Norway, Poland, Portugal, Scotland, Slovenia, Spain, Togo, Ukraine, United States and Viet Nam; 19 years in the Republic of Korea and 21 years in Honduras.

Sale

Sale of all types of e-cigarettes is banned in 27 countries (Argentina, Bahrain, Brazil, Brunei Darussalam, Cambodia, Colombia, Gambia, Greece, Jordan, Kuwait, Lebanon, Mauritius, Nepal, Nicaragua, Oman, Panama, Qatar, Saudi Arabia, Seychelles, Singapore, Suriname, Thailand, Turkey, Turkmenistan, Uganda, United Arab Emirates and Uruguay).

In thirty-three countries, that permit the sale of e-cigarettes, there are regulations around sale such as marketing authorization requirement, or cross-border sale restrictions/regulations (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Fiji, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Norway, Philippines, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, United States, Venezuela and Wales).

Nine countries prohibit the sale of nicotine-containing e-cigarettes (Australia, Canada, Costa Rica, Jamaica, Japan, Malaysia, Mexico, New Zealand and Switzerland).

Seven countries do not have regulations on sale beyond age of majority purchase rules (Ecuador, Honduras, Republic of Korea, Spain, Togo, Ukraine and Viet Nam).

Advertising, promotion and sponsorship

Fifty-eight countries prohibit or regulate advertising, promotion, or sponsorship of e-cigarettes (Argentina, Australia, Austria, Bahrain, Belgium, Brazil, Bulgaria, Canada, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, England, Estonia, Fiji, Finland, France, Gambia, Germany, Greece, Honduras, Hungary, Iceland, Ireland, Italy, Japan, Jordan, Latvia, Lithuania, Malta, Mexico, Nepal, Netherlands, New Zealand, Norway, Panama, Poland, Portugal, Qatar, Republic of Korea, Romania, Saudi Arabia, Scotland, Seychelles, Slovakia, Slovenia, Spain, Togo, Turkmenistan, United Arab Emirates, United States, Uruguay, Venezuela, Viet Nam and Wales).

[246] Kilde: Institute for Global Tobacco Control. Country Laws Regulating E-cigarettes: A Policy Scan. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health. http://globaltobaccocontrol.org/e-cigarette/country-laws-regulating-e-cigarettes [Oktober 13, 2017]

Six of these countries apply the advertising restrictions only to e-cigarettes that contain nicotine or that are regulated as medicines (Canada, Costa Rica, Ecuador, Japan, Mexico and New Zealand).

Packaging (child safety packaging, health warnings and trademark)

Twenty-seven countries have regulations on child safety packaging (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, England, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Philippines, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, United States and Wales).

Twenty-eight countries mandate the placement of health warnings on e-cigarette packaging (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, England, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Poland, Portugal, Republic of Korea, Romania, Scotland, Slovakia, Slovenia, United States and Wales).

Uruguay prohibits brands/patents for e-cigarettes.

Product regulation (nicotine volume/concentration, safety/hygiene, ingredients/flavours)

Twenty-six countries regulate the amount (concentration/volume) of nicotine in e-liquids – in the EU the threshold concentration is 20mg/mL (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, and Wales).

Twenty-six countries do not permit the use of ingredients (other than nicotine) that pose a risk to human health in heated or unheated form in nicotine-containing e-liquid (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, and Wales).

Twenty-six countries regulate the quality of nicotine and other ingredients used to manufacture the e-liquid, as well as regulate the flavours that can be used in e-liquids (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, England, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Philippines, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, and Wales).

Reporting/notification

Twenty-seven countries have regulations that require manufacturers/retailers to notify the competent authority prior to introducing e-cigarettes to the market, as well as submit an annual report of sales and other specified information (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, United States and Wales).

Vape-free public places

Thirty-nine countries prohibit or restrict the use of e-cigarettes in public places (Argentina, Australia, Austria, Bahrain, Barbados, Belgium, Brazil, Brunei Darussalam, Cambodia, Colombia, Costa Rica, Croatia, Cyprus, Denmark, Ecuador, Estonia, Fiji, Finland, France, Greece, Honduras, Jamaica, Jordan, Malta, Nepal, Panama, Philippines, Poland, Portugal, Republic of Korea, Slovenia, Spain, Thailand, Togo, Turkmenistan, Ukraine, United Arab Emirates, Venezuela and Viet Nam).

Six of these ban use in entirety (Cambodia, Jordan, Nepal, Panama, Turkmenistan and United Arab Emirates).

Estonia, Germany and Lithuania prohibit use by minors under 18 years.

Use is prohibited in vehicles with minors in Cyprus (18 years), Finland (15 years) and Slovenia (18 years). Cyprus also prohibits use in personal vehicles with a pregnant woman.

Tax

England: As consumer products, they are subject to a 20% Value Added Tax; however, if they are regulated as Medicines, a 5% VAT is levied instead.

Italy: Tax on e-liquid for the year 2017 is 0.393 Euros per mL of e-liquid and this is related to the Weighted Average Price (WAP) of tobacco cigarettes calculated every year; there is also a 22% Value Added Tax (VAT) of the final retail price.

Latvia: Tax on e-liquid is 0.01 euro per mL and about 0.005 Euros per 1mg of nicotine. There is also a 21% Value Added Tax (VAT) of the final retail price.

Northern Ireland: As consumer products, they are subject to a 20% Value Added Tax; however, if they are regulated as Medicines, a 5% VAT is levied instead.

Portugal: Excise tax on e-liquid for the year 2017 is 0.30 Euros per mL of e-liquid.

Republic of Korea: Nicotine-containing e-cigarettes are subject to a number of taxes and charges (national health promotion, tobacco consumption, local education, and individual consumption taxes) proportional to 1,799 won/mL nicotine liquid; in addition there is a waste charge of 24 won/20 cartridges and a 10% Value Added Tax (VAT).

Scotland: As consumer products, they are subject to a 20% Value Added Tax; however, if they are regulated as Medicines, a 5% VAT is levied instead.

Togo: E-cigarettes are subject to duties/fees and are not eligible for tax exemptions; they are taxed at a ceiling of 45 percent.

Wales: As consumer products, they are subject to a 20% Value Added Tax; however, if they are regulated as Medicines, a 5% VAT is levied instead.

Product Classifications

Countries classify e-cigarettes as tobacco products (or imitation/derivative/substitute products), medicinal/pharmaceutical products, consumer products, electronic nicotine delivery systems (ENDS)/e-cigarettes or poisons.

Sixteen countries classify or regulate e-cigarettes as consumer products, in addition to classifying them as other types of products (Australia, Canada, England, France, Germany, Hungary, Iceland, Ireland, Netherlands, New Zealand, Northern Ireland, Republic of Korea, Scotland, Switzerland, Venezuela and Wales). Hungary regulates e-cigarettes primarily as consumer goods.

Fifty-five countries refer to e-cigarettes as ENDS/e-cigarettes (Argentina, Austria, Bahrain, Barbados, Belgium, Bulgaria, Cambodia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, England, Estonia, Fiji, Finland, France, Gambia, Germany, Greece, Ireland, Italy, Jamaica, Jordan, Kuwait, Latvia, Lebanon, Lithuania, Malta, Nepal, Netherlands, Northern Ireland, Norway, Oman, Panama, Poland, Portugal, Qatar, Romania, Saudi Arabia, Scotland, Slovakia, Slovenia, Spain, Suriname, Switzerland, Thailand, Turkey, Turkmenistan, Uganda, Ukraine, United Arab Emirates, Uruguay and Wales).

Twenty-two countries regulate e-cigarettes that make a cessation claim and/or contain a specific threshold of nicotine as medicines/drugs/medical devices (Austria, Belgium, Canada, Chile, Denmark,

England, Estonia, Finland, France, Iceland, Ireland, Jamaica, Japan, New Zealand, Northern Ireland, Norway, Philippines, Scotland, South Africa, Thailand, Venezuela and Wales).

Forty-two countries classify or regulate e-cigarettes (in their entirety or only certain dimensions of sale, advertisement, use, etc.) as tobacco products, tobacco related products, tobacco imitation, tobacco derivatives, or tobacco surrogates.(Argentina, Austria, Bahrain, Brazil, Brunei Darussalam, Bulgaria, Colombia, Costa Rica, Croatia, Ecuador, England, Estonia, Finland, Germany, Honduras, Italy, Latvia, Lithuania, Malta, Mauritius, Mexico, Nepal, Netherlands, New Zealand, Nicaragua, Northern Ireland, Norway, Panama, Poland, Republic of Korea, Romania, Scotland, Seychelles, Singapore, Slovakia, Slovenia, Togo, Turkey, Turkmenistan, Venezuela, Viet Nam and Wales).

Three countries regulate nicotine as poisons or hazardous substances (Australia and Malaysia) and Brunei Darussalam classifies nicotine liquid as poisons if nicotine concentration is above 7.5 percent

Regulatory Mechanisms

Thirty nine countries have a law/decree/resolution/circular/notification regarding e-cigarettes (Belgium, Brazil, Bulgaria, Cambodia, Chile, Croatia, Cyprus, Czech Republic, England, Estonia, Finland, Gambia, Germany, Italy, Jordan, Kuwait, Latvia, Lebanon, Lithuania, Malta, Nepal, Northern Ireland, Oman, Panama, Philippines, Poland, Portugal, Qatar, Romania, Saudi Arabia, Scotland, Slovakia, Slovenia, Suriname, Togo, Uganda, United Arab Emirates, United States and Wales).

Eleven countries use existing legislation (Australia, Brunei Darussalam, Canada, Iceland, Malaysia, Mauritius, New Zealand, Norway, South Africa, Venezuela and Viet Nam) and six countries use existing bans on imitation products (Colombia, Honduras, Mexico, Nicaragua, Seychelles and Singapore).

Seven countries made amendments to existing legislation (Barbados, Fiji, Greece, Hungary, Spain, Turkmenistan and Uruguay).

Ten countries used a combination of new and existing regulation (Argentina, Bahrain, Costa Rica, Denmark, Ecuador, Ireland, Japan, Netherlands Switzerland and Thailand).

Four countries use a combination of amended tobacco control legislation and existing legislation to regulate e-cigarettes (Jamaica, Republic of Korea, Turkey and Ukraine).

Austria and France use a combination of new, amended and existing regulation.